

Phone: 608-266-2112 Web: http://dsps.wi.gov Email: dsps@wisconsin.gov

Tony Evers, Governor Dawn B. Crim, Secretary

CONTROLLED SUBSTANCES BOARD VIRTUAL/TELECONFERENCE

Virtual, 4822 Madison Yards Way, Madison Contact: Carl Hampton (608) 266-2112 January 15, 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

9:30 A.M.

OPEN SESSION - CALL TO ORDER - ROLL CALL

- A. Adoption of Agenda (1-3)
- **B.** Approval of Minutes
 - 1) November 13, 2020 (4-6)
 - 2) December 7, 2020 (**7**)
- C. Reminders: Conflicts of Interests, Scheduling Concerns

Introductions, Announcements and Recognition

1) Herbert Kaske, Dentistry Examining Board Representative

9:30 A.M. Public Hearing on CR 19-156 Relating to Designating Gabapentin as a Monitored Substance (8-18)

1) Review and Consider Clearinghouse Report and Public Hearing Comments

9:30 A.M. Public Hearing on CR 20-079 Relating to Scheduling Flualprazolam (8, 19-26)

1) Review and Consider Clearinghouse Report and Public Hearing Comments

D. Administrative Matters – Discussion and Consideration

- 1) Department, Staff and Board Updates
- 2) Annual Policy Review (27)
- 3) Election of Officers (28-29)
- 4) Appointment of Liaisons and Alternates (28-29)
- 5) Delegation of Authorities (28, 30-31)
- 6) Board Members Term Expiration Dates
 - a. Barman, Subhadeep -5/1/2019
 - b. Bellay, Yvonne
 - c. Bloom, Alan -5/1/2020
 - d. Bryce, David (Medical Examining Board-Alternate Representative)
 - e. Doniparthi, Padmaja (Medical Examining Board-Primary Representative)

- f. Englebert, Doug
- g. Kallio, Peter
- h. Kaske, Herbert
- i. Koresch, Sandy
- j. Weitekamp, John

E. Controlled Substances Board Annual Reports – Discussion and Consideration

F. Administrative Rule Matters – Discussion and Consideration (32-33)

- 1) Review and Consider Clearinghouse and Public Hearing Comments for CSB 4 Relating to Designating Gabapentin as a Monitored Substance
- 2) Review and Consider Clearinghouse and Public Hearing Comments for CSB 2.77 Relating to Scheduling Flualprazolam
- 3) Review and Consider Clearinghouse and Public Hearing Comments for CSB 2.71 Relating to Scheduling Lasmiditan (34-39)
- 4) Review and Consider Clearinghouse and Public Hearing Comments for CSB 2.73 Relating to Scheduling Cenobamate (40-48)
- 5) Review and Consider Clearinghouse and Public Hearing Comments for CSB 2.74 Relating to Scheduling Lemborexant (49-54)
- 6) Review and Consider Clearinghouse and Public Hearing Comments for CSB 2.75 Relating to Removing FDA Approved Cannabidiol from Schedule V and Exempting it from Schedule I (55-61)
- 7) Review and Consider Clearinghouse and Public Hearing Comments for CSB 2.76 Relating to Scheduling Norfentanyl **(62-67)**
- 8) Review and Consider Statement for CSB 2.80 Relating to Scheduling Oliceridine (68-69)
- 9) Law Enforcement Hearing Follow Up Discussion
- 10) Review of Administrative Rules under s. 227.29, Stats. (70-71)
- 11) Pending and Possible Rulemaking Projects

G. Prescription Drug Monitoring Program (PDMP) Update – Discussion and Consideration (72)

- 1) WI ePDMP Operations
 - a. Introduction of New Program and Policy Analyst
 - b. Recent and Upcoming Releases (73-75)
 - c. Status of Grants
 - d. Interstate Data Sharing
 - e. Proactive Prescribing Metrics Notifications
- 2) EHR Integration Status (76)
- 3) Updates on Interstate Data Integration Projects (VA & Appriss, RxCheck, & eHealth)
- 4) WI ePDMP Outreach (77)

H. Board Member Reports – Discussion and Consideration

- 1) Medical Examining Board
- 2) Dentistry Examining Board
- 3) Board of Nursing
- 4) Pharmacy Examining Board

I. Report from the Referral Criteria Work Group – Discussion and Consideration

- **J.** Special Use Authorizations Discussion and Consideration
- K. Discussion and Consideration of Items Received After Preparation of the Agenda
 - 1) Introductions, Announcements, and Recognition
 - 2) Administrative Matters
 - 3) Election of Officers
 - 4) Appointment of Liaisons and Alternates
 - 5) Delegation of Authorities
 - 6) Informational Items
 - 7) Division of Legal Services and Compliance (DLSC) Matters
 - 8) Education and Examination Matters
 - 9) Credentialing Matters
 - 10) Practice Matters
 - 11) Legislative and Administrative Rule Matters
 - 12) Liaison Reports
 - 13) Appearances from Requests Received or Renewed
 - 14) Speaking Engagements, Travel, or Public Relations Requests, and Reports
 - 15) Consulting with Legal Counsel
- L. Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).

- M. Deliberation on Special Use Authorizations Discussion and Consideration
- N. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

- O. Vote on Items Considered or Deliberated Upon in Closed Session if Voting is Appropriate
- **P.** Open Session Items Noticed Above Not Completed in the Initial Open Session

ADJOURNMENT

NEXT MEETING: MARCH 12, 2021

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.

VIRTUAL/TELECONFERENCE CONTROLLED SUBSTANCES BOARD MEETING MINUTES NOVEMBER 13, 2020

PRESENT: Subhadeep Barman (excused at 11:30 a.m.), Yvonne Bellay, Alan Bloom, Padmaja

Doniparthi, Doug Englebert, Leonardo Huck (arrived at 9:34 a.m.), Peter Kallio,

Sandy Koresch, John Weitekamp

STAFF: Carl Hampton, Administrator, Division of Policy Development; Jameson Whitney,

Board Legal Counsel; Jon Derenne, Administrative Rules Coordinator; Kimberly Wood, Program Assistant Supervisor-Adv.; Daniel Betekhtin, Bureau Assistant;

Megan Glaeser, Bureau Assistant; and other DSPS Staff

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 9:30 a.m. A quorum was confirmed with eight (8) members present.

ADOPTION OF AGENDA

MOTION: Alan Bloom moved, seconded by Peter Kallio, to adopt the Agenda as

published. Motion carried unanimously.

(Leonardo Huck arrived at 9:34 a.m.)

9:30 A.M. ANNUAL HEARING WITH LAW ENFORCEMENT LEADERS, AGENCIES, AND PROSECUTORS

Receive Testimony Discussion Regarding Drug Trends

MOTION: Alan Bloom moved, seconded by John Weitekamp, to acknowledge and thank the following individuals for their presentations to the Controlled Substances Board:

- Tony Evers, Governor, State of Wisconsin
- Dawn B. Crim, Secretary, Department of Safety & Professional Services
- Josh Kaul, Attorney General, State of Wisconsin
- John Chisholm, District Attorney, Milwaukee
- Karen Loebel, Deputy District Attorney, Milwaukee
- Laura Reid, Drug Enforcement Administration
- Paul Krupski, Department of Health Services
- Christopher Jushka, Captain, Department of Transportation
- Sandy Koresch, Wisconsin State Crime Lab Bureau Motion carried unanimously.

APPROVAL OF MINUTES

September 11, 2020

MOTION: Peter Kallio moved, seconded by Sandy Koresch, to approve the Minutes of

September 11, 2020 as published. Motion carried unanimously.

October 9, 2020

MOTION: Peter Kallio moved, seconded by Sandy Koresch, to approve the Minutes of

October 9, 2020 as published. Motion carried unanimously.

(Subhadeep Barman was excused at 11:30 a.m.)

ADMINISTRATIVE RULE MATTERS

<u>CR 20-048 Relating to Scheduling of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144</u>

MOTION: Sandy Koresch moved, seconded by Alan Bloom, to authorize the

Chairperson to approve the Legislative Report and Draft for Clearinghouse Rule (CR) 20-048, relating to scheduling of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144, for submission to

the Governor's Office and Legislature. Motion carried unanimously.

CR 20-049 Relating to Scheduling of Brexanolone and Solriamfetol

MOTION: Alan Bloom moved, seconded by John Weitekamp, to authorize the

Chairperson to approve the Legislative Report and Draft for CR 20-049, relating to scheduling of Brexanolone and Solriamfetol, for submission to the

Governor's Office and Legislature. Motion carried unanimously.

<u>CR 20-050 Relating to Scheduling of N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP,PV8 and 4-chloro-a-PVP</u>

MOTION: John Weitekamp moved, seconded by Peter Kallio, to authorize the

Chairperson to approve the Legislative Report and Draft for CR 20-050, relating to scheduling of N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP, for submission to the Governor's Office and Legislature.

Motion carried unanimously.

CR 20-051 Relating to Scheduling of Noroxymorphone

MOTION: Alan Bloom moved, seconded by Padmaja Doniparthi, to authorize the

Chairperson to approve the Legislative Report and Draft for CR 20-051, relating to scheduling of Noroxymorphone, for submission to the Governor's

Office and Legislature. Motion carried unanimously.

Proposed Affirmative Action Order for CSB 2.78 Relating to Scheduling Crotonyl Fentanyl

MOTION: Peter Kallio moved, seconded by John Weitekamp, to schedule by affirmative

action Crotonyl Fentanyl as a schedule I. The order shall take effect on November 23, 2020 to allow for publication in the Administrative Register.

Motion carried unanimously.

Proposed Affirmative Action Order for CSB 2.79 Relating to Scheduling Remimazolam

MOTION: Sandy Koresch moved, seconded by Alan Bloom, to schedule by affirmative

action Remimazolam as a schedule IV. The order shall take effect on November 23, 2020 to allow for publication in the Administrative Register.

Motion carried unanimously.

ADJOURNMENT

MOTION: Peter Kallio moved, seconded by John Weitekamp, to adjourn the meeting.

Motion carried unanimously.

The meeting adjourned at 12:30 p.m.

VIRTUAL/TELECONFERENCE CONTROLLED SUBSTANCES BOARD MEETING MINUTES DECEMBER 7, 2020

PRESENT: Subhadeep Barman, Alan Bloom, Doug Englebert, Peter Kallio, Sandy Koresch

EXCUSED: Yvonne Bellay, Padmaja Doniparthi, Leonardo Huck, John Weitekamp

STAFF: Carl Hampton, Administrator, Division of Policy Development; Jameson Whitney,

Board Legal Counsel; Jon Derenne, Administrative Rules Coordinator; Kimberly Wood, Program Assistant Supervisor-Adv.; Daniel Betekhtin, Bureau Assistant;

Megan Glaeser, Bureau Assistant; and other DSPS Staff

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 10:02 a.m. A quorum was confirmed with five (5) members present.

ADOPTION OF AGENDA

MOTION: Peter Kallio moved, seconded by Subhadeep Barman, to adopt the Agenda as

published. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Affirmative Action Order for CSB 2.80 Relating to Scheduling Oliceridine as a Schedule II Controlled Substance

MOTION: Peter Kallio moved, seconded by Subhadeep Barman, to schedule by

affirmative action Oliceridine as a Schedule II controlled substances. The order shall take effect on December 14, 2020 to allow for publication in the

Administrative Register. Motion carried unanimously.

ADJOURNMENT

MOTION: Alan Bloom moved, seconded by Sandy Koresch, to adjourn the meeting.

Motion carried unanimously.

The meeting adjourned at 10:09 a.m.

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:				
Jon Derenne, Administrat	ive Rules Coordinator		January 5, 2021				
				red late if submitted after 12:00 p.m. on the deadline			
a) Name of Decord Course			date which is 8 busin	ess days before the meeting			
	mittee, Council, Sections:						
Controlled Substances Bo	oard						
4) Meeting Date:	5) Attachments:	6) How	should the item be tit	tled on the agenda page?			
January 15, 2021			c hearing on CR 19-150 ed substance.	6 relating to designating gabapentin as a			
		-Re	eview and consider clea	aringhouse and public hearing comments.			
				9 relating to scheduling flualprazolam.			
			J				
7) Place Item in:	8) Is an annearan		e the Board being	aringhouse and public hearing comments. 9) Name of Case Advisor(s), if required:			
<u> </u>	scheduled? (If ye			7) Name of ouse Navisor(s), il required.			
Open Session	Appearance Requ						
☐ Closed Session	☐ Yes						
	□ 1e3 ⊠ No						
10) Describe the issue a	and action that should be add	dressed:					
,							
11)	I	Authoriza	tion				
Jon Derenne January 5, 2021				January 5, 2021			
Signature of person mal	king this request			Date			
Supervisor (if required)				Date			
Supervisor (in required)				24.0			
Evacutive Director signature (indicates approved to add next agenda deadline item to agenda). Data							
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.							
				e to the Bureau Assistant prior to the start of a			
meeting.							

State of Wisconsin Department of Safety & Professional Services

LCRC FORM 2



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Scott Grosz Clearinghouse Director Anne Sappenfield Legislative Council Director

Margit S. Kelley Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE 20-080

AN ORDER to create CSB 4.03 (2), relating to designating Gabapentin as a monitored drug having a substantial potential for abuse.

Submitted by CONTROLLED SUBSTANCES BOARD

11-16-2020 RECEIVED BY LEGISLATIVE COUNCIL.

12-07-2020 REPORT SENT TO AGENCY.

MSK:BL

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1.	STATUTORY AUTHORITY	[s. 227.15 (2) (a)]		
	Comment Attached	YES	NO 🗸	
2.	FORM, STYLE AND PLACE	EMENT IN ADMINIST	RATIVE CODE [s. 227.15 (2) (c)]	
	Comment Attached	YES 🗸	NO 🗌	
3.	CONFLICT WITH OR DUPL	ICATION OF EXISTI	NG RULES [s. 227.15 (2) (d)]	
	Comment Attached	YES	NO 🗸	
4.	ADEQUACY OF REFERENCE [s. 227.15 (2) (e)]	CES TO RELATED ST	ATUTES, RULES AND FORMS	
	Comment Attached	YES	NO 🗸	
5.	CLARITY, GRAMMAR, PU	NCTUATION AND U	SE OF PLAIN LANGUAGE [s. 22	7.15 (2) (f)
	Comment Attached	YES	NO 🗸	
6.	POTENTIAL CONFLICTS W REGULATIONS [s. 227.15 (2		ABILITY TO, RELATED FEDER	AL
	Comment Attached	YES	NO 🗸	
7.	COMPLIANCE WITH PERM	IIT ACTION DEADLI	NE REQUIREMENTS [s. 227.15 (2) (h)]
	Comment Attached	YES 🗍	NO 🗸	



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Scott Grosz Clearinghouse Director Anne Sappenfield Legislative Council Director

Margit Kelley Clearinghouse Assistant Director

CLEARINGHOUSE RULE 20-080

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated November 2020.]

2. Form, Style and Placement in Administrative Code

In the agency's analysis for the proposed rule, an entry should be inserted to describe the analysis and supporting documents used to determine the effect on small business. Also, the entry for the fiscal estimate and economic impact analysis should be revised to reflect that they are attached.

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)

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 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:

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis will be attached upon completion.

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)

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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

Type of Estimate and Analysis Original □ Updated □ Corrected	2. Date November 12, 2020						
Administrative Rule Chapter, Title and Number (and Clearinghous CSB 4							
4. Subject Relating to designating Gabapentin as a monitored drug havin	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 ☐ Indeterminate ☐ Decrease Existing Revenues	☐ Increase Costs ☐ Decrease Costs ☐ Could Absorb Within Agency's Budget						
☐ Local Government Units ☐ Public	ic Businesses/Sectors Utility Rate Payers Businesses (if checked, complete Attachment A)						
9. Estimate of Implementation and Compliance to Businesses, Local \$0	Governmental Units and Individuals, per s. 227.137(3)(b)(1).						
10. Would Implementation and Compliance Costs Businesses, Local Any 2-year Period, per s. 227.137(3)(b)(2)? ☐ Yes ☐ No	Governmental Units and Individuals Be \$10 Million or more Over						
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 Rethat may be Affected by the Proposed Rule that were Contacted. The rule was posted on the department's website for 14 days to business sectors, associations representing business, local governceived.	for Comments. o solicit economic impact comments from businesses,						

13. Identify the Local Governmental Units that Participated in the Development of this EIA.

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

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.

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	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) 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

ATTACHMENT A

 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

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)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.77 relating to scheduling flualprazolam.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

Statutory authority: ss. 961.11 (1), (1m), (1r), and (2) and (4m), and 961.19 (2m), 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.]

In making a determination regarding a substance, the board shall consider the following:

- (a) The actual or relative potential for abuse.
- (b) The scientific evidence of its pharmacological effect, if known.
- (c) The state of current scientific knowledge regarding the substance.
- (d) The history and current pattern of abuse.
- (e) The scope, duration and significance of abuse.
- (f) The risk to the public health.
- (g) The potential of the substance to produce psychological or physical dependence liability.
- (h) Whether the substance is an immediate precursor of a substance already controlled under this chapter.

The controlled substances board may consider findings of the federal food and drug administration or the drug enforcement administration as prima facie evidence relating to one or more of the determinative factors.

After considering the factors, the controlled substances board shall make findings with respect to them and promulgate a rule controlling the substance upon finding that the substance has a potential for abuse. [s. 961.11 (1m), (1r), and (2), Stats.]

The controlled substances board may add a substance to schedule IV without making the finding required under sub. (1m) if the substance is controlled under schedule IV of 21 USC 812 (c) by a federal agency as the result of an international treaty, convention or protocol. [s. 961.19 (2m), Stats.]

Related statute or rule: s. 961.20, Stats.

Plain language analysis:

This rule schedules flualprazolam as a Schedule IV controlled substance.

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

Flualprazolam is not currently scheduled under the Controlled Substances Act.

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: N/A

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled flualprazolam as a controlled substance.

Iowa: Iowa has not scheduled flualprazolam as a controlled substance.

Michigan: Michigan has not scheduled flualprazolam as a controlled substance.

Minnesota: Minnesota has not scheduled flualprazolam as a controlled substance.

Summary of factual data and analytical methodologies:

Flualprazolam is an analog of alprazolam (a FDA approved schedule IV controlled substance), differing in chemical composition by the presence of a fluorine atom. Flualprazolam is a benzodiazepine synthesized and patented in 1970s for research purposes but was never marketed as a medicine. Flualprazolam is not used clinically.

The onset of action due to flualprazolam is reported to be 10-20 minutes after oral use with a duration of action of 6-14 hours. Flualprazolam depresses the central nervous system resulting in sedation, reduced anxiety, and loss of consciousness. Flualprazolam is similar to alprazolam which has demonstrably greater abuse liability compared to diazepam, especially for those with a personal or family substance use disorder history.

The World Health Organization released a critical review report on flualprazolam in October 2019. On March 4, 2020, the United Nations Commission on Narcotic Drugs placed flualprazolam under international control as a Schedule IV. Delaware added several

benzodiazepines, including flualprazolam, to Schedule IV due to the serious potential for abuse. Flualprazolam is on several states' law enforcement watchlists or alerts.

In 2019 and 2020, there has been an increased prevalence of flualprazolam in the United States. Law enforcement officers and medical examiners have provided information to the Controlled Substances Board indicating this substance is implicated in Wisconsin overdose cases, including those resulting in death. Alprazolam is not a schedule I controlled substance, therefore, a prosecution involving flualprazolam can't be commenced under Wisconsin's analog law (s. 961.25, Stats).

Public health concerns are similar to other benzodiazepines which are higher potency with a relatively fast time of onset. When flualprazolam is combined with opioids, this contributes to increased overdose through benzodiazepine-potentiated opioid-induced respiratory depression. In addition, flualprazolam causes disinhibition and sedation that impair driving. There have been reports of intentionally counterfeit alprazolam product containing flualprazolam entering the drug supply chain in other states.

Flualprazolam has a fast onset of action and similarities to alprazolam and has a relatively high dependence liability.

The Controlled Substances Board considered the following factors in making the determination to add flualprazolam to the controlled substance schedules in ch. 961, Stats.:

- The actual or relative potential for abuse.
- The scientific evidence of its pharmacological effect.
- The state of current scientific knowledge regarding the substance.
- The history and current pattern of abuse.
- The scope, duration and significance of abuse.
- The risk to the public health.
- The potential of the substance to produce psychological or physical dependence liability.
- Whether the substance is an immediate precursor of a substance already controlled under ch. 961, Stats.

The Controlled Substances Board makes a finding that flualprazolam has a potential for abuse.

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

The rule schedules flualprazolam as a Schedule IV controlled substance which will not have any effect on small business.

Fiscal Estimate:

There is no fiscal impact.

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 rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.77 is created to read:

CSB 2.72 Scheduling of flualprazolam. Section 961.20 (2) (ef), Stats., is created to read:

961.20 (2) (ef) flualprazolam.

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)

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

Type of Estimate and Analysis	2. Date					
□ Original □ Updated □ Corrected	November 12, 2020					
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 2.77						
4. Subject Relating to scheduling flualprazolam						
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 ☐ Indeterminate ☐ Decrease Existing Revenues	☐ Increase Costs ☐ Decrease Costs ☐ Could Absorb Within Agency's Budget					
☐ Local Government Units ☐ Publ	ific Businesses/Sectors c Utility Rate Payers ll Businesses (if checked, complete Attachment A)					
Estimate of Implementation and Compliance to Businesses, Local						
\$0						
10. Would Implementation and Compliance Costs Businesses, Loca Any 2-year Period, per s. 227.137(3)(b)(2)? ☐ Yes ☒ No	al Governmental Units and Individuals Be \$10 Million or more Over					
11. Policy Problem Addressed by the Rule						
Flualprazolam is an analog of alprazolam (a FDA approved schedule IV controlled substance), differing in chemical composition by the presence of a fluorine atom. Flualprazolam is a benzodiazepine synthesized and patented in 1970s for research purposes but was never marketed as a medicine. Flualprazolam is not used clinically.						
The onset of action due to flualprazolam is reported to be 10-20 minutes after oral use with a duration of action of 6-14 hours. Flualprazolam depresses the central nervous system resulting in sedation, reduced anxiety, and loss of consciousness. Flualprazolam is similar to alprazolam which has demonstrably greater abuse liability compared to diazepam, especially for those with a personal or family substance use disorder history.						
The World Health Organization released a critical review report on flualprazolam in October 2019. On March 4, 2020, the United Nations Commission on Narcotic Drugs placed flualprazolam under international control as a Schedule IV. Delaware added several benzodiazepines, including flualprazolam, to Schedule IV due to the serious potential for abuse. Flualprazolam is on several states' law enforcement watchlists or alerts.						
In 2019 and 2020, there has been an increased prevalence of flualprazolam in the United States. Law enforcement officers and medical examiners have provided information to the Controlled Substances Board indicating this substance is implicated in Wisconsin overdose cases, including those resulting in death. Alprazolam is not a schedule I controlled substance, therefore, a prosecution involving flualprazolam can't be commenced under Wisconsin's analog law (s. 961.25, Stats).						
Public health concerns are similar to other benzodiazepines which are higher potency with a relatively fast time of one When flualprazolam is combined with opioids, this contributes to increased overdose through benzodiazepine-potentiated opioid-induced respiratory depression. In addition, flualprazolam causes disinhibition and sedation that						

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ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

impair driving. There have been reports of intentionally counterfeit alprazolam product containing flualprazolam entering the drug supply chain in other states.

Flualprazolam has a fast onset of action and similarities to alprazolam and has a relatively high dependence liability.

The Controlled Substances Board considered the following factors in making the determination to add flualprazolam to the controlled substance schedules in ch. 961, Stats.:

- The actual or relative potential for abuse.
- The scientific evidence of its pharmacological effect.
- The state of current scientific knowledge regarding the substance.
- The history and current pattern of abuse.
- The scope, duration and significance of abuse.
- The risk to the public health.
- The potential of the substance to produce psychological or physical dependence liability.
- Whether the substance is an immediate precursor of a substance already controlled under ch. 961, Stats.

The Controlled Substances Board makes a finding that flualprazolam has a potential for abuse.

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. 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 to protect Wisconsin residents by scheduling flualprazolam as a Schedule IV controlled substance.

16. Long Range Implications of Implementing the Rule

The long range implication of implementing the rule will be to schedule flualprazolam as a controlled substance in Wisconsin and potentially prevent harm caused by the abuse of flualprazolam.

17. Compare With Approaches Being Used by Federal Government

Flualprazolam is not currently scheduled under the Controlled Substances Act.

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

Illinois: Illinois has not scheduled flualprazolam as a controlled substance.

Iowa: Iowa has not scheduled flualprazolam as a controlled substance.

Michigan: Michigan has not scheduled flualprazolam as a controlled substance.

Minnesota: Minnesota has not scheduled flualprazolam as a controlled substance.

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

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

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

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ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

 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

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:			
Kimberly Wood, Program Assistant Supervisor-Adv.		12/29/2020	12/29/2020		
			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, Com	mittee, Council, Section	ns:			
All Boards					
4) Meeting Date:	5) Attachments:	6) How	should the item be tit	tled on the agenda page?	
	☐ Yes ⊠ No	Annı	ual Policy Review		
7) Place Item in:			e the Board being	9) Name of Case Advisor(s), if required:	
	scheduled?			N/A	
☐ Closed Session	Yes				
	⊠ No				
10) Describe the issue a	and action that should I	oe addressed:			
Please be advised of the	e f <mark>ollowing Annual Poli</mark>	cy Review iten	ns:		
a meeting or if	you have scheduling o	onflicts impac	cting your attendance	ent to meeting attendance. If you cannot attend e, please let us know ASAP. Timely notification cils to meet pursuant to Open Meetings Law.	
	um: Please refrain from I meetings so to avoid v			business with other members outside of Open Meetings Law.	
 Agenda Deadlines: Please communicate agenda topics to your Executive Director before the agenda submission deadline which is 8 business days prior to a meeting. 					
4. Travel Voucher and Per Diem Submissions: Please submit all Per Diem and Reimbursement claims to DSPS within 30 days of the close of each month in which expenses are incurred.					
 Lodging Accommodations/Hotel Cancellation Policy: Lodging accommodations are available to eligible members. Standard eligibility: member must leave home before 6:00 a.m. to attend a meeting by the indicated start time. 					
 If a member cannot attend a meeting it is their responsibility to cancel their reservation within the applicable cancellation timeframe. If a meeting is changed to occur remotely or is cancelled or rescheduled DSPS staff will cancel or modify reservations as appropriate. 					
6. Inclement Weather Policy: In the event of inclement weather the agency may change a meeting from an in-person venue to one that is executed remotely.					
11) Authorization					
Kimberly Woo				12/29/2020	
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 Deadlir	ne items must be autho	rized by a Sup	ervisor and the Policy	y Development Executive Director.	
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a					

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:			
Daniel Betekhtin, Bureau Assistant				12/21/2020			
Daniel Determin, Dureau Assistant			red late if submitted after 12:00 p.m. on the deadline ess days before the meeting				
3) Name of Board, Comr	nittee, Co	uncil, Sections:					
Controlled Substances	Board						
4) Meeting Date:	5) Attac	hments:	6) How	should the item be tit	led on the agenda page?		
1/15/2021	⊠ Ye		Adminis 1)	strative Matters Election of Officers Delegation of Autho	Election of Officers, Appointment of Liaisons and Alternates,		
7) Place Item in:		8) Is an appearance scheduled?	ce before	the Board being	9) Name of Case Advisor(s), if required:		
		scrieduleu:			N/A		
Closed Session		☐ Yes ⊠ No					
10) Describe the issue a	nd action	that should be add	dressed:				
 The Cemetery Board should conduct Election Officers: Chairperson, Vice Chairperson & Secretary The newly elected Chairperson should review and appoint/reappoint Liaisons and Alternates as appropriate The Board should review and then consider its existing delegated authorities and any proposals for modification of delegations. 							
11)	11) Authorization						
Tany beeth les 12/21/2020							
Signature of person making this request Date							
Supervisor (if required) Date				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.							

CONTROLLED SUBSTANCES BOARD

2020 Elections and Liaison Appointments

ELECTION RESULTS				
Chairperson	Doug Englebert			
Vice Chairperson	Alan Bloom			
Secretary	Yvonne Bellay			
LIAISON AP	POINTMENTS			
Special Use Authorization Liaison(s)	Alan Bloom, Yvonne Bellay			
PDMP Liaison(s)	Timothy Westlake Alternates: Subhadeep Barman, John Weitekamp-Pharmacy Issues			
Legislative Liaison(s)	Timothy Westlake Alternate: Doug Englebert			
SCAODA Representative	Subhadeep Barman			
Referral Criteria Workgroup	Doug Englebert, Peter Kallio, Timothy Westlake, John Weitekamp			

DELEGATION MOTIONS

Document Signature Delegations

MOTION: Yvonne Bellay moved, seconded by Leonardo Huck, to delegate authority

to the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to sign documents on behalf of the Board in order to carry out its duties. Motion

carried unanimously.

MOTION: Sandy Koresch moved, seconded by Peter Kallio, in order to carry out

duties of the Board, the Chairperson (or in absence of the Chairperson, the

highest-ranking officer or longest serving board member in that

succession) has the ability to delegate signature authority for purposes of facilitating the completion of assignments during or between meetings. The members of the Board hereby delegate to the Executive Director or DPD Division Administrator, the authority to sign on behalf of a board

member as necessary. Motion carried unanimously.

Delegated Authority for Urgent Matters

MOTION: Sandy Koresch moved, seconded by Yvonne Bellay, that in order to

facilitate the completion of urgent matters between meetings, the Board delegates its authority to the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession), to appoint liaisons to the Department to act in urgent

matters. Motion carried unanimously.

Special Use Authorization Liaison Delegation

MOTION: John Weitekamp moved, seconded by Sandy Koresch, to authorize the

Special Use Authorization (SUA) liaison(s) to review and make approval decisions regarding SUA applications and approve required training or credentialing on behalf of the Board. Furthermore, the Board authorizes DSPS staff to sign SUA permits on behalf of the Board. Motion carried

unanimously.

MOTION: Peter Kallio moved, seconded by Alan Bloom, to authorize the Special

Use Authorization (SUA) liaison(s) to make all decisions related to

Special Use Authorizations. Motion carried unanimously.

Legislative Liaison Delegation

MOTION: Yvonne Bellay moved, seconded by Peter Kallio, to delegate authority to

the Legislative Liaisons to speak on behalf of the Board regarding

legislative matters. Motion carried unanimously.

SCAODA Representative Delegation

MOTION: Alan Bloom moved, seconded by Yvonne Bellay, to authorize the

SCAODA representative to vote on behalf of the Board at the State Council on Alcohol and Other Drug Abuse meetings. Motion carried

unanimously.

PDMP Liaison Delegation

MOTION: Subhadeep Barman moved, seconded by John Weitekamp, to authorize

PDMP Liaisons to make individual decisions on behalf of the Board when waiting for a Board meeting would unreasonably delay the development, testing, deployment, or operation of the PDMP. The Board also grants the PDMP liaison the authority to suspend access to the PDMP pursuant to

CSB § 4.09(3). Motion carried unanimously.

State of Wisconsin Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of pers	son subr	nitting the request:		2) Date when reques	st submitted:	
Jon Derenne, Administrative Rules Coordinator		January 5, 2021				
		Items will be considered	ed late if submitted after 12:00 p.m. on the deadline ess days before the meeting			
3) Name of Board, Comr	nittee, C	ouncil, Sections:				
Controlled Substances Bo	oard					
4) Meeting Date:	5) Atta	chments:	6) How	should the item be title	ed on the agenda page?	
January 15, 2021	_	es Io		1. Review and consider clearinghouse and public hearing comments for CSB 4 relating to designating gabapentin as a monitored substance.		
				w and consider clearing ating to scheduling flual	ghouse and public hearing comments for CSB prazolam.	
				w and consider clearing ng Lasmiditan.	phouse comments for CSB 2.71 relating to	
				w and consider clearing ng cenobamate.	phouse comments for CSB 2.73 relating to	
				w and consider clearing ng Lemborexant.	phouse comments for CSB 2.74 relating to	
			removin	6. Review and consider clearinghouse comments for CSB 2.75 relating to removing FDA approved cannabidiol from schedule V and exempting it from schedule I.		
			7. Review and consider clearinghouse comments for CSB 2.76 relating to scheduling norfentanyl.			
		oliceridi		8. Review and consider scope statement for CSB 2.80 relating to scheduling oliceridine.		
				Law enforcement hearing follow up discussion.		
		10. Review of administrative		ew of administrative rule	es under s. 227.29, Stats.	
7) Place Item in: Open Session Closed Session		8) Is an appearar scheduled? (If you Appearance Req	es, please		9) Name of Case Advisor(s), if required:	
10) Describe the issue a	nd actio		dressed:			

State of Wisconsin Department of Safety & Professional Services

11)	Authorization			
Jon Derenne		January 5, 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 sup	porting documents:			

- This form should be attached to any documents submitted to the agenda.
 Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
 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 : PROPOSED ORDER OF THE

PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD

CONTROLLED SUBSTANCES BOARD : ADOPTING RULES

: (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.71 relating to scheduling of lasmiditan.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.22, 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. 961.14, Stats.

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

On January 31, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing lasmiditan into Schedule V of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating lasmiditan as a schedule V controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on March 13, 2020 to similarly treat lasmiditan under chapter 961 effective March 23, 2020 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 (8), Stats. which adds lasmiditan to schedule V.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled lasmiditan.

Iowa: Iowa has not scheduled lasmiditan.

Michigan: Michigan has not scheduled lasmiditan.

Minnesota: Minnesota has not scheduled lasmiditan.

Summary of factual data and analytical methodologies:

The methodology was to schedule lasmiditan 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:

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, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by January 14, 2021 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.71 is created to read:

CSB 2.71 Addition of lasmiditan to schedule V. Section 961.22(8), Stats., is created to read:

961.22 (8) Lasmiditan [2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-ylbenzamide].

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 RUI	E)

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

Type of Estimate and Analysis Original ☐ Updated ☐ Corrected	2. Date 10/13/2020		
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 2.71			
4. Subject Scheduling of lasmiditan			
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 ☐ Indeterminate ☐ Decrease Existing Revenues	☐ Increase Costs ☐ Decrease Costs ☐ Could Absorb Within Agency's Budget		
☐ Local Government Units ☐ Publ	cific Businesses/Sectors ic Utility Rate Payers Il Businesses (if checked, complete Attachment A)		
9. Estimate of Implementation and Compliance to Businesses, Loca \$0.00	al Governmental Units and Individuals, per s. 227.137(3)(b)(1).		
10. Would Implementation and Compliance Costs Businesses, Local Any 2-year Period, per s. 227.137(3)(b)(2)? ☐ Yes ☑ No	al Governmental Units and Individuals Be \$10 Million or more Over		
11. Policy Problem Addressed by the Rule The United States Department of Justice, Drug Enforcement Administration scheduled lasmiditan as a schedule V controlled substance effective January 31, 2020. The Wisconsin Controlled Substances Board took affirmative action on March 13, 2020 to similarly treat lasmiditan as a schedule V controlled substance effective March 23, 2020. The Board is currently promulgating a final rule.			
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. This rule was posted for Economic impact comments and none were received.			
13. Identify the Local Governmental Units that Participated in the Development of this EIA. 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) This rule schedules lasmiditan and does not have an economic or fiscal impact on businesses or the State's economy as a			
whole. 15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefit is for the federal and state controlled substances acts to be in conformity and alleviate confusion. In addition, it is in the best interest of Wisconsin citizens to schedule lasmiditan as a controlled substance.			
16. Long Range Implications of Implementing the Rule Lasmiditan will be treated as a schedule V controlled substance.			
17. Compare With Approaches Being Used by Federal Government The federal government has scheduled lasmiditan as a schedule V controlled substance.			

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

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota) Illinois, Iowa, Michigan and Minnesota have not scheduled lasmiditan 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.

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

ATTACHMENT A

 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

LCRC FORM 2



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Scott Grosz Clearinghouse Director Anne Sappenfield Legislative Council Director

Margit S. Kelley Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE 20-075

AN ORDER to create CSB 2.73, relating to scheduling of cenobamate.

Submitted by CONTROLLED SUBSTANCES BOARD

11-13-2020 RECEIVED BY LEGISLATIVE COUNCIL.

12-11-2020 REPORT SENT TO AGENCY.

SG:BL

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1.	STATUTORY AUTHORITY	[s. 227.15 (2) (a)]		
	Comment Attached	YES	NO 🗸	
2.	FORM, STYLE AND PLACE	MENT IN ADMINIS	FRATIVE CODE [s. 227.15 (2) (c)]	
	Comment Attached	YES	NO 🗸	
3.	CONFLICT WITH OR DUPL	ICATION OF EXISTI	NG RULES [s. 227.15 (2) (d)]	
	Comment Attached	YES	NO 🗸	
4.	ADEQUACY OF REFERENCE [s. 227.15 (2) (e)]	CES TO RELATED ST	CATUTES, RULES AND FORMS	
	Comment Attached	YES	NO 🗸	
5.	CLARITY, GRAMMAR, PUN	NCTUATION AND U	SE OF PLAIN LANGUAGE [s. 227.1	5 (2) (f)
	Comment Attached	YES 🗸	NO	
6.	POTENTIAL CONFLICTS W REGULATIONS [s. 227.15 (2)		ABILITY TO, RELATED FEDERAL	J
	Comment Attached	YES	NO 🗸	
7.	COMPLIANCE WITH PERM	IIT ACTION DEADLI	NE REQUIREMENTS [s. 227.15 (2) ((h)]
	Comment Attached	YES	NO 🗸	



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Scott Grosz Clearinghouse Director Anne Sappenfield Legislative Council Director

Margit Kelley Clearinghouse Assistant Director

CLEARINGHOUSE RULE 20-075

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated November 2020.]

5. Clarity, Grammar, Punctuation and Use of Plain Language

Based on comparison to similar provisions, it appears the text created in SECTION 1 of the proposed rule should end with a period.

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)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.73 relating to scheduling of cenobamate.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.22, Stats.

Statutory authority: s. 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. 961.22, Stats.

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

On March 10, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing cenobamate into Schedule V of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating cenobamate as a schedule V controlled substance under ch. 961, Stats., based upon the federal scheduling. The Controlled Substances Board took affirmative action on May 8, 2020 to similarly treat cenobamate under chapter 961 effective May 18, 2020 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 (9), Stats., which adds cenobamate to schedule V.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled cenobamate.

Iowa: Iowa has not scheduled cenobamate.

Michigan: Michigan has not scheduled cenobamate.

Minnesota: Minnesota has not scheduled cenobamate.

Summary of factual data and analytical methodologies:

The methodology was to schedule cenobamate 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:

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 608-261-2377; 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, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by January 14, 2021 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.73 is created to read:

CSB 2.73 Scheduling of cenobamate. Section 961.22 (9), Stats., is created to read:

961.22 (9) Cenobamate. Cenobamate ([(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate; 2H-tetrazole-2-ethanol, alpha-(2-chlorophenyl)-, carbamate (ester), (alphaR)-; carbamic acid (R)-(+)-1-(2-chlorophenyl)-2-(2H-tetrazol-2-yl)ethyl ester)

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)

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	2. Date		
☐ Original ☐ Updated ☐ Corrected	November 12, 2020		
3. Administrative Rule Chapter, Title and Number (and Clearinghous CSB 2.73	se Number if applicable)		
4. Subject Scheduling cenobamate			
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 ☐ Indeterminate ☐ Decrease Existing Revenues	☐ Increase Costs ☐ Decrease Costs ☐ Could Absorb Within Agency's Budget		
8. The Rule Will Impact the Following (Check All That Apply)			
	ific Businesses/Sectors		
	c Utility Rate Payers		
	Businesses (if checked, complete Attachment A)		
9. Estimate of Implementation and Compliance to Businesses, Loca	I Governmental Units and Individuals, per s. 227.137(3)(b)(1).		
\$0			
10. Would Implementation and Compliance Costs Businesses, Loca Any 2-year Period, per s. 227.137(3)(b)(2)?☐ Yes ☒ No	il Governmental Units and Individuals Be \$10 Million or more Over		
11. Policy Problem Addressed by the Rule			
On March 10, 2020, the Department of Justice, Drug Enforce	ment Administration published its final rule in the Federal		
Register placing cenobamate into Schedule V of the federal C			
schedule cenobamate to conform with the federal Controlled Substances Act.			
 Summary of the Businesses, Business Sectors, Associations Rethat may be Affected by the Proposed Rule that were Contacted 			
The rule was posted on the department's website for 14 days	•		
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. 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 is for the federal and state controlled substances acts to be in conformity and alleviate confusion. In			
addition, it is in the best interest of Wisconsin citizens to schedule cenobamate as a controlled substance.			
16. Long Range Implications of Implementing the Rule The long range implication of implementing the rule will be to schedule cenobamate as a schedule V controlled substance.			
17. Compare With Approaches Being Used by Federal Government			
The federal government has scheduled cenobamate as a schedule V controlled substance.			
18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)			

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

Illinois: Illinois has not scheduled cenobamate.

Iowa: Iowa has not scheduled cenobamate.

Michigan: Michigan has not scheduled cenobamate.

Minnesota: Minnesota has not scheduled cenobamate.

19. Contact Name 20. Contact Phone Number (608) 266-0955

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

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

ATTACHMENT A

 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

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)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.74 relating to scheduling of lemborexant.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

Statutory authority: s. 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. 961.14, Stats.

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

On April 7, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing lemborexant into Schedule IV of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating lemborexant as a schedule IV controlled substance under ch. 961, Stats., based upon the federal scheduling. The Controlled Substances Board took affirmative action on May 8, 2020 to similarly treat lemborexant under chapter 961 effective May 18, 2020 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.20 (2) (eqm), Stats., which adds lemborexant to schedule IV.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled lemborexant.

Iowa: Iowa has not scheduled lemborexant.

Michigan: Michigan has not scheduled lemborexant.

Minnesota: Minnesota has not scheduled lemborexant.

Summary of factual data and analytical methodologies:

The methodology was to schedule lemborexant 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:

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 608-261-2377; 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, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by January 14, 2021 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.74 is created to read:

CSB 2.74 Addition of Lemborexant to schedule IV. Section 961.20 (2) (eqm), Stats., is created to read:

961.20 (2) (eqm) Lemborexant.

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 DITE	E)	

Page 3

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

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 2.74			
4. Subject Scheduling lemborexant			
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 ☐ Indeterminate ☐ Decrease Existing Revenues	☐ Increase Costs ☐ Decrease Costs ☐ Could Absorb Within Agency's Budget		
☐ Local Government Units ☐ Public	fic Businesses/Sectors Utility Rate Payers Businesses (if checked, complete Attachment A)		
9. Estimate of Implementation and Compliance to Businesses, Local \$0			
10. Would Implementation and Compliance Costs Businesses, Local Any 2-year Period, per s. 227.137(3)(b)(2)? ☐ Yes ☒ No	Governmental Units and Individuals Be \$10 Million or more Over		
11. Policy Problem Addressed by the Rule On April 7, 2020, the Department of Justice, Drug Enforceme Register placing lemborexant into Schedule IV of the federal			
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. 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 is for the federal and state controlled substances acts to be in conformity and alleviate confusion. In addition, it is in the best interest of Wisconsin citizens to schedule lemborexant as a controlled substance. 16. Long Range Implications of Implementing the Rule The long range implication of implementing the rule will be to schedule lemborexant as a schedule IV controlled substance.			
17. Compare With Approaches Being Used by Federal Government The federal government has scheduled lemborexant as a schedule IV controlled substance.			
18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota) Illinois: Illinois has not scheduled lemborexant.			

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

Iowa: Iowa has not scheduled lemborexant.

Michigan: Michigan has not scheduled lemborexant.

Minnesota: Minnesota has not scheduled lemborexant.

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.

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

ATTACHMENT A

 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

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)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.75, relating to removing FDA approved cannabidiol from schedule V and excluding FDA approved cannabidiol from schedule I.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 961.14 and 961.22, Stats.

Statutory authority: s. 961.11 (1) and (4) (g), 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 or nabiximols is rescheduled or deleted as a controlled substance under federal law, the controlled substances board shall similarly treat cannabidiol or nabiximols 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 nabiximols 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 or nabiximols. [s. 961.11 (4g), Stats.]

Related statute or rule: s. 961.14, Stats.

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

On June 5, 2020, the Department of Justice, Drug Enforcement Administration provided a letter to the Controlled Substances Board indicating that as a result of the Agricultural Improvement Act of 2018, the Federal Drug Administration approved drug product Epidiolex is no longer controlled under the federal Controlled Substances Act.

The Agricultural Improvement Act of 2018 defines the term "hemp" to "mean the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol (also known as $\Delta 9$ -THC) concentration of not more than 0.3 percent on a dry weight basis." (7 U.S.C. § 1639o.). The Agricultural Improvement Act of 2018 also amended the Controlled Substances Act by excluding "hemp" from the definition of marihuana under 21 U.S.C. § 802 (16) and the listing of tetrahydrocannabinols under 21 U.S.C. § 812 (c).

The prescription drug product Epidiolex is a cannabis derivative with a $\Delta 9$ -THC concentration of not more than 0.3% on a dry weight basis. Therefore, as a result of the Department of Justice, Drug Enforcement Administration letter and the Agricultural Improvement Act, the drug product Epidiolex is no longer controlled under the federal Controlled Substances Act.

On August 21, 2020, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register removing drug products approved by the U.S. Food and Drug Administration that contain cannabidiol derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols from schedule V.

Plain language analysis:

The Controlled Substances Board took affirmative action on June 23, 2020 to similarly treat U.S. Food and Drug Administration approved cannabidiol under chapter 961 effective June 29, 2020 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule repeals s. 961.22 (7), Stats., removing Food and Drug Administration approved cannabidiol from Schedule V.

In addition, this rule creates s. 961.14 (4) (t) 4., Stats., creating an exception from Schedule I (under tetrahydrocannabinols) for an FDA approved cannabidiol derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols. This exception is created so that the repeal of FDA approved cannabidiol from Schedule V does not revert these substances to inclusion in Schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois does not schedule Food and Drug Administration approved cannabidiol.

Iowa: Iowa schedules Food and Drug Administration approved cannabidiol as Schedule V controlled substances.

Michigan: Michigan does not schedule Food and Drug Administration approved cannabidiol.

Minnesota: Minnesota does not schedule Food and Drug Administration approved cannabidiol.

Summary of factual data and analytical methodologies:

The methodology was to remove cannabidiol from scheduling.

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:

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, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by January 14, 2020 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.75 is created to read:

CSB 2.75 Exclusion of Approved Cannabidiol Drugs from schedule I and deleting from schedule V. (1) Section 961.14 (4) (t) 4., Stats., is created to read:

961.14 (4) (t) 4. 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)

(2) Section 961.22 (7), Stats., is repealed.

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

Type of Estimate and Analysis	2. Date		
☐ Original ☐ Updated ☐ Corrected	November 12, 2020		
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 2.75			
4. Subject Removing FDA approved cannabidiol from scheduling			
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 ☐ Indeterminate ☐ Decrease Existing Revenues	☐ Increase Costs ☐ Decrease Costs ☐ Could Absorb Within Agency's Budget		
☐ Local Government Units ☐ Public	ic Businesses/Sectors Utility Rate Payers Businesses (if checked, complete Attachment A)		
S. Estimate of Implementation and Compliance to Businesses, Local \$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 On August 21, 2020, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register removing drug products approved by the U.S. Food and Drug Administration that contain cannabidiol derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols from schedule V. This rule removes FDA approved cannabidiol from the Wisconsin drug schedules and creates an exception within Schedule V.			
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. 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 is for the federal and state controlled substances acts to be in conformity and alleviate confusion.			
16. Long Range Implications of Implementing the Rule The long range implication of implementing the rule will be to remove Food and Drug Administration approved cannabidiol from Schedule V.			

17. Compare With Approaches Being Used by Federal Government

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

On June 5, 2020, the Department of Justice, Drug Enforcement Administration provided a letter to the Controlled Substances Board indicating that as a result of the Agricultural Improvement Act of 2018, the Federal Drug Administration approved drug product Epidiolex is no longer controlled under the federal Controlled Substances Act.

The Agricultural Improvement Act of 2018 defines the term "hemp" to "mean the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol (also known as □9-THC) concentration of not more than 0.3 percent on a dry weight basis." (7 U.S.C. § 1639o.). The Agricultural Improvement Act of 2018 also amended the Controlled Substances Act by excluding "hemp" from the definition of marihuana under 21 U.S.C. § 802 (16) and the listing of tetrahydrocannabinols under 21 U.S.C. § 812 (c).

The prescription drug product Epidiolex is a cannabis derivative with a \Box 9-THC concentration of not more than 0.3% on a dry weight basis. Therefore, as a result of the Department of Justice, Drug Enforcement Administration letter and the Agricultural Improvement Act, the drug product Epidiolex is no longer controlled under the federal Controlled Substances Act.

On August 21, 2020, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register removing drug products approved by the U.S. Food and Drug Administration that contain cannabidiol derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols from schedule V.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota) Illinois: Illinois does not schedule Food and Drug Administration approved cannabidiol.

Iowa: Iowa schedules Food and Drug Administration approved cannabidiol as Schedule V controlled substances.

Michigan: Michigan does not schedule Food and Drug Administration approved cannabidiol.

Minnesota: Minnesota does not schedule Food and Drug Administration approved cannabidiol.		
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.

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

ATTACHMENT A

 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

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)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.76 relating to scheduling of norfentanyl.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, Stats.

Statutory authority: s. 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. 961.14, Stats.

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

On April 17, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing norfentanyl into Schedule II of the federal Controlled Substances Act effective May 18, 2020.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating norfentanyl as a schedule II controlled substance under ch. 961, Stats., based upon the federal scheduling. The Controlled Substances Board took affirmative action on June 23, 2020 to similarly treat norfentanyl under chapter 961 effective June 29, 2020 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule renumbers and amends 961.16 (8) (b) (intro.), Stats., and creates 961.16 (8) (b) 2. which adds norfentanyl to schedule II.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled norfentanyl.

Iowa: Iowa has not scheduled norfentanyl.

Michigan: Michigan has not scheduled norfentanyl.

Minnesota: Minnesota has not scheduled norfentanyl.

Summary of factual data and analytical methodologies:

The methodology was to schedule norfentanyl 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:

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, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by January 14, 2020 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.76 is created to read:

CSB 2.76 Addition of norfentanyl to schedule II. **(1)** Section 961.16 (8) (b), Stats., is renumbered 961.16 (8) (b) (intro.) and amended to read: 961.16 (8) (b) An immediate precursor to fentanyl, including all of the following: 1. 4-anilino-N-phenethyl-4-piperidine, commonly known as ANPP.

- (2) Section 961.16 (8) (b) 2., Stats. is created to read:
- 2. N-phenyl-N-(piperidin-4-yl)propionamide, commonly known as norfentanyl.

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)	

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

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 2.76						
4. Subject Scheduling norfentanyl						
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 ☐ Indeterminate ☐ Decrease Existing Revenues	☐ Increase Costs ☐ Decrease Costs ☐ Could Absorb Within Agency's Budget					
☐ Local Government Units ☐ Public	fic Businesses/Sectors Utility Rate Payers Businesses (if checked, complete Attachment A)					
9. Estimate of Implementation and Compliance to Businesses, Local \$0	<u> </u>					
10. Would Implementation and Compliance Costs Businesses, Local Any 2-year Period, per s. 227.137(3)(b)(2)? ☐ Yes ☒ No	Governmental Units and Individuals Be \$10 Million or more Over					
11. Policy Problem Addressed by the Rule On April 17, 2020, the Department of Justice, Drug Enforcem Register placing norfentanyl into Schedule II of the federal Co						
12. Summary of the Businesses, Business Sectors, Associations Rethat may be Affected by the Proposed Rule that were Contacted. The rule was posted on the department's website for 14 days to business sectors, associations representing business, local governeeived.	presenting Business, Local Governmental Units, and Individuals for Comments. o solicit economic impact comments from businesses,					
13. Identify the Local Governmental Units that Participated in the Development of this EIA. None.						
14. Summary of Rule's Economic and Fiscal Impact on Specific Busi Governmental Units and the State's Economy as a Whole (Inclu Incurred) No impact.						
15. Benefits of Implementing the Rule and Alternative(s) to Implement The benefit is for the federal and state controlled substances a addition, it is in the best interest of Wisconsin citizens to scheen 16. Long Range Implications of Implementing the Rule	cts to be in conformity and alleviate confusion. In dule norfentanyl as a controlled substance.					
The long range implication of implementing the rule will be to scheduled 17. Compare With Approaches Being Used by Federal Government The federal government has scheduled norfentanyl as a scheduled norfentanyl						
18. Compare With Approaches Being Used by Neighboring States (I Illinois: Illinois has not scheduled norfentanyl.						

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

Iowa: Iowa has not scheduled norfentanyl.

Michigan: Michigan has not scheduled norfentanyl.

Minnesota: Minnesota has not scheduled norfentanyl.

19. Contact Name 20. Contact Phone Number

Jon Derenne (608) 266-0955

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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

ATTACHMENT A

 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

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.:	CSB 2.80
Relating to:	Scheduling oliceridine
Rule Type:	Permanent

1. Finding/nature of emergency:

N/A

2. Detailed description of the objective of the proposed rule:

The objective of the proposed rule is to schedule oliceridine as a schedule II controlled substance under s. 961.11 (4), Stats.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

On October 30, 2020, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing oliceridine into schedule II of the federal Controlled Substances Act. The scheduling action was effective October 30, 2020.

The Controlled Substances Board did not receive an objection to similarly treat oliceridine as a Schedule II controlled substance under ch. 961, Stats within 30 days of the date of publication in the Federal Register of the final order designating oliceridine as a controlled substance.

Pursuant to s. 961.11 (4), Stats., the Controlled Substances Board took affirmative action to similarly treat oliceridine under ch. 961, Stats. by creating the following:

961.16 (3) (ta) Oliceridine.

The Affirmative Action order, dated December 7, 2020, took effect on December 14, 2020 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

4. Detailed explanation of statutory authority for the rule:

Section 961.11 (1), Stats. provides that "[t]he 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."

Section 961.11(4), Stats. provides that "[i]f 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, Rev. 3/6/2012

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)."

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

Approximately 80 hours.

6. List with description of all entities that may be affected by the proposed rule:

Law enforcement, district attorney offices, Dept of Justice, state courts and the Controlled Substances Board.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

On October 30, 2020, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing oliceridine into schedule II of the federal Controlled Substances Act. The scheduling action was effective October 30, 2020.

8. Anticipated economic impact of implementing the rule:

None to minimal.

Contact Person: Jon Derenne, Administrative Rules Coordinator, (608) 266-0955, DSPSAdminRules@wisconsin.gov
Approved for Publication:
Chairperson
Date Submitted

Doug Englebert Chairperson

Alan BloomVice Chairperson

Yvonne Bellay Secretary CONTROLLED SUBSTANCES BOARD



4822 Madison Yards Way PO Box 8366 Madison WI 53708-8366

Email: dsps@wisconsin.gov Voice: 608-266-2112 FAX: 608-251-3032

March 22, 2019

Senator Stephen Nass, Senate Co-Chairperson Joint Committee for Review of Administrative Rules Room 10 South, State Capitol Madison, WI 53702

Representative Joan Ballweg, Assembly Co-Chairperson Joint Committee for Review of Administrative Rules Room 210 North, State Capitol Madison, WI 53702

RE: Report Submitted in Compliance with s. 227.29 (1), Stats.

Dear Senator Nass and Representative Ballweg:

This report has been prepared and submitted in compliance with s. 227.29 (1), Stats.

I. Unauthorized rules, as defined in s. 227.26 (4) (a):

After careful review of the Board's administrative rules, the Board has determined that no promulgated rules are unauthorized.

II. Rules for which the authority to promulgate has been restricted:

After careful review of the Board's administrative rules, the Board has determined that no promulgated rules have restricted authority.

III. Rules that are obsolete or that have been rendered unnecessary:

After careful review of the Board's administrative rules, the Board has determined that no promulgated rules are obsolete or have been rendered unnecessary.

IV. Rules that are duplicative of, superseded by, or in conflict with another rule, a state statute, a federal statute or regulation, or a ruling of a court of competent jurisdiction:

After careful review of the Board's administrative rules, the Board has determined that no promulgated rules are duplicative of, superseded by, or in conflict with another rule, a state statute, a federal statute or regulation, or a ruling of a court of competent jurisdiction.

V. Rules that are economically burdensome:

Jaga Land

After careful review of the Board's administrative rules, the Board has determined that no promulgated rules are economically burdensome. Thank you.

Cordially,

Doug Englebert

Chairperson

State of Wisconsin Department of Safety & Professional Services

AGENDA REQUEST FORM

		7.02	110/11	LGOLOT TOTAL	•
1) Name and Title of Per	son Subi	mitting the Reques	t:	2) Date When Requ	est Submitted:
Mariaria Liu				01/04/2021	
Marjorie Liu Program Lead, PDMP				Items will be conside date which is 8 busin	red late if submitted after 12:00 p.m. on the deadline less days before the meeting
3) Name of Board, Comi	mittee, Co	ouncil, Sections:			
Controlled Substance					
4) Meeting Date:		chments:	6) How	should the item be til	tled on the agenda page?
01/15/2021	_	es			(22142) 11 1 2 2 1
	□ N	0	Conside		Program (PDMP) Updates – Discussion and
7) Place Item in:		8) Is an appearar	 nce before	e the Board being	9) Name of Case Advisor(s), if required:
Open Session		scheduled?		3	(),
Closed Session		Yes (Fill out Bo	ard Appe	earance Request)	
		x No			
10) Describe the issue a			dressed:		
	DMP Ope				
		of New Program and	l Policy An	nalyst	
	itus of Gra	Jpcoming Releases			
		ta Sharing			
		escribing Metrics No	tifications		
	Integration				
			ion project	ts (VA & APRIS; RX C	heck & eHealth)
4. WI eF	PDMP Out	reach			
11)			Authoriza	tion	
Signature of person ma	king this	request			Date 01/04/2021
Marjorie Liu					
Supervisor (if required)					Date
Executive Director signs	ature (ind	licates approval to	add post	agenda deadline iten	n to agenda) Date
Directions for including	supporti	na documents:			
This form should be			submitted	d to the agenda.	
					y Development Executive Director.
	original	documents needin	g Board C	Chairperson signature	e to the Bureau Assistant prior to the start of a
meeting.					

2019-2021 Development and Release Summary

Updated 1.6.2021

Release Date	Description
Pending	
R20 Release date TBD	 WI DOJ-Medical College of Wisconsin DataShare Project Automatically send data extracts to DOJ-MCW Automatically receive data extracts from DOJ-MCW Administrative-Related Enhancements Additional improvements to query process Additional administrator tools
Completed	
R19 September 2020	New Design Enhancements • Enhanced MME calculation process • Ability to set map display defaults Administrative-Related Enhancements • Improvements to query approval process Search Engine Optimization Updates to non-user facing parts of the PDMP to optimize search engine results
R18 July 2020	 New Design Enhancements Updated layout and design of Patient Report including alerts and dispensing details, based on user feedback Opioid naïve alert; history of buprenorphine alert Additional EHR Enhancements Multi-state default settings Prescriber Metrics Notifications Proactive notice to prescribers to review metrics, based on time and/or prescribing thresholds
R17.1 April 2020	Pharmacy-Related Enhancements Display of Date Sold, if provided in the submission ASAP file processing improvements

	1
	Pharmacy-Related Enhancements
	 Improvements to workflow for error corrections/void Display of Date Sold, if provided in the submission
	New Design Enhancements
	Better access to history of recent Patient Reports for Delegates
R17	Additional data element on overdose alerts entered by law enforcement
March 2020	to capture administration of Naloxone
	MME calculator
	Additional EHR Enhancements
	Expanded patient search from within EHR
	Expanded navigation from within EHR
	Patients Panel Improvements
	Additional data fields EHR Enhancements
D4.C	Additional state query from within the EHR, as contractually allowable
R16 Dec 2019	(initially RxCheck states only)
Dec 2013	 Delegate Management ability from within EHR Ability of Delegates to identify as licensed/unlicensed
	Ability of Delegates to identify as licensed/utilicensed
Minor Interim Release	Patient matching updates
Oct 2019	Specific improvement for linking patients based on nicknames
R15.1	Performance-Related Enhancements
Sept 2019	Performance improvements for Medical Coordinator role
	User Management Enhancements
R15	Annual acceptance of Term and Conditions of the WI ePDMP
Aug 2019	Renewal process for Medical Coordinator access to metrics
	Periodic review of linked delegates
_	RxCheck
R14	Technical tasks to establish connection to RxCheck interstate data
April 2019	sharing hub
	Data Quality Software Stability Work
R12 and R13	 Technical tasks to simplify workflows and improve
March 2019	identification/resolution of workflow issues
	DHS Extract
R11	Addition of patient geocode latitude and longitude
February 2019	Quality Assurance and Support Items

WI ePDMP Interstate Data Exchange Summary

Current as of 1.6.2021

Wisconsin is now connected with 28 state PDMPs and Military Health System.

RxCheck/EHR	PMPi		
In Discussion	In Progress		
MN			
Connected			
IL, NE, PA, UT, WA,	AZ, CO, DE, FL, HI, IA, ID, IN, KS, ME, MI, MN, MT, NC, ND, NM, NV, NY, PR , SC, SD, TN , WV, Military Health System		

WI ePDMP Integration Services Summary

Current as of 1.6.2021

Pending Health Systems and EHR Platforms
Advanced Pain Management (In Development)
ADVENT (In Development)
Athena (In Discussion)
Essentia (In Discussion/Contracting)
Prairie Clinic (In Discussion)
Connected Health Systems (approx. 50% of monthly patient queries)
Ascension Wisconsin
Aspirus Health Care
Aurora Health Care
Children's Hospital of Wisconsin
Froedtert & the Medical College of Wisconsin
GHC of South Central Wisconsin
Gundersen Health System
HealthPartners
HSHS / Prevea Health
Marshfield Clinic
Mayo Clinic
Mercy Health
Monroe Clinic
ProHealth Care
SSM Health
Thedacare
UnityPoint
UW Health
Wisconsin Statewide Health Information Network

2021 WI PDMP Outreach Calendar

MONTH	EVENT	DESCRIPTION	DATES	NOTES
January				
February				
March	Law Enforcement Outreach	Self-Paced PDMP Training, Lake Delton PD	By End of March	
April	Rx Drug Abuse & Heroin Summit	Panelist, PDMP & Patitent Privacy	4/5-4/8/2021	Vitural Conference
May	WI Overdose Fatality Review Spring Summit	Presenter	TBD	TBD
June				
July				
August				
September				
October				
November				
December				