Wisconsin Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way
PO Box 8366
Madison WI 53708-8366

Phone: 608-266-2112
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Tony Evers, Governor
Dawn B. Crim, Secretary

CONTROLLED SUBSTANCES BOARD
VIRTUAL/TELECONFERENCE
Virtual, 4822 Madison Yards Way, Madison
Contact: Adam Barr (608) 266-2112
March 11, 2022

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.
OR IMMEDIATELY FOLLOWING THE REFERRAL CRITERIA WORK GROUP MEETING

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-3)

B. Approval of Minutes January 14, 2022 (4-8)

C. Reminders: Conflicts of Interests, Scheduling Concerns

D. Introductions, Announcements and Recognition

E. Administrative Matters – Discussion and Consideration
1) Department, Staff, and Board Updates
2) Board Members – Term Expiration Dates
   a. Alton, Troy
   b. Barman, Subhadeep – 5/1/2019
   c. Bellay, Yvonne
   d. Bloom, Alan – 5/1/2020
   e. Englebert, Doug
   f. Ferguson, Kris
   g. Kallio, Peter
   h. Koresch, Sandy
   i. Weitekamp, John

F. Administrative Rule Matters – Discussion and Consideration (9)
1) Final Rule Draft and Legislative Report
   a. CSB 2.78, Relating to Crotonyl Fentanyl **(10-17)**
   b. CSB 2.79, Relating to Scheduling Remimazolam **(18-25)**
   c. CSB 2.81, Relating to Scheduling Brorphine **(26-34)**
2) Preliminary Rule Draft
   a. CSB 2.82, Relating to Scheduling Serdexmethylphenidate **(35-37)**
   b. CSB 2.83, Relating to Scheduling 10 Fentanyl Related Substances **(38-41)**

c. CSB 2.84, Relating to Scheduling Alfaxalone **(42-45)**
d. CSB 2.85, Relating to Excluding 6-beta-natrexol **(46-49)**
e. CSB 2.86, Relating to Scheduling Fospropofol **(50-52)**
f. CSB 2.87, Relating to Scheduling Embutramide **(53-55)**
g. CSB 2.88, Relating to Scheduling Lacosamide **(56-58)**
h. CSB 2.89, Relating to Scheduling Perampanel **(59-61)**
i. CSB 2.90, Relating to Transferring 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile **(62-65)**

3) Pending and Possible Rulemaking Projects

G. Prescription Drug Monitoring Program (PDMP) Update – Discussion and Consideration (66)

1) WI ePDMP Operations
   a. CSB 2021 Q4 Report
   b. NPI Requirement for ePDMP User Accounts
   c. Recent and Upcoming Releases **(67-68)**
   d. Status of Grant Projects:
      1. FY 2020 Harold Rogers Prescription Drug Monitoring Program
      2. FY 2021 Harold Rogers Prescription Drug Monitoring Program
      3. Buprenorphine Exclusion Project
   e. Interstate Data Sharing **(69-70)**
   f. EHR Integration Status
2) WI ePDMP Outreach **(71)**

H. COVID-19 – Discussion and Consideration

I. Board Member Reports – Discussion and Consideration

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

J. Liaison Reports

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

L. Deliberation on Special Use Authorizations – Discussion and Consideration

M. 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

N. 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.).

O. Deliberation on Special Use Authorizations – Discussion and Consideration

P. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

Q. Vote on Items Considered or Deliberated Upon in Closed Session if Voting is Appropriate

R. Open Session Items Noticed Above Not Completed in the Initial Open Session

ADJOURNMENT

NEXT MEETING: MAY 13, 2022

CONTROLLED SUBSTANCES BOARD
VIRTUAL/TELECONFERENCE
Virtual, 4822 Madison Yards Way, Madison
Contact: Adam Barr (608) 266-2112
March 11, 2022

CONTROLLED SUBSTANCES BOARD
2021 WISCONSIN PUBLIC RECORDS LAW FACILITATED TRAINING
9:45 A.M. OR IMMEDIATELY FOLLOWING THE FULL BOARD MEETING

A quorum of the Controlled Substances Board may be present; however, no board business will be conducted.

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

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

VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
JANUARY 14, 2022

PRESENT: Troy Alton, Subhadeep Barman, Yvonne Bellay, Alan Bloom, Rosemary Dolatowski, Doug Englebert, Kris Ferguson, Sandy Koresch, John Weitekamp

EXCUSED: Peter Kallio

STAFF: Adam Barr, Executive Director; Jameson Whitney, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Katlin Schwartz, Bureau Assistant; Kimberly Wood, Program Assistant Supervisor-Adv.; and other DSPS Staff

Rosemary Dolatowski served as the Board of Nursing Representative at this meeting.

CALL TO ORDER

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

ADOPTION OF AGENDA

MOTION: Alan Bloom moved, seconded by Sandy Koresch, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF NOVEMBER 12, 2021

MOTION: Subhadeep Barman moved, seconded by John Weitekamp, to adopt the Minutes of November 12, 2021 as published. Motion carried unanimously.

INTRODUCTIONS, ANNOUNCEMENTS AND RECOGNITION

Recognition: Herbert Kaske, Dentistry Examining Board Representative

MOTION: Troy Alton moved, seconded by Sandy Koresch, to recognize and thank Herbert Kaske for his years of dedicated service to the Board and State of Wisconsin. Motion carried unanimously.

Recognition: Special Guests of the November 2021 Annual Law Enforcement Hearing

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

- Dawn B. Crim, Secretary, Department of Safety & Professional Services
- Josh Kaul, Attorney General, State of Wisconsin
- Nilajah Hardin, Department of Safety & Professional Services
- Sandy Koresch, Wisconsin State Crime Lab Bureau

Motion carried unanimously.

ADMINISTRATIVE MATTERS

Elections of Officers

Slate of Officers

NOMINATION: Sandy Koresch nominated the 2021 slate of officers to continue in 2022. All officers accepted their nominations.

Adam Barr, Executive Director, called for nominations three (3) times.

The Slate of Officers were elected by unanimous voice vote.

ELECTION RESULTS	
Chairperson	Doug Englebert
Vice Chairperson	Alan Bloom
Secretary	Yvonne Bellay

Appointment of Liaison and Alternates

LIAISON APPOINTMENTS	
Special Use Authorization (SUA) Liaison(s)	Alan Bloom, Yvonne Bellay *Alternate:* Doug Englebert
PDMP Liaison(s)	Subhadeep Barman *Alternates:* Kris Ferguson, John Weitekamp-Pharmacy Issues, Doug Englebert
Legislative Liaison(s)	Doug Englebert *Alternates:* Peter Kallio, John Weitekamp

SCAODA Representative	Subhadeep Barman *Alternate:* Kris Ferguson
Referral Criteria Workgroup	Doug Englebert, Peter Kallio, John Weitekamp, Subhadeep Barman

Delegation of Authorities

Document Signature Delegations

MOTION: Alan Bloom moved, seconded by Yvonne Bellay, 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: Rosemary Dolatowski moved, seconded by Sandy Koresch, 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: John Weitekamp 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(s) Delegation

MOTION: Sandy Koresch moved, seconded by John Weitekamp, to authorize the 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: Sandy Koresch moved, seconded by John Weitekamp, to authorize the SUA Liaison(s) to make all decisions related to Special Use Authorizations. Motion carried unanimously.

Authorization for DSPS to Provide Board Member Contact Information to National Regulatory Related Bodies

MOTION: Alan Bloom moved, seconded by Yvonne Bellay, to authorize the Department staff to provide national regulatory related bodies with all board member contact information that the Department retains on file. Motion carried unanimously.

Legislative Liaison Delegation

MOTION: Sandy Koresch moved, seconded by Subhadeep Barman, to delegate authority to the Legislative Liaisons to speak on behalf of the Board regarding legislative matters. Motion carried unanimously.

SCAODA Representative Delegation

MOTION: Yvonne Bellay moved, seconded by Alan Bloom, 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(s) Delegation

MOTION: John Weitekamp moved, seconded by Sandy Koresch, to authorize PDMP Liaison(s) 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.

Referral Criteria Workgroup Membership Delegation

MOTION: Alan Bloom moved, seconded by Troy Alton, that in order to facilitate the completion of its duties between meetings, the Board delegates 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 members to the Referral Criteria Workgroup between meetings as necessary. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Final Rule Draft and Legislative Report – CSB 2.80, Relating to Scheduling Oliceridine

MOTION: Subhadeep Barman moved, seconded by Sandy Koresch, to approve the Legislative Report and Draft for Clearinghouse Rule 21-098 (CSB 2.80), relating to Scheduling Oliceridine, for submission to the Governor's Office and Legislature. Motion carried unanimously.

Scope Statement – CSB 2.91, Relating to Scheduling 4,4' – Dimethylaminorex

MOTION: John Weitekamp moved, seconded by Sandy Koresch, to approve the Scope Statement on CSB 2.91, relating to Scheduling 4,4'-Dimethylaminorex, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on the Scope Statement, the Chairperson is authorized to approve the required notice of hearing. Motion carried unanimously.

REPORT FROM THE REFERRAL CRITERIA WORK GROUP

MOTION: Troy Alton moved, seconded by John Weitekamp, to accept the recommendations of the Referral Criteria Work Group and refer the specified providers to the appropriate examining boards for further proceedings. Motion carried unanimously.

ADJOURNMENT

MOTION: Subhadeep Barman moved, seconded by Alan Bloom, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 10:11 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:
Nilajah Hardin, Administrative Rules Coordinator	**02/28/22** **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**

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

Controlled Substances Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
03/11/22	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Final Rule Draft and Legislative Report** **a. CSB 2.78, Relating to Scheduling Crotonyl Fentanyl** **b. CSB 2.79, Relating to Scheduling Remimazolam** **c. CSB 2.81, Relating to Scheduling Brorphine** **2. Preliminary Rule Draft** **a. CSB 2.82, Relating to Scheduling Serdexmethylphenidate** **b. CSB 2.83, Relating to Scheduling 10 Fentanyl Related Substances** **c. CSB 2.84, Relating to Scheduling Alfaxalone** **d. CSB 2.85, Relating to Excluding 6-beta-natrexol** **e. CSB 2.86, Relating to Scheduling Fospropofol** **f. CSB 2.87, Relating to Scheduling Embutramide** **g. CSB 2.88, Relating to Scheduling Lacosamide** **h. CSB 2.89, Relating to Scheduling Perampanel** **i. CSB 2.90, Relating to Transferring 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile** **3. Pending or Possible Rulemaking Projects**

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

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

Attachments:

Final Rule Draft and Legislative Report – CSB 2.78, 2.79, and 2.81

Preliminary Rule Draft – CSB 2.82-2.90

Rule Projects Chart

Copies of all current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx

11) Authorization

Nilajah D. Hardin — 02/28/22

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

Supervisor (if required) — **Date**

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

Directions for including supporting documents:

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

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	**:**	**REPORT TO THE LEGISLATURE CR 22-011**

I. THE PROPOSED RULE:

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

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

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

This rule schedules Crotonyl Fentanyl as a Schedule I controlled substance.

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

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

961.14 (2) (nd) 9m. Crotonyl Fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide).

The Affirmative Action order, dated November 13, 2020, took effect on November 23, 2020 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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

Per s. 961.11(4), Stats., if no objection is made, the board shall promulgate a final rule for which notice of proposed rulemaking is omitted. Therefore, the Board did not hold a public hearing.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Legislative Council staff did not make any recommendations.

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

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 22-011)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.78 relating to scheduling Crotonyl Fentanyl.

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:
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, 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)."

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On October 2, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Crotonyl Fentanyl into schedule I of the federal Controlled Substances Act. The scheduling action was effective October 2, 2020.

Plain language analysis:
This rule schedules Crotonyl Fentanyl as a Schedule I controlled substance.

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

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

961.14 (2) (nd) 9m. Crotonyl Fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide).

The Affirmative Action order, dated November 13, 2020, took effect on November 23, 2020 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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 Crotonyl Fentanyl as a controlled substance.

Iowa: Iowa has not scheduled Crotonyl Fentanyl as a controlled substance.

Michigan: Michigan has not scheduled Crotonyl Fentanyl as a controlled substance.

Minnesota: Minnesota has not scheduled Crotonyl Fentanyl as a controlled substance.

Summary of factual data and analytical methodologies:
The methodology was to schedule Crotonyl Fentanyl 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:
The proposed rules were posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate:
The Fiscal Estimate and Economic Impact Analysis are attached.

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by March 11, 2022 to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.78 is created to read:

CSB 2.78 Scheduling of Crotonyl Fentanyl. Section 961.14 (2) (nd) 9m, Stats., is created to read:

961.14 (2) (nd) 9m. Crotonyl Fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide).

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

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

Dated _____ Agency _____

Chairperson
Controlled Substances Board

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

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
January 25, 2022

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.78

4. Subject
Scheduling Crotonyl Fentanyl

5. Fund Sources Affected
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected

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

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
On October 2, 2020, the Department of Justice, Drug Enforcement Administration published a final rule in the Federal Register placing Crotonyl Fentanyl into schedule I of the federal Controlled Substances Act.

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 for 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)
None

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is that the federal and state controlled substances acts will be uniform to avoid confusion. In addition it is in the best interest of Wiscsonsin citizens to schedule Crotonyl Fentanyl as a controlled substance.

16. Long Range Implications of Implementing the Rule
The long range implication of implementing the rule will be to schedule Crotonyl Fentanyl as a schedule I controlled substance.

17. Compare With Approaches Being Used by Federal Government
The federal government has scheduled Crotonyl Fentanyl as a schedule I controlled substance.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
Illinois: Illinois has not scheduled Crotonyl Fentanyl as a 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

Iowa: Iowa has not scheduled Crotonyl Fentanyl as a controlled substance.

Michigan: Michigan has not scheduled Crotonyl Fentanyl as a controlled substance.

Minnesota: Minnesota has not scheduled Crotonyl Fentanyl as a controlled substance.

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Adminstrative Rule Coordinator	608-267-7139

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

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

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

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

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

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	**:**	**REPORT TO THE LEGISLATURE CR 22-014**

I. THE PROPOSED RULE:

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

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

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

This rule schedules Remimazolam as a Schedule IV controlled substance.

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

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

961.20 (2) (mo) Remimazolam.

The Affirmative Action order, dated November 13, 2020, took effect on November 23, 2020 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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

Per s. 961.11(4), Stats., if no objection is made, the board shall promulgate a final rule for which notice of proposed rulemaking is omitted. Therefore, the Board did not hold a public hearing.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Legislative Council staff did not make any recommendations.

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

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 22-014)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.79 relating to scheduling Remimazolam.

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:
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, 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)."

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On October 6, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Remimazolam into schedule IV of the federal Controlled Substances Act. The scheduling action was effective October 6, 2020.

Plain language analysis:
This rule schedules Remimazolam as a Schedule IV controlled substance.

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

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

961.20 (2) (mo) Remimazolam.

The Affirmative Action order, dated November 13, 2020, took effect on November 23, 2020 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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 Remimazolam as a controlled substance.

Iowa: Iowa temporarily designated Remimazolam as a Schedule IV controlled substance, via their temporary amendment process, effective May 12, 2021 (ARC 5541C - Iowa Administrative Rules).

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

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

Summary of factual data and analytical methodologies:
The methodology was to schedule Remimazolam 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:
The proposed rules were posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate:
The Fiscal Estimate and Economic Impact are attached.

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by March 11, 2022 to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.79 is created to read:

CSB 2.79 Scheduling of Remimazolam. Section 961.20 (2) (mo), Stats., is created to read:

961.20 (2) (mo) Remimazolam.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

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

Dated _____ Agency _____

Chairperson
Controlled Substances Board

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

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
January 26, 2022

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.79

4. Subject
Scheduling Remimazolam

5. Fund Sources Affected
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected

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

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
On October 6, 2020, the Department of Justice, Drug Enforcement Administration published a final rule in the Federal Register placing Remimazolam into schedule IV of the federal Controlled Substances Act.

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 for 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)
None

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is that the federal and state controlled substances acts will be uniform to avoid confusion. In addition it is in the best interest of Wiscsonsin citizens to schedule Remimazolam as a controlled substance.

16. Long Range Implications of Implementing the Rule
The long range implication of implementing the rule will be to schedule Remimazolam as a schedule IV controlled substance.

17. Compare With Approaches Being Used by Federal Government
The federal government has scheduled Remimazolam 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 Remimazolam as a controlled substance.

DIVISION OF EXECUTIVE BUDGET AND FINANCE
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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Iowa: Iowa temporarily designated Remimazolam as a Schedule IV controlled substance, via their temporary amendment process, effective May 12, 2021 (ARC 5541C - Iowa Administrative Rules).

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

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

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Adminstrative Rule Coordinator	608-267-7139

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
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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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

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

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

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

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	**:**	**REPORT TO THE LEGISLATURE CR 22-016**

I. THE PROPOSED RULE:

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

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

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

This rule schedules Brorphine as a Schedule I controlled substance.

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

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

961.14 (2) (et) Brorphine.

The Affirmative Action order, dated April 16, 2021, took effect on May 3, 2021 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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

Per s. 961.11(4), Stats., if no objection is made, the board shall promulgate a final rule for which notice of proposed rulemaking is omitted. Therefore, the Board did not hold a public hearing.

The Board received a public comment from Charles Mollien on February 7, 2022. Their comment was that Michigan has scheduled Brorphine as a Schedule I controlled substance effective January 6, 2022.

The Board updated the Comparison with Rules in Adjacent States section of the rule analysis to reflect that Michigan has scheduled Brorphine based on the public comment above.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Legislative Council staff did not make any recommendations.

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

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 22-016)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.81 relating to scheduling Brorphine.

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:
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, 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)."

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On March 1, 2021, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Brorphine into schedule I of the federal Controlled Substances Act. The scheduling action was effective March 1, 2021.

Plain language analysis:
This rule schedules Brorphine as a Schedule I controlled substance.

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

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

961.14 (2) (et) Brorphine.

The Affirmative Action order, dated April 16, 2021, took effect on May 3, 2021 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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 Brorphine as a controlled substance.

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

Michigan: Michigan has listed Brorphine as a Schedule I controlled substance [Michigan Administrative Code R 338.3111 (3) (f)].

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

Summary of factual data and analytical methodologies:
The methodology was to schedule Brorphine 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:
The proposed rules were posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate:
The Fiscal Estimate and Economic Impact Analysis are Attached.

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by March 11, 2022 to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.81 is created to read:

CSB 2.81 Scheduling of Brorphine. 961.14 (2) (et), Stats., is created to read:

961.14 (2) (et) Brorphine.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

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

Dated _____ Agency _____

Chairperson
Controlled Substances Board

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

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
February 2, 2022

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.81

4. Subject
Scheduling Brorphine

5. Fund Sources Affected
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected

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

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
On March 1, 2021, the Department of Justice, Drug Enforcement Administration published a final rule in the Federal Register placing Brorphine into schedule I of the federal Controlled Substances Act.

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 for 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)
None.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is that the federal and state controlled substances acts will be uniform to avoid confusion. In addition it is in the best interest of Wiscsonsin citizens to schedule Brorphine as a controlled substance.

16. Long Range Implications of Implementing the Rule
The long range implication of implementing the rule will be to schedule Brorphine as a schedule I controlled substance.

17. Compare With Approaches Being Used by Federal Government
The federal government has scheduled Brorphine as a schedule I controlled substance.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
Illinois: Illinois has not scheduled Brorphine as a controlled substance.

DIVISION OF EXECUTIVE BUDGET AND FINANCE
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FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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

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

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

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Adminstrative Rule Coordinator	608-267-7139

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
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FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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

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

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

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

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

From:	Software-Notification@legis.wisconsin.gov
To:	DSPS Admin Rules
Cc:	
Subject:	Public comment on CR 22-016
Date:	Monday, February 7, 2022 1:04:40 PM

Name: Charlie Mollien
Address: -, Grand Rapids MI 49544
Email: -

Organization:

Comments: Michigan scheduled brorphine as a schedule 1 controlled substance effective January 6, 2022 through administrative authority by the Michigan Board of Pharmacy. See MAC Rule 338.3111(3)(f) available at https://ars.apps.lara.state.mi.us/AdminCode/DownloadAdminCodeFile?FileName=R%20338.3101%20to%20R%20338.3199q.pdf&ReturnHTML=True.

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.82 relating to scheduling Serdexmethylphenidate.

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:
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, 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)."

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On May 7, 2021, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing Serdexmethylphenidate into schedule IV of the federal Controlled Substances Act. The scheduling action is effective May 7, 2021.

Plain language analysis:
This rule schedules Serdexmethylphenidate as a Schedule IV controlled substance.

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

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

961.20 (2m) (em) Serdexmethylphenidate.

The Affirmative Action order, dated June 28, 2021, took effect on July 12, 2021 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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 Serdexmethylphenidate as a controlled substance.

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

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

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

Summary of factual data and analytical methodologies:
The methodology was to schedule Serdexmethylphenidate 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:
The rule schedules Serdexmethylphenidate as a Schedule IV controlled substance which will not have any effect on small business.

Fiscal Estimate:
The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by (date) to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.82 is created to read:

CSB 2.82 Addition of Serdexmethylphenidate to Schedule IV. 961.20 (2m) (em), Stats., is created to read:

961.20 (2m) (em) Serdexmethylphenidate.

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
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.83 relating to scheduling ten (10) fentanyl related substances.

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:
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, 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)."

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On April 27, 2021, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing ten Fentanyl-related substances into schedule I of the federal Controlled Substances Act. The scheduling action is effective immediately.

Plain language analysis:
The objective of the rule is to schedule ten (10) Fentanyl related substances as a schedule I controlled substances.

The Controlled Substances Board did not receive an objection to similarly treating the ten (10) Fentanyl-related substances listed in schedule I under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating the ten (10) Fentanyl-related substances listed above as controlled substances.

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

CSB 2.83 Addition of ten (10) Fentanyl-related substances to schedule I. *Section 961.14 (2) (nd) 21., 22., 23., 24., 25., 26., 27., 28., 29., and 30., Stats., is created to read:*

961.14 (2) (nd)

21. *N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-fluorofentanyl);*
22. *N-(1-(4-methylphenethyl)piperidin-4-yl)-N-phenylacetamide (4'-methyl acetyl fentanyl);*
23. *N-(1-phenethylpiperidin-4-yl)-N,3-diphenylpropanamide (β'-phenyl fentanyl; beta'-Phenyl fentanyl; 3-phenylpropanoyl fentanyl);*
24. *N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)propionamide (β-methyl fentanyl);*
25. *N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide (ortho-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl);*
26. *N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl acetylfentanyl; 2-methyl acetylfentanyl);*
27. *2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl);*
28. *N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)propionamide (para-methylfentanyl; 4-methylfentanyl);*
29. *N-(1-phenethylpiperidin-4-yl)-N-phenylbenzamide (phenyl fentanyl; benzoyl fentanyl); and*
30. *N-(1-phenethylpiperidin-4-yl)-N-phenylthiophene-2-carboxamide (thiofuranyl fentanyl; 2-thiofuranyl fentanyl; thiophene fentanyl).*

The Affirmative Action order, dated July 9, 2021, took effect on July 19, 2021 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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 the 10 fentanyl related substances listed above as controlled substances.

Iowa: Iowa has not scheduled the 10 fentanyl related substances listed above as controlled substances.

Michigan: Michigan has not scheduled the 10 fentanyl related substances listed above as controlled substances.

Minnesota: Minnesota has not scheduled the 10 fentanyl related substances listed above as controlled substances.

Summary of factual data and analytical methodologies:
The methodology was to schedule the 10 fentanyl related substances listed above 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:
The rule schedules 10 fentanyl related substances as Schedule I controlled substances which will not have any effect on small business.

Fiscal Estimate:
The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by (date) to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.83 is created to read:

CSB 2.83 Addition of ten (10) Fentanyl-related substances to schedule I. Section 961.14 (2) (nd) 21., 22., 23., 24., 25., 26., 27., 28., 29., and 30., Stats., is created to read:

961.14 (2) (nd)

21. N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-fluorofentanyl);
22. N-(1-(4-methylphenethyl)piperidin-4-yl)-N-phenylacetamide (4'-methyl acetyl fentanyl);
23. N-(1-phenethylpiperidin-4-yl)-N,3-diphenylpropanamide (β'-phenyl fentanyl; beta'-Phenyl fentanyl; 3-phenylpropanoyl fentanyl);
24. N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)propionamide (β-methyl fentanyl);
25. N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide (ortho-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl);
26. N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl acetylfentanyl; 2-methyl acetylfentanyl);
27. 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl);
28. N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)propionamide (para-methylfentanyl; 4-methylfentanyl);
29. N-(1-phenethylpiperidin-4-yl)-N-phenylbenzamide (phenyl fentanyl; benzoyl fentanyl); and
30. N-(1-phenethylpiperidin-4-yl)-N-phenylthiophene-2-carboxamide (thiofuranyl fentanyl; 2-thiofuranyl fentanyl; thiophene fentanyl).

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
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.84 relating to scheduling Alfaxalone.

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:
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, 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)."

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On February 27, 2014, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Alfaxalone into schedule IV of the federal Controlled Substances Act. The scheduling action is effective March 31, 2014.

Plain language analysis:
This rule schedules Alfaxalone as a Schedule IV controlled substance.

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

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

> ***CSB 2.84 Addition of Alfaxalone to schedule IV****. Section 961.20 (2) (a), Stat., is repealed and recreated to read:*
>
> *961.20 (2) (a) Alfaxalone.*
>
> *Section 961.20 (2) (ak) is created to read:*
>
> *961.20 (2) (ak) Alprazolam*

The Affirmative Action order, dated July 9, 2021, took effect on July 19, 2021 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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 Alfaxalone as a controlled substance.

Iowa: Iowa has listed Alfaxalone as a schedule IV controlled substance [Iowa Administrative Code s. 124.210 (3) (bb)].

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

Minnesota: Minnesota has listed Alfaxalone as a schedule IV controlled substance [Minnesota State Statutes s. 152.02 (5) (c) (1)].

Summary of factual data and analytical methodologies:
The methodology was to schedule Alfaxalone 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:
The rule schedules Alfaxalone as a Schedule IV controlled substance which will not have any effect on small business.

Fiscal Estimate:
The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by (date) to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.84 is created to read:

CSB 2.84 Addition of Alfaxalone to schedule IV. Section 961.20 (2) (a), Stats., is repealed and recreated to read:

961.20 (2) (a) Alfaxalone.

Section 961.20 (2) (ak), Stats. is created to read:

961.20 (2) (ak) Alprazolam.

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
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.85 relating to Excluding 6-beta-Naltrexol.

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:
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, 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)."

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On January 24, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing 6-beta-Naltrexol from schedule II of the federal Controlled Substances Act. The scheduling action is effective January 24, 2020.

Plain language analysis:
This rule excludes 6-beta-Naltrexol from schedule II.

The Controlled Substances Board did not receive an objection to similarly removing 6-beta-Naltrexol 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 removing 6-beta-Naltrexol as a schedule II controlled substance.

Pursuant to s. 961.11 (4), Stats., the Controlled Substances Board took affirmative action to similarly treat 6-beta-Naltrexol under ch. 961, Stats. by creating the following:

CSB 2.85 Excluding 6-beta-Naltrexol from schedule II. *Section 961.16 (2) (a), Stats., is amended to read:*

961.16 (2) (a) *Opium and substances derived from opium, and any salt, compound, derivative or preparation of opium or substances derived from opium. Apomorphine, dextrorphan, nalbuphine, butorphanol, naldemedine, nalmefene, naloxegol, naloxone, 6-beta-naltrexol, and naltrexone and their respective salts and the isoquinoline alkaloids of opium and their respective salts are excluded from this paragraph. The following substances, and any of their salts, isomers and salts of isomers that are theoretically possible within the specific chemical designation, are included in this paragraph:*

The Affirmative Action order, dated July 9, 2021, took effect on July 19, 2021 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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 excluded 6-beta-naltrexol from their schedule II controlled substances list.

Iowa: Iowa has excluded 6-beta-naltrexol from their schedule II controlled substances list [Iowa Administrative Code s. 124.206 (2) (a)].

Michigan: Michigan has not excluded 6-beta-naltrexol from their schedule II controlled substances list.

Minnesota: Minnesota has not excluded 6-beta-naltrexol from their schedule II controlled substances list.

Summary of factual data and analytical methodologies:
This rule excludes 6-beta-Naltrexol from schedule II 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 excludes 6-beta-Naltrexol from schedule II which will not have any effect on small business.

Fiscal Estimate:
The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by (date) to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.85 is created to read:

CSB 2.85 Excluding 6-beta-Naltrexol from schedule II. Section 961.16 (2) (a), Stats., is amended to read:

961.16 (2) (a) Opium and substances derived from opium, and any salt, compound, derivative or preparation of opium or substances derived from opium. Apomorphine, dextrorphan, nalbuphine, butorphanol, naldemedine, nalmefene, naloxegol, naloxone, 6-beta-naltrexol, and naltrexone and their respective salts and the isoquinoline alkaloids of opium and their respective salts are excluded from this paragraph. The following substances, and any of their salts, isomers and salts

of isomers that are theoretically possible within the specific chemical designation, are included in this paragraph:

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
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.86 relating to scheduling Fospropofol.

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:
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, 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)."

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On October 6, 2009, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Fospropofol into schedule IV of the federal Controlled Substances Act. The scheduling action is effective November 5, 2009.

Plain language analysis:
This rule schedules Fospropofol as a Schedule IV controlled substance.

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

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

CSB 2.86 Addition of Fospropofol to schedule IV*. Section 961.20 (2) (en), Stats., is created to read:*

961.20 (2) (en) Fospropofol.

The Affirmative Action order, dated July 9, 2021, took effect on July 19, 2021 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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 listed Fospropofol a schedule IV controlled substance [720 Illinois Compiled Statutes 570/210 (c) (11.1)].

Iowa: Iowa has listed Fospropofol a schedule IV controlled substance [Iowa Administrative Code 124.210 (3) (ba)].

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

Minnesota: Minnesota has listed Fospropofol a schedule IV controlled substance [Minnesota Statutes 152.02 (5) (c) (24)].

Summary of factual data and analytical methodologies:
The methodology was to schedule Fospropofol 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:

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

Fiscal Estimate:
The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by (date) to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.86 is created to read:

CSB 2.86 Addition of Fospropofol to schedule IV. Section 961.20 (2) (en), Stats., is created to read:

961.20 (2) (en) Fospropofol.

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
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.87 relating to scheduling Embutramide.

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:
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, 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)."

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On August 29, 2006, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Embutramide into schedule III of the federal Controlled Substances Act. The scheduling action is effective September 28, 2006.

Plain language analysis:
This rule schedules Embutramide as a Schedule III controlled substance.

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

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

CSB 2.87 Addition of Embutramide to schedule III*. Section 961.18 (3) (bm), Stats., is created to read:*

961.18 (3) (bm) Embutramide.

The Affirmative Action order, dated July 9, 2021, took effect on July 19, 2021, when it was published in the Administrative Register and expires upon promulgation of a final rule.

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 Embutramide as a controlled substance.

Iowa: Iowa has listed Embutramide as a schedule III controlled substance [Iowa Administrative Code 124.208 (3) (n)].

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

Minnesota: Minnesota has listed Embutramide as a schedule III controlled substance [Minnesota Statutes 152.02 (4) (c) (5) (x)].

Summary of factual data and analytical methodologies:
The methodology was to schedule Embutramide 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:

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

Fiscal Estimate:
The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by (date) to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.87 is created to read:

CSB 2.87 Addition of Embutramide to schedule III. Section 961.18 (3) (bm), Stats., is created to read:

961.18 (3) (bm) Embutramide.

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
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.88 relating to scheduling Lacosamide.

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:
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, 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)."

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On May 21, 2009, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Lacosamide into schedule V of the federal Controlled Substances Act. The scheduling action is effective June 22, 2009.

Plain language analysis:
This rule schedules Lacosamide as a Schedule V controlled substance.

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

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

CSB 2.88 Addition of Lacosamide to schedule V*. Section 961.22 (10), Stats., is created to read:*

961.22 (10) Lacosamide.

The Affirmative Action order, dated July 9, 2021, took effect on July 19, 2021, when it was published in the Administrative Register and expires upon promulgation of a final rule.

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 listed Lacosamide as a schedule V as a controlled substance [720 Illinois Compiled Statutes 570/212 (c-1)].

Iowa: Iowa has listed Lacosamide as a schedule V as a controlled substance [Iowa Administrative Code 124.212 (5) (b)].

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

Minnesota: Minnesota has listed Lacosamide as a schedule V as a controlled substance [Minnesota Statutes 152.02 (6) (3) (iii)].

Summary of factual data and analytical methodologies:
The methodology was to schedule Lacosamide 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:

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

Fiscal Estimate:
The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by (date) to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.88 is created to read:

CSB 2.88 Addition of Lacosamide to schedule V. Section 961.22 (10), Stats., is created to read:

961.22 (10) Lacosamide.

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
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.89 relating to scheduling Perampanel.

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:
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, 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)."

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On December 2, 2013, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Perampanel into schedule III of the federal Controlled Substances Act. The scheduling action is effective January 2, 2014.

Plain language analysis:
This rule schedules Perampanel as a Schedule III controlled substance.

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

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

CSB 2.89 Addition of Perampanel to schedule III*. Section 961.18 (3) (fm), Stats., is created to read:*

961.18 (3) (fm) Perampanel.

The Affirmative Action order, dated July 9, 2021, took effect on July 19, 2021, when it was published in the Administrative Register and expires upon promulgation of a final rule.

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 Perampanel as a controlled substance.

Iowa: Iowa has listed Perampanel as a schedule III controlled substance [Iowa Administrative Code 124.208 (3) (o)].

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

Minnesota: Minnesota has listed Perampanel as schedule III controlled substance [Minnesota Statutes 152.02 (4) (c) (5) (xi)].

Summary of factual data and analytical methodologies:
The methodology was to schedule Perampanel 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:

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

Fiscal Estimate:
The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by (date) to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.89 is created to read:

CSB 2.89 Addition of Perampanel to schedule III. Section 961.18 (3) (fm), Stats., is created to read:

961.18 (3) (fm) Perampanel.

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
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.90, relating to transferring 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP.

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:
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, 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)."

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On May 17, 1978, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, into schedule II of the federal Controlled Substances Act. The scheduling action was effective June 16, 1978.

Plain language analysis:
This rule transfers 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, from schedule I to schedule II of the chapter 961, stats.

The Controlled Substances Board did not receive an objection to similarly listing 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, as schedule II controlled substances under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order listing 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, as a schedule II controlled substances.

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, under chapter 961, Stats. by repealing s. 961.14 (6) and creating the following:

CSB 2.90 Transfer of 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, from Schedule I to schedule II*. Section 961.16 (8) (c), Stats. is created to read:*

961.16 (8) (c) *Immediate precursors to phencyclidine, also known as PCP:*
1. *1-phenylcyclohexylamine.*
2. *1-piperidinocyclohexanecarbonitrile.*

The Affirmative Action order, dated July 9, 2021, took effect on July 19, 2021, when it was published in the Administrative Register and expires upon promulgation of a final rule.

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 listed 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile as a schedule II controlled substances [720 Illinois Compiled Statutes 520/206 (f) (2)].

Iowa: Iowa has listed 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile as a schedule II controlled substances [Iowa Administrative Code 124.206 (6) (b)].

Michigan: Michigan has not scheduled 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile as controlled substances.

Minnesota: Minnesota has listed 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile as a schedule II controlled substances [Minnesota Statutes 152.02 (3) (e) (6)].

Summary of factual data and analytical methodologies:
The methodology was to transfer 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, from schedule I to schedule II 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:
The rule transfers 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, from schedule I to schedule II which will not have any effect on small business.

Fiscal Estimate:
The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by (date) to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. s. 961.14 (6), stats. is repealed.

SECTION 2. CSB 2.90 is created to read:

CSB 2.90 Transfer of 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, from Schedule I to schedule II. Section 961.16 (8) (c), Stats. is created to read:

961.16 (8) (c) Immediate precursors to phencyclidine, also known as PCP:
1. 1-phenylcyclohexylamine.
2. 1-piperidinocyclohexanecarbonitrile.

SECTION 3. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

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:
Marjorie Liu **Program Lead, PDMP**	3/1/2022 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

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

Controlled Substances Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
3/11/2022	☒ Yes ☐ No	Prescription Drug Monitoring Program (PDMP) Updates – Discussion and Consideration

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

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

1. WI ePDMP Operations
    a. PDMP 2021 Q4 Report
    b. NPI Requirement for ePDMP User Accounts
    c. Recent and Upcoming Releases
    d. Status of Grant Projects:
        i. FY 2020 Harold Rogers Prescription Drug Monitoring Program
        ii. FY 2021 Harold Rogers Prescription Drug Monitoring Program
        iii. Buprenorphine Exclusion Project
    e. Interstate Data Sharing
    f. EHR Integration Status
2. WI ePDMP Outreach

11) Authorization

Marjorie Liu 03/01/2022

Signature of person making this request — Date

Supervisor (if required) — Date

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

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

2020-2022 Development and Release Summary

Updated 02.28.2022

Release Date	Description
Pending	
R26 **Release date TBD**	Buprenorphine Exclusion • Ability to override prescriber facing alerts, metrics, and MME calculations for certain drugs. Maintenance Updates RxCheck 3.0 Upgrades
Harold Rogers Grant 2020 **Component 3** **Release date TBD**	Ability for users to change the order in which the sections of the patient report are presented. Adding a Buprenorphine Naïve Alert section to the patient report.
Harold Rogers Grant 2020 **Component 2** **Release date TBD**	Infrastructure and technology stack changes to improve performance in the following areas: • Patient Matching • Dispensing Matching • Reporting Statistics
Completed	
Harold Rogers Grant 2020 **Component 1** **December 2021**	Security Enhancements • Two-Factor Authentication • Compromised Email Address Check Patient Report and other User Experience Updates
R25 **November 2021**	Maintenance Updates • Adjustments to triggering Annual Terms and Conditions prompt • Enhanced EHR Integration Testing capabilities Chatbot display changes
R24 **August 2021**	Text Updates • Gabapentin related text changes to the Submitter Error Email. Security-Related Enhancements
R23 **July 2021**	Text Updates • Gabapentin related text changes to the Submitter Error Email.
R22 **July 2021**	Pharmacy-Related Enhancements • Missing DEA Number Error Process Updates Administrative-Related Enhancements

R21 **May 2021**	New Design Enhancements • Proactive MC/HCP linkage renewals • Search enhancements Administrative-Related Enhancements Additional administrator tools
R20 **March 2021**	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
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 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
R17 **March 2020**	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 • Additional data element on overdose alerts entered by law enforcement to capture administration of Naloxone • MME calculator Additional EHR Enhancements • Expanded patient search from within EHR • Expanded navigation from within EHR

Interstate Data Sharing

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

WI ePDMP Integration Services Summary

Current as of 02.28.2022

Pending Health Systems and EHR Platforms
Advent Health (In Development)
Advent Health - Cerner
Marshfield EHR System Change (In Discussion/Contracting)
Wisconsin Statewide Health Information Network (Converting to new Platform)
Bluestone Physician Services (In Discussion/Contracting)
Clean Slate (In Development)
Connected Health Systems (approx. 50% of monthly patient queries)
Ascension Wisconsin
Aspirus Health Care
Aurora Health Care
Children's Hospital of Wisconsin
Dr First
Froedtert & the Medical College of Wisconsin
GHC of South Central Wisconsin
Gundersen Health System

HealthPartners
HSHS / Prevea Health
M Health Fairview
Marshfield Clinic
Mayo Clinic
Mercy Health
Monroe Clinic
NOVO Health Technology Group
ProHealth Care
SSM Health
Thedacare
UnityPoint
UW Health
Wisconsin Statewide Health Information Network

2022 WI PDMP Outreach Calendar

MONTH	EVENT	DESCRIPTION	DATES	NOTES
January	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	1/13, 4/14	Quarterly meeting
February				
March				
April	DOJ Law Enforcement (LE) Bulletin	Updated FAQ for LE alert reporting	WILENET April Issue	
	RxCheck Governance Board Annual Meeting	Participant; Annual meeting for state PDMP administrators	TBD	TBD
	Rx Drug Abuse & Heroin Summit	Participant; national conference led by multidisciplinary experts for stakeholders addressing the opioid crisis	4/18-4/21	Atlanta, GA
May				
June				
July				
August				
September				
October				
November				
December				