Wisconsin Department of Safety and Professional Services
Division of Policy Development
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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD
Virtual, 4822 Madison Yards Way, Madison
Contact: Tom Ryan (608) 266-2112
March 8, 2024

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

10:00 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. **Adoption of Agenda (1-3)**

B. **Approval of Minutes January 19, 2024 (4-7)**

C. Reminders: Conflicts of Interests, Scheduling Concerns

D. Introductions, Announcements and Recognition

E. **10:00 A.M. Public Hearing for Clearinghouse Rule 24-013 on CSB-4, Relating to National Provider Identifier Requirement (8)**
   1) Review Public Hearing Comments and Respond to Clearinghouse Report **(9-18)**

F. **10:00 A.M. Preliminary Hearing on Statement of Scope – SS 022-24 on CSB-4, Relating to Mail Delivered Prescription (19)**
   1) Review Preliminary Hearing Comments **(20-22)**

G. Administrative Matters – Discussion and Consideration
   1) Department, Staff, and Board Updates
   2) Board Members – Term Expiration Dates
      a. Alton, Troy – Dentistry Examining Board Representative
      b. Barman, Subhadeep – 5/1/2019
      c. Bellay, Yvonne – DATCP Representative
      d. Bloom, Alan – 5/1/2020
      e. Eberhardy, Cullen – AG Representative
      f. Englebert, Doug – DHS Representative
      g. Kane, Amanda – Board of Nursing Representative
      h. Schmeling, Gregory – Medical Examining Board Representative
      i. Weitekamp, John – Pharmacy Examining Board Representative
   3) Alternates
      a. Bistan, Matthew – Dentistry Examining Board Representative
      b. Ferguson, Kris – Medical Examining Board Representative
      c. Weinman, Robert – Board of Nursing Representative

H. **Administrative Rule Matters – Discussion and Consideration (23)**
   1) Scope Statement:
      a. CSB 2.004, Relating to Scheduling Zuranolone **(24-25)**
      b. CSB 2.005, Relating to Scheduling Nine Fentanyl Analogs **(26-27)**
      c. CSB 2.006, Relating to Scheduling Five Synthetic Cannabinoids **(28-29)**
   2) Preliminary Rule Draft:
      a. CSB 2.003, Relating to Five Synthetic Benzodiazepine Substances **(30-33)**
   3) Final Rule Draft:
      a. CSB 2.98, Relating to Excluding [^{18} F]FP-CIT **(34-44)**
      b. CSB 2.99, Relating to Scheduling Mesocarb **(45-53)**
   4) Adoption Order:
      a. CSB 2.92, Relating to Scheduling 35 Anabolic Steroids **(54-58)**
      b. CSB 2.93, Relating to Scheduling Daridorexant **(59-61)**
      c. CSB 2.94, Relating to Scheduling Seven Synthetic Benzimidazole-Opioids **(62-65)**
      d. CSB 2.95, Relating to Scheduling Ganaxolone **(66-68)**
   5) Pending and Possible Rulemaking Projects
      a. Rule Projects Chart **(69-70)**

I. **Prescription Drug Monitoring Program (PDMP) Updates – Discussion and Consideration (71)**
   1) WI ePDMP Operations
      a. Recent and Upcoming Releases **(72-74)**
      b. EHR Integration Status **(75-76)**
   2) WI ePDMP Outreach **(77)**

J. **Board Member Reports – Discussion and Consideration**
   1) Medical Examining Board
   2) Dentistry Examining Board
   3) Board of Nursing
   4) Pharmacy Examining Board

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

L. Liaison Reports

M. Deliberation on Special Use Authorizations – Discussion and Consideration

N. 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) Public Health Emergencies

14) Appearances from Requests Received or Renewed
15) Speaking Engagements, Travel, or Public Relations Requests, and Reports
16) Consulting with Legal Counsel

O. **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.).

P. Deliberation on Special Use Authorizations – Discussion and Consideration

Q. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: MAY 10, 2024

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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 virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. 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 hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, or the Meeting Staff at 608-267-7213.

VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
JANUARY 19, 2024

PRESENT: Yvonne Bellay, Alan Bloom, Cullen Eberhardy, Doug Englebert, Gregory Schmeling, John Weitekamp

EXCUSED: Subhadeep Barman, Troy Alton, Amanda Kane

STAFF: Tom Ryan, Executive Director; Whitney DeVoe, Legal Counsel; Dialah Azam, Board Administration Specialist; and other DSPS Staff

Robert Weinman served as the Board of Nursing Representative at this meeting.

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 10:00 a.m. A quorum was confirmed with seven (7) members present.

ADOPTION OF AGENDA

Amendments to the Agenda:

- **CHANGE** starting time to 9:30 a.m. to 10:00 a.m.

MOTION: Robert Weinman moved, seconded by Alan Bloom, to adopt the Agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF NOVEMBER 10, 2023

MOTION: Alan Bloom moved, seconded by Cullen Eberhardy, to adopt the Minutes of November 10, 2023 as published. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Election of Officers, Appointments of Liaisons and Alternates, Delegation of Authorities

Election of Officers

Slate of Officers

NOMINATION: Robert Weinman nominated the 2023 slate of officers to continue in 2024. All officers accepted their nominations.

Tom Ryan, Executive Director, called for nominations three (3) times.

The Slate of Officers was 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:* John Weitekamp
SCAODA Representative	Subhadeep Barman *Alternate:* Kris Ferguson
Referral Criteria Workgroup	Doug Englebert, John Weitekamp, Subhadeep Barman, Amanda Kane

Delegation of Authorities

Review and Approval of 2023 Delegations

MOTION: Alan Bloom moved, seconded by Yvonne Bellay, to reaffirm all delegation motions from 2023 as reflected in the agenda materials. Motion carried unanimously.

Document Signature Delegations

MOTION: Doug Englebert moved, seconded by Yvonne Bellay, 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, Board Counsel, or DPD Division Administrator, the authority to sign on behalf of a board member as necessary. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Affirmative Action Order

CSB 2.004, Relating to Scheduling Zuranolone

MOTION: Doug Englebert moved, seconded by John Weitekamp, to schedule by affirmative action Zuranolone as a schedule IV controlled substance. The order shall take effect upon publication in the Administrative Register. Motion carried unanimously.

CSB 2.005, Relating to Scheduling 9 Fentanyl Related Substances

MOTION: Alan Bloom moved, seconded by Cullen Eberhardy, to schedule by affirmative action 9 Fentanyl Related Substances as schedule I controlled substances. The order shall take effect upon publication in the Administrative Register. Motion carried unanimously.

CSB 2.006, Relating to Scheduling 5 Synthetic Cannabinoids

MOTION: Doug Englebert moved, seconded by Yvonne Bellay, to schedule by affirmative action 5 Synthetic Cannabinoids as schedule I controlled substances. The order shall take effect upon publication in the Administrative Register. Motion carried unanimously.

CSB 2.007, Relating to Scheduling ADB-BUTINACA, α-PiHP, and 3-MMC

MOTION: Alan Bloom moved, seconded by Cullen Eberhardy, to designate the Chairperson to schedule by affirmative action ADB-BUTINACA, α-PiHP, and 3-MMC as schedule I controlled substances. The order shall take effect upon publication in the Administrative Register. Motion carried unanimously.

Scope Statement: CSB 4, Relating to Mail Delivered Prescriptions

MOTION: John Weitekamp moved, seconded by Doug Englebert, to approve the Scope Statement creating CSB 4, relating to Mail Delivered Prescriptions, 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.

Preliminary Rule Draft

CSB 2.001, Relating to Scheduling Methiopropamine

CSB 2.002, Relating to Scheduling Fenfluramine

MOTION: Alan Bloom moved, seconded by Cullen Eberhardy, to approve the preliminary rule draft for the following rules for posting for economic impact comments and submission to the Clearinghouse:

- CSB 2.001, Relating to Scheduling Methiopropamine
- CSB 2.002, Relating to Excluding Fenfluramine

Motion carried unanimously.

CSB 4, Relating to Monitored Prescription Drug History Reports

MOTION: Yvonne Bellay moved, seconded by John Weitekamp, to designate the Chairperson to approve the preliminary rule draft of CSB 4, relating to Monitored Prescription Drug History Reports, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

Final Rule Draft

CSB 2.96, Relating to Scheduling Amineptine

CSB 2.97, Scheduling Zipeprol

MOTION: John Weitekamp moved, seconded by Alan Bloom, to approve the Legislative Report and Draft for the following rules for submission to the Governor's Office and Legislature:

- Clearinghouse Rule 23-068 on CSB 2.96, relating to Scheduling Amineptine
- Clearinghouse Rule 23-069 on CSB 2.97, relating to Scheduling Zipeprol

Motion carried unanimously.

REPORT FROM THE REFERRAL CRITERIA WORK GROUP

MOTION: Robert Weinman moved, seconded by Gregory Schmeling, to accept the recommendations of the Referral Criteria Work Group and refer the specified providers to the appropriate professional boards for further action. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 10:31 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**	**2/26/24** 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?
03/08/24	☒ Yes ☐ No	**10:00 A.M. Public Hearing for Clearinghouse Rule 24-013 on CSB 4, Relating to National Provider Identifier Requirement** 1. **Review Public Hearing Comments and Respond to Clearinghouse Report**

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:

The Board will hold a public hearing on this rule as required by the rulemaking process.

11) Authorization

Nilajah D. Hardin — 2/26/24

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	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 4.02 (12s), 4.04 (2) (bm) and (im), 4.04 (5), and 4.097 (1) (i), and amend CSB 4.05 (1) (b) (Note), 4.06 (3) (b) (Note), 4.07 (2) (Note), and 4.08 (1) (b) (Note), and repeal CSB 4.08 (4), relating to national provider identifier requirement.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 961.385 (2) (b) and (7s), Stats.

Statutory authority: s. 961.385 (2) (b), Stats.

Explanation of agency authority:
961.385 (2) (b) states that the board shall establish by rule and have the prescription drug monitoring program "Identify specific data elements to be contained in a record documenting the dispensing of a monitored prescription drug, including the method of payment and, subject to sub. (2m), the name recorded under s. 450.44 (1b) (bm). In identifying specific data elements, the board shall consider data elements identified by similar programs in other states and shall ensure, to the extent possible, that records generated by the program are easily shared with other states."

Related statute or rule: None.

Plain language analysis:
The objective of the proposed rule is to add the National Provider Identifier (NPI) for all dispensing and prescribing Prescription Drug Monitoring Program (PDMP) records by creating CSB 4.02 (12s), 4.04 (2) (im), and 4.04 (5). The Board also repealed the exemption requirement under CSB 4.08 (4) that allowed dispensers to be exempt from reporting Gabapentin prescribing if they do not have a DEA number. Section CSB 4.097 (1) (i) was created to reflect that access to the PDMP can be restricted for failure to provide an NPI number. Updates were also made to the mailing address for the Department in ss CSB 4.05 (1) (b) (Note), 4.06 (3) (b) (Note), 4.07 (2) (Note), and 4.08 (1) (b) (Note).

Summary of, and comparison with, existing or proposed federal regulation: None.

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: No comments were received.

Comparison with rules in adjacent states:

Illinois: The Illinois Prescription Monitoring Program does not require an NPI number to be reported [720 Illinois Compiled Statutes Chapter 570 Section 316].

Iowa: The Iowa Prescription Monitoring Program does not require an NPI number to be reported [657 Iowa Administrative Code Chapter 37 Section 12].

Michigan: The Michigan Automated Prescription System, the states electronic system for monitoring schedule II to V controlled substances, does not require an NPI number to be reported [Michigan Administrative Rules R 338.3162b].

Minnesota: The Minnesota Prescription Monitoring Program requires the NPI number of the prescriber and the NPI number of the dispenser to be reported for all controlled substances dispensed in the state [Minnesota Statutes Chapter 152 Section 152.126 Subdivision 4].

Summary of factual data and analytical methodologies:
The Board reviewed Wisconsin Administrative Code Chapter CSB 4 in consultation with Wisconsin Prescription Drug Monitoring Program staff to determine where the NPI number requirement can be added and if updates to other sections in the chapter were needed.

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

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

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, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on March 8, 2024, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 4.02 (12s), 4.04 (2) (bm) and (im), and 4.04 (5) are created to read:

CSB 4.02 (12s) "NPI number" means national provider identifier number, the unique number used in the U.S. to identify each health care provider.

CSB 4.04 (2) (bm) The dispenser's NPI number.

CSB 4.04 (2) (im) The prescriber's NPI number.

CSB 4.04 (5) Beginning December 1, 2024, all healthcare professionals and pharmacies shall comply with the application of an NPI number to each prescription record required to be reported to the PDMP.

SECTION 2. CSB 4.05 (1) (b) (Note), 4.06 (3) (b) (Note), 4.07 (2) (Note), and 4.08 (1) (b) (Note) are amended to read:

CSB 4.05 (1) (b) (Note) The guide for dispensers which specifies the data standards in version 4 release 2 of the ASAP implementation guide for prescription monitoring programs and other electronic formats identified by the board may be obtained online at https://pdmp.wi.gov or obtained at no charge from the Department of Safety and Professional Services, ~~1400 East Washington Avenue~~4822 Madison Yards Way, P.O. Box 8366, Madison, WI ~~53708~~53705.

CSB 4.06 (3) (b) (Note) The application for an emergency waiver may be obtained online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, ~~1400 East Washington Avenue~~4822 Madison Yards Way, P.O. Box 8366, Madison, WI ~~53708~~53705.

CSB 4.07 (2) (Note) The written notice to the board may be submitted through an account with the board, sent by electronic mail or sent by U.S. mail to the Department of Safety and Professional Services ~~1400 East Washington Avenue~~,4822 Madison Yards Way, P.O. Box 8366, Madison, WI ~~53708~~53705.

CSB 4.08 (1) (b) (Note) The application for an exemption may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services ~~1400 East Washington Avenue~~,4822 Madison Yards Way, P.O. Box 8366, Madison, WI ~~53708~~53705. A dispenser who is already exempt can renew his or her exemption as part of the licensure renewal process.

SECTION 3. CSB 4.08 (4) is repealed.

SECTION 4. CSB 4.097 (1) (i) is created to read:

CSB 4.097 (1) (i) Beginning December 1, 2024, the board may temporarily suspend access to monitored prescription drug history reports when the healthcare professional fails to enter an NPI number into the PDMP system where required.

SECTION 5. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

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

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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

2. Date
February 5, 2024

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 4

4. Subject
National Provider Identifier Requirement

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

6. Chapter 20, Stats. Appropriations Affected
s. 20.165 (1) (g)

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
The objective of the proposed rule is to add the National Provider Identifier (NPI) for all dispensing and prescribing Prescription Drug Monitoring Program (PDMP) records.

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 of Safety and Professional Service's (DSPS) website for 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.

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

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)
DSPS estimates no one-time or annual costs to implement this rule.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit of implementing the rule is increased accuracy and reporting on the prescribing of Gabapentin and any other monitored drug reported to the PDMP which does not require a DEA number to be prescribed and dispensed. All individual HIPAA-covered healthcare providers are required to have an individual NPI number and therefore NPI numbers can be reported by providers to the PDMP for monitored drugs in lieu of a DEA number. The alternative to implementing this rule is that Gabapentin, and any other future monitored drug that is not a controlled substance, will continue to be inconsistently reported in the PDMP system.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing the rule are accruate reporting and tracking of Gabapentin and any other future monitored drug that is not a controlled substance in the PDMP..

17. Compare With Approaches Being Used by Federal Government

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

None.

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

Illinois: The Illinois Prescription Monitoring Program does not require an NPI number to be reported [720 Illinois Compiled Statutes Chapter 570 Section 316].

Iowa: The Iowa Prescription Monitoring Program does not require an NPI number to be reported [657 Iowa Administrative Code Chapter 37 Section 12].

Michigan: The Michigan Automated Prescription System, the states electronic system for monitoring schedule II to V controlled substances, does not require an NPI number to be reported [Michigan Administrative Rules R 338.3162b].

Minnesota: The Minnesota Prescription Monitoring Program requires the NPI number of the prescriber and the NPI number of the dispenser to be reported for all controlled substances dispensed in the state [Minnesota Statutes Chapter 152 Section 152.126 Subdivision 4].

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules 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

LCRC
FORM 2

Wisconsin Legislative Council
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

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

CLEARINGHOUSE RULE **24-013**

AN ORDER to repeal CSB 4.08 (4); to amend CSB 4.05 (1) (b) (Note), 4.06 (3) (b) (Note), 4.07 (2) (Note), and 4.08 (1) (b) (Note); and to create CSB 4.02 (12s), 4.04 (2) (bm) and (im) and (5), and 4.097 (1) (i), relating to national provider identifier requirement.

Submitted by **CONTROLLED SUBSTANCES BOARD**

02-05-2024 RECEIVED BY LEGISLATIVE COUNCIL.

02-26-2024 REPORT SENT TO AGENCY.

SG:KAM

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

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

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☐ NO ☑

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☑ NO ☐

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☐ NO ☑

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☑ NO ☐

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☐ NO ☑

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

Wisconsin Legislative Council
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE RULE 24-013

Comments

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

2. Form, Style and Placement in Administrative Code

In SECTION 1 of the proposed rule, s. CSB 4.04 (5) specifies when health care professionals and pharmacies must comply with the changed rule requirement. Similarly, in SECTION 4 of the proposed rule, s. CSB 4.097 specifies the date the provision begins. Separately, the rule also specifies an effective date. Consider whether the provisions delaying the effect of the rule could be achieved by a delayed effective date instead of inclusion in the substantive rule text. With respect to the treatment of s. CSB 4.04, if retained in the rule text, consider placing the date in newly created s CSB 4.04 (2) (bm) and (im), rather than creating sub. (5). [For example, for s. CSB 4.04 (2) (bm), "Beginning December 1, 2024, the dispenser's NPI number".]

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

a. As created by the proposed rule, s. CSB 4.097 (1) (i) specifies a consequence for failure to enter an NPI number into the PDMP system. What is the consequence for failure to enter other data into the PDMP system as required under s. CSB 4.04 (2)?

b. Consider further defining the term, "NPI number". For example, consider specifying whether an NPI number is issued by the National Plan and Provider Enumeration System of the federal Centers for Medicare and Medicaid Services. [See, for comparison, 2023 Senate Bill 158.]

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**	**2/26/24** 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?
03/08/24	☒ Yes ☐ No	**10:00 A.M. Preliminary Hearing on Statement of Scope – SS 022-24 on CSB 4, Relating to Mail Delivered Prescriptions** **1. Review Preliminary Hearing Comments**

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:

The Board will hold a Preliminary Hearing on this scope statement as directed by the Joint Committee for Review of Administrative Rules.

11) Authorization

Nilajah D. Hardin — 02/26/24

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.

From:	Sen.Nass
To:	Hereth, Daniel - DSPS; DSPS; DSPS Admin Rules
Cc:	Tierney, Michael - DSPS; Sen.Nass - LEGIS; Rep.Neylon - LEGIS; Grosz, Scott A - LEGIS; Kauffman, Jill - LEGIS; Duchek, Mike - LEGIS
Subject:	JCRAR Directive to Hold Preliminary Hearing on Scope Statement SS 022-24
Date:	Thursday, February 22, 2024 2:11:26 PM

February 22, 2024

Doug Englebert, Chairperson
Controlled Substances Board
Department of Safety & Professional Services
P.O. Box 8366
Madison, WI 53708-8366

RE: SS 022-24 – Mail Delivered Prescriptions

Dear Chairperson Englebert:

As co-chairperson of the Joint Committee for Review of Administrative Rules (JCRAR) and pursuant to s. 227.136 (1), Stats., I write to direct the Controlled Substances Board to hold a preliminary public hearing and comment period on Scope Statement SS 022-24, which was published in the Wisconsin Administrative Register on February 12, 2024.

Additionally, pursuant to s. 227.135 (2), Stats., please note that a scope statement may not be approved by the Secretary, the Department of Safety & Professional Services (DSPS), or any of the agencies under DSPS until after the preliminary public hearing and comment period is held by the agency, and accordingly, no activity may be conducted in connection with the drafting of a proposed rule until after such hearing and approval have occurred.

Please confirm receipt of this letter directing a preliminary hearing and comment period on the above scope statement.

Sincerely,

Steve Nass

Senator Steve Nass
Co-Chair, JCRAR

Cc: Dan Hereth, Secretary-designee, DSPS

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 4

Relating to: Mail Delivered Prescriptions

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule:
The objective of the proposed rule is to review the requirements in CSB 4.04 to determine whether an exemption created by the Pharmacy Examining Board under s. Phar 8.06 (2) should be adopted to avoid discrepancies between code provisions. This exemption would allow for a valid signature to be recorded in lieu of an Identification Card for mail delivered controlled substances. The name from the valid signature is what will then be entered into the Prescription Drug Monitoring Program (PDMP) as part of that prescription record.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:
Wisconsin Administrative Code Chapter CSB 4 currently outlines requirements for data that is entered into the PDMP for prescriptions. Section CSB 4.04 (2) (p) requires that the name from Wis. Stat. s. 450.11 (1b) (1m) to be entered into the PDMP. The Pharmacy Examining Board has created an exemption for that statutory requirement for when the prescription is delivered by mail. Without making changes under the proposed rule there will continue to be a discrepancy in what is allowed for mail delivered prescriptions versus what is required to be entered into the PDMP.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):
961.385 (2) (a) states that the board shall establish by rule and have the prescription drug monitoring program “require a pharmacy or a practitioner to generate a record documenting each dispensing of a monitored prescription drug at the pharmacy, or if the monitored prescription drug is not dispensed at the pharmacy, by the practitioner and to submit the record to the board no later than 11:59 p.m. of the next business day after the monitored prescription drug is dispensed…”

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule: 60 hours

6. List with description of all entities that may be affected by the proposed rule:
Wisconsin Licensed Prescribers who report to the PDMP.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule: None.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):
None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Nilajah Hardin, (608) 267-7139, DSPSAdminRules@wisconsin.gov

Approved for publication:

Douglas Englebert

Authorized Signature

01/24/24

Date Submitted

Approved for implementation:

Authorized Signature

Date Submitted

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**	**2/26/24** **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?
03/08/24	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Scope Statement:** **a. CSB 2.004, Relating to Scheduling Zuranolone** **b. CSB 2.005, Relating to Scheduling Nine Fentanyl Analogs** **c. CSB 2.006, Relating to Scheduling Five Synthetic Cannabinoids** **2. Preliminary Rule Draft:** **a. CSB 2.003, Relating to Five Synthetic Benzodiazepine Substances** **3. Final Rule Draft:** **a. CSB 2.98, Relating to Excluding [^{18} F]FP-CIT** **b. CSB 2.99, Relating to Scheduling Mesocarb** **4. Adoption Order:** **a. CSB 2.92, Relating to Scheduling 35 Anabolic Steroids** **b. CSB 2.93, Relating to Scheduling Daridorexant** **c. CSB 2.94, Relating to Scheduling Seven Synthetic Benzimidazole-Opioids** **d. CSB 2.95, Relating to Scheduling Ganaxolone** **5. Pending or Possible Rulemaking Projects** **a. Rule Projects Chart**

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:

Review and take action on Affirmative Action Orders, Scope Statement, Preliminary Rules Drafts, and Final Rule Drafts.

Attachments:

- Scope Statement – CSB 2.004-2.006
- Preliminary Rule Draft – CSB 2.003
- Legislative Report, Final Rule Draft, EIA, and Clearinghouse Report – CSB 2.98 and 2.99
- Adoption Order – CSB 2.92 to 2.95
- Rule Projects Chart

(All Board Rule Projects can be Viewed Here if Needed: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx)

11) Authorization

Nilajah D. Hardin — 2/26/24

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.

Revised 03/2021

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 2.004

Relating to: Scheduling Zuranolone

Rule Type: Permanent

1. Finding/nature of emergency: N/A

2. Detailed description of the objective of the proposed rule:
The objective of the proposed rule is to schedule Zuranolone as a schedule IV controlled substance under s. 961.11 (4), Stats.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:
On October 31, 2023, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register adding Zuranolone to schedule IV of the federal Controlled Substances Act. The scheduling action was effective October 31, 2023. The Controlled Substances Board did not receive an objection to similarly listing Zuranolone 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 Zuranolone as a schedule IV controlled substance. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Zuranolone under chapter 961, Stats. by creating the following:

> **CSB 2.003 Addition of Zuranolone to Schedule I**V. Section 961.20 (2) (r), Stats., is created to read:
>
> **961.20 (2) (r)** Zuranolone.

The Affirmative Action order, dated January 24, 2024, took effect on February 5, 2024, upon publication in the Administrative Register and expires upon promulgation of a final rule.

4. Detailed explanation of statutory authority for the rule:
Section 961.11 (1), Stats. provides that "[t]he controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227."

Section 961.11(4), Stats. provides that "[i]f a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30−day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2)."

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:
Approximately 80 hours.

6. List with description of all entities that may be affected by the proposed rule:
Law enforcement, district attorney offices, Dept of Justice, state courts and the Controlled Substances Board.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:
On October 31, 2023, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register adding Zuranolone to schedule IV of the federal Controlled Substances Act. The scheduling action was effective October 31, 2023.

8. Anticipated economic impact of implementing the rule: None to minimal.

Contact Person: Nilajah Hardin, Administrative Rules Coordinator, DSPSAdminRules@wisconsin.gov

Approved for publication:	Approved for implementation:
_____	_____
Authorized Signature	Authorized Signature
_____	_____
Date Submitted	Date Submitted

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 2.005

Relating to: Scheduling Nine Fentanyl-Related Substances

Rule Type: Permanent

1. Finding/nature of emergency: N/A

2. Detailed description of the objective of the proposed rule:
The objective of the proposed rule is to schedule the following nine fentanyl-related substances as a schedule I controlled substance under s. 961.11 (4), Stats:

- *Meta*-fluorofentanyl
- *Meta*-fluoroisobutyryl fentanyl
- *Para*-methoxyfuranyl fentanyl
- 3-furanyl fentanyl
- 2',5'-dimethoxyfentanyl
- Isovaleryl fentanyl
- *Ortho*-fluorofuranyl fentanyl
- *Alpha*'-methyl butyryl fentanyl
- *Para*-methylcyclopropyl fentanyl

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:
On December 7, 2023, the Department of Justice, Drug Enforcement Administration published its temporary amendment and scheduling order in the Federal Register adding the nine fentanyl-related substances listed about to schedule I of the federal Controlled Substances Act. The scheduling action was effective December 7, 2023.The Controlled Substances Board did not receive an objection to similarly adding the nine fentanyl-related substances listed above as schedule I controlled substances under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order listing the nine fentanyl-related substances listed about as schedule I controlled substances. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats the nine fentanyl-related substances listed above under chapter 961, Stats. by creating the following:

CSB 2.005 Addition of 9 Fentanyl Related Substances to Schedule I. **(1)** Section 961.14 (2) (nd) 3m., 10m., 11m., 12e., 12m., 12s., 16n., 17g., and 17r., are created to read:

961.14 (2) (nd) 3m. *Alpha*'-methyl butyryl fentanyl (2-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide);
10m. 2',5'-dimethoxyfentanyl (*N*-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-*N*-phenylpropionamide);
11m. 3-furanyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-3-carboxamide);
12e. Isovaleryl fentanyl (3-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide);
12m. *Meta*-fluorofentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide);
12s. *Meta*-fluoroisobutyryl fentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide);
16n. *Ortho*-fluorofuranyl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);
17g. *Para*-methoxyfuranyl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

17r. *Para*-methylcyclopropyl fentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);

The Affirmative Action order, dated January 24, 2024, took effect on February 5, 2024, upon publication in the Administrative Register and expires upon promulgation of a final rule.

4. Detailed explanation of statutory authority for the rule:
Section 961.11 (1), Stats. provides that "[t]he controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227."

Section 961.11(4), Stats. provides that "[i]f a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30−day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2)."

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:
Approximately 80 hours.

6. List with description of all entities that may be affected by the proposed rule:
Law enforcement, district attorney offices, Dept of Justice, state courts and the Controlled Substances Board.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:
On December 7, 2023, the Department of Justice, Drug Enforcement Administration published its temporary amendment and scheduling order in the Federal Register adding the nine fentanyl-related substances listed about to schedule I of the federal Controlled Substances Act. The scheduling action was effective December 7, 2023.

8. Anticipated economic impact of implementing the rule: None to minimal.

Contact Person: Nilajah Hardin, Administrative Rules Coordinator, DSPSAdminRules@wisconsin.gov

Approved for publication:

Authorized Signature

Date Submitted

Approved for implementation:

Authorized Signature

Date Submitted

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 2.006

Relating to: Scheduling Five Synthetic Cannabinoids

Rule Type: Permanent

1. Finding/nature of emergency: N/A

2. Detailed description of the objective of the proposed rule:
The objective of the proposed rule is to add the following five synthetic cannabinoids as a schedule I controlled substance under s. 961.11 (4), Stats:

- MDMB-4en-PINACA
- 4F-MDMB-BUTICA or 4F-MDMB-BICA
- ADB-4en-PINACA
- CUMYL-PEGACLONE or SGT-151
- 5F-EDMB-PICA or 5F-EDMB-2201

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:
On December 12, 2023, the Department of Justice, Drug Enforcement Administration published its temporary amendment and scheduling order in the Federal Register adding the following 6 synthetic cannabinoids to schedule I of the federal Controlled Substances Act:

- MDMB-4en-PINACA
- 4F-MDMB-BUTICA or 4F-MDMB-BICA
- ADB-4en-PINACA
- CUMYL-PEGACLONE or SGT-151
- 5F-EDMB-PICA or 5F-EDMB-2201
- MMB-FUBICA

The scheduling action was effective December 12, 2023. The Controlled Substances Board did not receive an objection to similarly listing five of the above synthetic cannabinoids as schedule I controlled substances under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order listing those 5 synthetic cannabinoids as schedule I controlled substances. The remaining synthetic cannabinoid, MMB-FUBICA, is already included in schedule I of ch. 961, Stats. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats the above 5 synthetic cannabinoids under chapter 961, Stats. by creating the following:

CSB 2.006 Adding 5 Synthetic Cannabinoids to Schedule I. (1) Section 961.14 (4) (tb) 54. to 58., Stats., are created to read:

> **961.14 (4) (tb)** 54. Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate, commonly known as MDMB-4en-PINACA.
> 55. Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate**,** commonly known as 4F-MDMB-BUTICA or 4F-MDMB-BICA.
> 56. *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxaminde, commonly known as ADB-4en-PINACA.
> 57. 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one, commonly known as CUMYL-PEGACLONE or SGT-151.
> 58. Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, commonly known as 5F-EDMB-PICA or 5F-EDMB-2201.

The Affirmative Action order, dated January 24, 2024, took effect on February 5, 2024, upon publication in the Administrative Register and expires upon promulgation of a final rule.

4. Detailed explanation of statutory authority for the rule:
Section 961.11 (1), Stats. provides that "[t]he controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227."

Section 961.11(4), Stats. provides that "[i]f a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30−day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2)."

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:
Approximately 80 hours.

6. List with description of all entities that may be affected by the proposed rule:
Law enforcement, district attorney offices, Dept of Justice, state courts and the Controlled Substances Board.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:
On December 12, 2023, the Department of Justice, Drug Enforcement Administration published its temporary amendment and scheduling order in the Federal Register adding the following 6 synthetic cannabinoids to schedule I of the federal Controlled Substances Act:

- MDMB-4en-PINACA
- 4F-MDMB-BUTICA or 4F-MDMB-BICA
- ADB-4en-PINACA
- CUMYL-PEGACLONE or SGT-151
- 5F-EDMB-PICA or 5F-EDMB-2201
- MMB-FUBICA

The scheduling action is effective December 12, 2023.

8. Anticipated economic impact of implementing the rule: None to minimal.

Contact Person: Nilajah Hardin, Administrative Rules Coordinator, DSPSAdminRules@wisconsin.gov

Approved for publication:

Authorized Signature

Date Submitted

Approved for implementation:

Authorized Signature

Date Submitted

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 2.003 relating to transferring Flualprazolam and scheduling four (4) synthetic benzodiazepine substances.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

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

Summary of, and comparison with, existing or proposed federal regulation:
On July 26, 2023, the Department of Justice, Drug Enforcement Administration published its temporary amendment and scheduling order in the Federal Register adding the following 5 synthetic benzodiazepine substances to schedule I of the federal Controlled Substances Act:

- Etizolam
- Flualprazolam
- Clonazolam
- Flubromazolam
- Diclazepam

The scheduling action was effective July 26, 2023.

Plain language analysis:
The objective of the proposed rule is to transfer Flualprazolam from schedule IV to schedule I and add Etizolam, Clonazolam, Flubromazolam, and Diclazepam to schedule I of Wis. Stat. ch. 961.

The Controlled Substances Board did not receive an objection to similarly listing the above 5 synthetic benzodiazepine substances as schedule I controlled substances under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order listing the above 5 synthetic benzodiazepine substances as schedule I controlled substances.

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treated the above 5 synthetic benzodiazepine substances under chapter 961, Stats. by creating the following:

CSB 2.003 Transfer of Flualprazolam and Addition of 4 Other Synthetic Benzodiazepine Substances to Schedule I. **(1)** Section 961.20 (2) (ef), Stats. is repealed.

(2) Section 961.14 (5) (aa), (ab), (ac), (ad), and (ae) Stats., are created to read:

961.14 (5) (aa) Clonazolam (6-(2-chlorophenyl)-1-methyl-8-nitro-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

(ab) Diclazepam (7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2*H*-benzo[*e*][1,4]diazepin-2-one).

(ac) Etizolam (4-(2-chlorophenyl)-2-ethyl-9-methyl-6*H*-thieno[3,2-*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

(ad) Flualprazolam (8-chloro-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

(ae) Flubromazolam.(8-bromo-6-(2-fluorophenyl)-1-methly-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

The Affirmative Action order, dated September 19, 2023, took effect on September 25, 2023, upon publication in the Administrative Register and expires upon promulgation of this 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 specifically included Clonazolam, Flualprazolam, and Etizolam as schedule I controlled substances [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not included the five (5) synthetic benzodiazepine substances listed in this rule as schedule I controlled substances [Iowa Code 124.204].

Michigan: Michigan has not included the five (5) synthetic benzodiazepine substances listed in this rule as schedule I controlled substances [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has specifically included Clonazolam, Etizolam, and Flubromazolam as schedule I controlled substances [Minnesota Statutes 152.02 (2)].

Summary of factual data and analytical methodologies:
The methodology was to transfer Flualprazolam and add four other synthetic benzodiazepine substances to Schedule I 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 Flualprazolam and adds four other synthetic benzodiazepine substances to Schedule I which will not have any effect on small business.

Fiscal Estimate:
The proposed rule 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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

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 2.003 is created to read:

CSB 2.003 Transfer of Flualprazolam and Addition of 4 Other Synthetic Benzodiazepine Substances to Schedule I. **(1)** Section 961.20 (2) (ef), Stats. is repealed.

(2) Section 961.14 (5) (aa), (ab), (ac), (ad), and (ae) Stats., are created to read:

961.14 (5) (aa) Clonazolam (6-(2-chlorophenyl)-1-methyl-8-nitro-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

(ab) Diclazepam (7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2*H*-benzo[*e*][1,4]diazepin-2-one).

(ac) Etizolam (4-(2-chlorophenyl)-2-ethyl-9-methyl-6*H*-thieno[3,2-*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

(ad) Flualprazolam (8-chloro-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

(ae) Flubromazolam.(8-bromo-6-(2-fluorophenyl)-1-methly-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

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 RULEMAKING	**:**	
PROCEEDINGS BEFORE THE	**:**	**REPORT TO THE LEGISLATURE**
CONTROLLED SUBSTANCES BOARD	**:**	**CR 24-004**

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 excludes [^{18} F]FP-CIT from schedule II. The Controlled Substances Board did not receive an objection to similarly excluding [^{18} F]FP-CIT from schedule II under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order removing [^{18} F]FP-CIT as a schedule II controlled substance. Pursuant to s. 961.11 (4), Stats., the Controlled Substances Board took affirmative action to similarly treat [^{18} F]FP-CIT under ch. 961, Stats. by creating the following:

CSB 2.98 Excluding [^{18} F]FP-CIT from schedule II. Section 961.16 (2) (b), Stats., is amended to read:

> **961.16 (2) (b)** Coca leaves and any salt, compound, derivative, or preparation of coca leaves. Decocainized coca leaves or extractions which do not contain cocaine or ecgonine are excluded from this paragraph. [^{123}I]Ioflupane ~~is~~ and [^{18} F]FP-CIT are excluded from this paragraph. The following substances and any of their salts, esters, isomers, and salts of esters and isomers that are theoretically possible within the specific chemical designation, are included in this paragraph:

The Affirmative Action order, dated February 24, 2023, took effect on March 6, 2023 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 24-004)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.98, relating to Excluding [^{18} F]FP-CIT.

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 November 21, 2022, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing [^{18} F]FP-CIT from schedule II of the federal Controlled Substances Act. The scheduling action is effective December 21, 2022.

Plain language analysis:
This rule excludes [^{18} F]FP-CIT from schedule II.

The Controlled Substances Board did not receive an objection to similarly excluding [^{18} F]FP-CIT from schedule II under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order removing [^{18} F]FP-CIT as a schedule II controlled substance.

Pursuant to s. 961.11 (4), Stats., the Controlled Substances Board took affirmative action to similarly treat [^{18} F]FP-CIT under ch. 961, Stats. by creating the following:

CSB 2.98 Excluding [^{18} F]FP-CIT from schedule II. Section 961.16 (2) (b), Stats., is amended to read:

> **961.16 (2) (b)** Coca leaves and any salt, compound, derivative, or preparation of coca leaves. Decocainized coca leaves or extractions which do not contain cocaine or ecgonine are excluded from this paragraph. [^{123}I]Ioflupane ~~is~~ and [^{18} F]FP-CIT are excluded from this paragraph. The following substances and any of their salts, esters, isomers, and salts of esters and isomers that are theoretically possible within the specific chemical designation, are included in this paragraph:

The Affirmative Action order, dated February 24, 2023, took effect on March 6, 2023 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 [^{18} F]FP-CIT from their schedule II controlled substances list [720 Illinois Compiled Statutes 570/206].

Iowa: Iowa has not excluded [^{18} F]FP-CIT from their schedule II controlled substances list [Iowa Administrative Code s. 124.206].

Michigan: Michigan has not excluded [^{18} F]FP-CIT from their schedule II controlled substances list [Michigan Compiled Laws s. 333.7214].

Minnesota: Minnesota has not excluded [^{18} F]FP-CIT from their schedule II controlled substances list [Minnesota Statutes 152.02 (3)].

Summary of factual data and analytical methodologies:
This rule excludes [^{18} F]FP-CIT 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:
The proposed rule was 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 and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

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 8, 2024, to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.98 is created to read:

CSB 2.98 Excluding [^{18} F]FP-CIT from schedule II. Section 961.16 (2) (b), Stats., is amended to read:

> **961.16 (2) (b)** Coca leaves and any salt, compound, derivative, or preparation of coca leaves. Decocainized coca leaves or extractions which do not contain cocaine or ecgonine are excluded from this paragraph. [^{123}I]Ioflupane ~~is~~ and [^{18} F]FP-CIT are excluded from this paragraph. The following substances and any of their salts, esters, isomers, and salts of esters and 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)

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
01/24/24

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.98

4. Subject
Excluding [18F]FP-CIT

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

6. Chapter 20, Stats. Appropriations Affected
s. 20.165 (1) (g) and (hg)

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 ☐ Specific Businesses/Sectors
☐ Local Government Units ☐ 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 November 21, 2022, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing [18 F]FP-CIT from schedule II of the federal Controlled Substances Act. The scheduling action is effective December 21, 2022.

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 will be posted on the Department's website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule aligns Wisconsin statute with federal scheduling and removes [18F]FP-CIT as a schedule II controlled substance. DSPS estimates a total of $3,500 in one-time staffing costs to implement the rule. The estimated need for 0.1 limited term employee (LTE) is for rule drafting and communications necessary for implementation. The estimated costs may not be absorbed in the currently appropriated budget.

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.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing the rule are that [18F] FP-CIT will be explicitly excluded from Wis. Stat. ch. 961 as a schedule II controlled substance.

17. Compare With Approaches Being Used by Federal Government
The federal government has excluded [18F]FP-CIT as schedule II controlled substance.

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

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

Illinois: Illinois has not excluded [18 F]FP-CIT from their schedule II controlled substances list [720 Illinois Compiled Statutes 570/206].

Iowa: Iowa has not excluded [18 F]FP-CIT from their schedule II controlled substances list [Iowa Administrative Code s. 124.206].

Michigan: Michigan has not excluded [18 F]FP-CIT from their schedule II controlled substances list [Michigan Compiled Laws s. 333.7214].

Minnesota: Minnesota has not excluded [18 F]FP-CIT from their schedule II controlled substances list [Minnesota Statutes 152.02 (3)].

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules 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

LCRC
FORM 2

Wisconsin Legislative Council

RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

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

CLEARINGHOUSE RULE **24-004**

AN ORDER to create CSB 2.98, relating to excluding [18 F]FP-CIT.

Submitted by **CONTROLLED SUBSTANCES BOARD**

01-24-2024 RECEIVED BY LEGISLATIVE COUNCIL.
01-31-2024 REPORT SENT TO AGENCY.

MSK:SM

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

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

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☐ NO ☑

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☐ NO ☑

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☐ NO ☑

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☐ NO ☑

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☐ NO ☑

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING	**:**	
PROCEEDINGS BEFORE THE	**:**	**REPORT TO THE LEGISLATURE**
CONTROLLED SUBSTANCES BOARD	**:**	**CR 24-005**

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 Mesocarb as a schedule I controlled substance. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing Mesocarb as a schedule I controlled substance. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Mesocarb under chapter 961, Stats. by creating the following:

CSB 2.99 Addition of Mesocarb to schedule I. Section 961.14 (7) (s), Stats., is created to read:

> **961.14 (7) (s)** N-phenyl-N'–(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate, commonly known as Mesocarb.

The Affirmative Action order, dated February 24, 2023, took effect on March 6, 2023, when it was published 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 24-005)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.99, relating to scheduling Mesocarb.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

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

Summary of, and comparison with, existing or proposed federal regulation:
On November 22, 2022, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing Mesocarb into schedule I of the federal Controlled Substances Act. The scheduling action is effective December 22, 2022.

Plain language analysis:
This rule schedules Mesocarb as a schedule I controlled substance.

The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing Mesocarb as a schedule I controlled substance.

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

CSB 2.99 Addition of Mesocarb to schedule I. Section 961.14 (7) (s), Stats., is created to read:

> **961.14 (7) (s)** N-phenyl-N'–(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate, commonly known as Mesocarb.

The Affirmative Action order, dated February 24, 2023, took effect on March 6, 2023, 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 listed Mesocarb as a schedule I controlled substance [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not listed Mesocarb as a schedule I controlled substance [Iowa Code 124.204].

Michigan: Michigan has not listed Mesocarb as a schedule I controlled substance [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not listed Mesocarb as a schedule I controlled substance [Minnesota Statutes 152.02 (2)].

Summary of factual data and analytical methodologies:
The methodology was to schedule Mesocarb 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 rule was 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 and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

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 8, 2024, to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.99 is created to read:

CSB 2.99 Addition of Mesocarb to schedule I. Section 961.14 (7) (s), Stats., is created to read:

> **961.14 (7) (s)** N-phenyl-N'–(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate, commonly known as Mesocarb.

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
01/24/24

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.99

4. Subject
Scheduling Mesocarb

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

6. Chapter 20, Stats. Appropriations Affected
s. 20.165 (g) and (h)(g)

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 November 22, 2022, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register adding Mesocarb to schedule I of the federal Controlled Substances Act. The scheduling action is effective December 22, 2022.

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 will be posted on the Department's website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule aligns Wisconsin statute with federal scheduling and classifies Mesocarb as a schedule I controlled substance. DSPS estimates a total of $3,500 in one-time staffing costs to implement the rule. The estimated need for 0.1 limited term employee (LTE) is for rule drafting and communications necessary for implementation. The estimated costs may not be absorbed in the currently appropriated budget.

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.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing the rule are that Mesocarb will be added to Wis. Stat. ch. 961 as a schedule I controlled substance.

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

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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

Illinois: Illinois has not listed Mesocarb as a schedule I controlled substance [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not listed Mesocarb as a schedule I controlled substance [Iowa Code 124.204].

Michigan: Michigan has not listed Mesocarb as a schedule I controlled substance [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not listed Mesocarb as a schedule I controlled substance [Minnesota Statutes 152.02 (2)].

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules 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

LCRC
FORM 2

Wisconsin Legislative Council

RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

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

CLEARINGHOUSE RULE **24-005**

AN ORDER to create CSB 2.99, relating to scheduling Mesocarb.

Submitted by **CONTROLLED SUBSTANCES BOARD**

01-24-2024 RECEIVED BY LEGISLATIVE COUNCIL.
02-14-2024 REPORT SENT TO AGENCY.

SG:SM

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

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

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☐ NO ☑

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☐ NO ☑

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☐ NO ☑

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☐ NO ☑

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☐ NO ☑

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 23-018)

ORDER

An order of the Controlled Substances Board to create CSB 2.92 relating to scheduling thirty-five (35) anabolic steroids.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.18, 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. 961.18, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On December 16, 2005 and July 30, 2012, the Department of Justice, Drug Enforcement Administration published its final rules in the Federal Register placing a number of anabolic steroids into schedule III of the federal Controlled Substances Act. The scheduling actions are effective January 20, 2005 and August 29, 2012. Of the substances scheduled in these actions, thirty-five (35) have been determined to not have been previously scheduled in Wisconsin.

Plain language analysis:
This rule adds thirty-five (35) anabolic steroids not previously scheduled in Wisconsin to schedule III under ch. 961, Stats.

The Controlled Substances Board did not receive an objection to similarly treating these thirty-five (35) anabolic steroids as schedule III under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating these thirty-five (35) anabolic steroids as controlled substances.

Therefore, pursuant to s. 961.11(4), Stats., the Controlled Substances Board by Affirmative Action similarly treated thirty-five (35) anabolic steroids under chapter 961, Stats and is now following up with a final rule.

The Affirmative Action order, dated July 20, 2022, took effect on July 25, 2022, 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 included the thirty-five (35) anabolic steroids added in this rule as schedule III controlled substances [720 Illinois Compiled Statutes 570/102 (c-1) and 208 (f)].

Iowa: Iowa has included the thirty-five (35) anabolic steroids added in this rule as schedule III controlled substances [Iowa Code 124.208 (6)].

Michigan: Michigan has not included the thirty-five (35) anabolic steroids added in this rule as schedule III controlled substances [Michigan Compiled Laws s. 333.7201-7231].

Minnesota: Minnesota has included the thirty-five (35) anabolic steroids added in this rule as schedule III controlled substances [Minnesota Statutes 152.02 (4) (f) (1)].

Summary of factual data and analytical methodologies:
The methodology was to add thirty-five (35) anabolic steroids to schedule III of ch. 961, Stats. 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 adds thirty-five (35) anabolic steroids as Schedule III controlled substances which will not have any effect on small business.

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

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

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.

TEXT OF RULE

SECTION 1. CSB 2.92 is created to read:

CSB 2.92 Addition of thirty-five (35) Anabolic Steroids to schedule III. Section 961.18 (7), Stats., is repealed and recreated to read:

961.18 (7) ANABOLIC STEROIDS. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation containing any quantity of any of the following anabolic steroids, including any of their esters, ethers, isomers, esters or ethers of isomers, salts and salts of esters or ethers, isomers and esters or ethers of isomers that are theoretically possible within the specific chemical designation. Except such terms do not include an anabolic steroid that is expressly intended for administration through implants to cattle or other nonhuman species and that has been approved by the Secretary of Health and Human Services for such administration. If any person prescribes, dispenses, or distributes such steroid for human use, the person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this section:

(a) 3beta,17-dihydroxy-5alpha-androstane.
(ag) 3alpha,17beta-dihydroxy-5alpha-androstane.
(ar) 5alpha-androstan-3,17-dione.
(b) 1-androstenediol (3beta,17beta-dihydroxy-5alpha-androst-1-ene; 3alpha,17beta-dihydroxy-5alpha-androst-1-ene).
(bg) 4-androstenediol.
(br) 5-androstenediol.
(c) 1-androstenedione.
(cg) 4-androstenedione.
(cr) 5-androstenedione.

(d) Bolasterone.
(dg) Boldenone.
(dr) Boldione.
(e) Calusterone.
(eg) 4-chlorotestosterone, which is also called clostebol.
(er) Dehydrochloromethyltestosterone.
(f) Desoxymethyltestosterone.
(fg) delta1-dihydrotestosterone.
(fr) 4-dihydrotestosterone, which is also called stanolone.
(g) Drostanolone.
(gg) Ethylestrenol.
(gr) Fluoxymesterone.
(h) Formebulone, which is also called fromebolone.
(hg) Furazabol.
(hr) 13beta-ethyl-17beta-hydroxygon-4-en-3-one.
(i) 4-hydroxytestosterone.
(ig) 4-hydroxy-19-nortestosterone.
(ir) Mestanolone.
(j) Mesterolone.
(jg) Methandienone, which is also called methandrostenolone.
(jr) Methandriol.
(k) Methasterone.
(kg) Methenolone.
(kr) 17alpha-methyl-3beta, 17beta-dihydroxy-5alpha-androstane.
(L) 17alpha-methyl-3alpha,17beta-dihydroxy-5alpha-androstane.
(Lg) 17alpha-methyl-3beta,17beta-dihydroxyandrost-4-ene.
(Lr) 17alpha-methyl-4-hydroxynandrolone.
(m) Methyldienolone.
(mg) Methyltrienolone.
(mr) Methyltestosterone.
(n) Mibolerone.
(ng) 17alpha-methyl-delta1-dihydrotestosterone, which is also called 17-alpha-methyl-1-testosterone.
(nr) Nandrolone.
(o) 19-nor-4-androstenediol (3beta, 17beta-dihydroxyestr-4-ene; 3alpha, 17beta-dihydroxyestr-4-ene).
(og) 19-nor-5-androstenediol (3beta, 17beta-dihydroxyestr-5-ene; 3alpha, 17beta-dihydroxyestr-5-ene).
(or) 19-nor-4,9(10)-androstadienedione.
(p) 19-nor-4-androstenedione (estr-4-en-3,17-dione).
(pg) 19-nor-5-androstenedione (estr-5-en-3,17-dione).
(pr) Norbolethone.
(q) Norclostebol.
(qg) Norethandrolone.
(qr) Normethandrolone.
(r) Oxandrolone.

(rg) Oxymesterone.
(rr) Oxymetholone.
(s) Prostanozol.
(sg) Stanozolol.
(sr) Stenbolone.
(t) Testolactone.
(tg) Testosterone.
(tr) Tetrahydrogestrinone.
(u) Trenbolone.

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)

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 23-019)

ORDER

An order of the Controlled Substances Board to create CSB 2.93 relating to scheduling Daridorexant.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

Statutory authority: s. 961.11 (1) and (4), Stats.

Explanation of agency authority:
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. 961.20, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On April 7, 2022, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing Daridorexant into schedule IV of the federal Controlled Substances Act. The scheduling action is effective April 7, 2022.

Plain language analysis:
This rule schedules Daridorexant as a schedule IV controlled substance. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing Daridorexant as a schedule IV controlled substance. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Daridorexant under chapter 961, Stats. by creating the following:

CSB 2.93 Addition of Daridorexant to schedule IV. Section 961.20 (2) (cpm), Stats., is created to read:

961.20 (2) (cpm) Daridorexant.

The Affirmative Action order, dated July 20, 2022, took effect on July 25, 2022, 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 Daridorexant as a schedule IV controlled substance [720 Illinois Compiled Statutes 570/210 (c)].

Iowa: Iowa has not scheduled Daridorexant as a schedule IV controlled substance [Iowa Code 124.210 (3)].

Michigan: Michigan has not scheduled Daridorexant as a schedule IV controlled substance [Michigan Compiled Laws s. 333.7218].

Minnesota: Minnesota has not scheduled Daridorexant as a schedule IV controlled substance [Minnesota Statutes 152.02 (5)].

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

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

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

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.

TEXT OF RULE

SECTION 1. CSB 2.93 is created to read:

CSB 2.93 Addition of Daridorexant to schedule IV. Section 961.20 (2) (cpm), Stats., is created to read:

961.20 (2) (cpm) Daridorexant.

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)

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 23-020)

ORDER

An order of the Controlled Substances Board to create CSB 2.94 relating to scheduling seven (7) synthetic benzimidazole-opioid substances.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

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

Summary of, and comparison with, existing or proposed federal regulation:
On April 12, 2022, the Department of Justice, Drug Enforcement Administration published its temporary scheduling order in the Federal Register placing the following seven (7) synthetic benzimidazole-opioid substances into schedule I of the federal Controlled Substances Act. The scheduling action was effective immediately.

Plain language analysis:
This rule adds seven (7) synthetic benzimidazole-opioid substances to schedule I under ch. 961, Stats. This rule also amends ss. 961.14 (2) (mm) and (pe), Stats. to add the scientific descriptions for two already scheduled synthetic benzimidazole-opioid substances and renumbers them to group them with the seven new substances being added.

The Controlled Substances Board did not receive an objection to similarly treating the following seven (7) synthetic benzimidazole-opioid substances as schedule I under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating them as controlled substances:

- 2-(2-(4-butoxybenzyl)-5-nitro-1Hbenzimidazol-1-yl)-N,N-diethylethan-1- amine (butonitazene),
- 2-(2-(4-ethoxybenzyl)-1Hbenzimidazol-1-yl)-N,N-diethylethan-1- amine (etodesnitazene; etazene),
- N,N-diethyl-2-(2-(4-fluorobenzyl)-5- nitro-1H-benzimidazol-1-yl)ethan-1- amine (flunitazene),
- N,N-diethyl-2-(2-(4- methoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine (metodesnitazene),
- N,N-diethyl-2-(2-(4- methoxybenzyl)-5-nitro-1Hbenzimidazol-1-yl)ethan-1-amine (metonitazene),
- 2-(4-ethoxybenzyl)-5-nitro-1-(2- (pyrrolidin-1-yl)ethyl)-1Hbenzimidazole (N-pyrrolidino etonitazene; etonitazepyne), and
- N,N-diethyl-2-(5-nitro-2-(4- propoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine (protonitazene).

Therefore, pursuant to s. 961.11(4), Stats., the Controlled Substances Board by Affirmative Action similarly treated the seven (7) synthetic benzimidazole-opioid substances listed above, under chapter 961, Stats and is now following up with a final rule.

The Affirmative Action order, dated July 20, 2022, took effect on July 25, 2022, 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 included the seven (7) synthetic benzimidazole-opioid substances listed in this rule as schedule I controlled substances [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not included the seven (7) synthetic benzimidazole-opioid substances listed in this rule as schedule I controlled substances [Iowa Code 124.204].

Michigan: Michigan has not included the seven (7) synthetic benzimidazole-opioid substances listed in this rule as schedule I controlled substances [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not included the seven (7) synthetic benzimidazole-opioid substances listed in this rule as schedule I controlled substances [Minnesota Statutes 152.02 (2)].

Summary of factual data and analytical methodologies:
The methodology was to schedule seven (7) synthetic benzimidazole-opioid substances 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 seven (7) synthetic benzimidazole-opioid substances as Schedule III controlled substances which will not have any effect on small business.

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

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

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.

TEXT OF RULE

SECTION 1. CSB 2.94 is created to read:

CSB 2.94 Addition of seven (7) synthetic benzimidazole-opioid substances to schedule I.
(1) Section 961.14 (2) (mm) and (pe), Stats. are renumbered to 961.14 (2) (xm) 3. and 5. And amended to read:

961.14 (2) (xm) 3. Etonitazene (2-(2-(4-ethoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)-N,N-diethylethan-1- amine).

961.14 (2) (xm) 5. Isotonitazene (N,N -diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benizimidazol-1-yl)ethan-1-amine).

(2) Section 961.14 (2) (xm) 1., 2., 4., and 6. to 9., Stats., are created to read:

961.14 (2) (xm) Synthetic Benzimidazole-opioid Substances, specifically including all of the following:

1. Butonitazene (2-(2-(4-butoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine).

2. Etodesnitazene also known as Etazene (2-(2-(4-ethoxybenzyl)-1H-benzimidazol-1-yl)-N,N-diethylethan-1- amine).

4. Flunitazene (N,N-diethyl-2-(2-(4-fluorobenzyl)-5- nitro-1H-benzimidazol-1-yl)ethan-1-amine).

6. Metodesnitazene (N,N-diethyl-2-(2-(4- methoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine).

7. Metonitazene (N,N-diethyl-2-(2-(4- methoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine).

8. N-pyrrolidino etonitazene also known as etonitazepyne (2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole).

9. Protonitazene (N,N-diethyl-2-(5-nitro-2-(4- propoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine).

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)

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 23-021)

ORDER

An order of the Controlled Substances Board to create CSB 2.95 relating to scheduling Ganaxolone.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.22, Stats.

Statutory authority: s. 961.11 (1) and (4), Stats.

Explanation of agency authority:
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. 961.22, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On June 1, 2022, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing Ganaxolone into schedule V of the federal Controlled Substances Act. The scheduling action is effective June 1, 2022.

Plain language analysis:
This rule schedules Ganaxolone as a schedule V controlled substance.

The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing Ganaxolone as a schedule V controlled substance.

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

> **CSB 2.95 Addition of Ganaxolone to schedule V**. Section 961.22 (11), Stats., is created to read:
>
> 961.22 (11) Ganaxolone.

The Affirmative Action order, dated July 20, 2022, took effect on July 25, 2022, 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 listed Ganaxolone as a schedule V controlled substance [720 Illinois Compiled Statutes 570/212].

Iowa: Iowa has not listed Ganaxolone as a schedule V controlled substance [Iowa Code 124.212].

Michigan: Michigan has not listed Ganaxolone as a schedule V controlled substance [Michigan Compiled Laws s. 333.7220].

Minnesota: Minnesota has not listed Ganaxolone as a schedule V controlled substance [Minnesota Statutes 152.02 (6)].

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

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

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

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 July 14, 2023 to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.95 is created to read:

CSB 2.95 Addition of Ganaxolone to schedule V. Section 961.22 (11), Stats., is created to read:

961.22 (11) Ganaxolone.

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)

Dated _____ Agency _____

Chairperson
Controlled Substances Board

Controlled Substances Board
Rule Projects (updated 02/26/24)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
23-018	091-22	05/21/2025	CSB 2.92	Scheduling 35 Anabolic Steroids	Review of Adoption Order at 3/8/24 Meeting	Submission for Publication; Anticipated Effective Date of 5/1/24
23-019	092-22	05/21/2025	CSB 2.93	Scheduling Daridorexant	Review of Adoption Order at 3/8/24 Meeting	Submission for Publication; Anticipated Effective Date of 5/1/24
23-020	093-22	05/21/2025	CSB 2.94	Scheduling 7 Synthetic Benzimidazole-Opioids	Review of Adoption Order at 3/8/24 Meeting	Submission for Publication; Anticipated Effective Date of 5/1/24
23-021	094-22	05/21/2025	CSB 2.95	Scheduling Ganaxolone	Review of Adoption Order at 3/8/24 Meeting	Submission for Publication; Anticipated Effective Date of 5/1/24
23-068	051-23	02/07/2026	CSB 2.96	Scheduling Amineptine	Legislative Review	Board Review of Adoption Order at a future meeting
23-069	052-23	02/07/2026	CSB 2.97	Scheduling Zipeprol	Legislative Review	Board Review of Adoption Order at a future meeting
24-004	053-23	02/07/2026	CSB 2.98	Excluding [^{18} F] FP-CIT	Review of Final Rule Draft at 3/8/24 Meeting	Submission for Governor's Approval and Legislative Review
24-005	054-23	02/07/2026	CSB 2.99	Scheduling Mesocarb	Review of Final Rule Draft at 3/8/24 Meeting	Submission for Governor's Approval and Legislative Review
Not Assigned Yet	078-23	04/23/2026	CSB 2.001	Scheduling Methiopropamine	Clearinghouse Review	Board Review of Final Rule Draft at a future meeting
Not Assigned Yet	079-23	04/23/2026	CSB 2.002	Excluding Fenfluramine	Clearinghouse Review	Board Review of Final Rule Draft at a future meeting
Not Assigned Yet	001-24	07/02/2026	CSB 2.003	Transferring Flualprazolam and Scheduling 4 Other Synthetic Benzodiazepine Substances	Review of Preliminary Rule Draft at 3/8/24 Meeting	Submission for EIA Comment and Clearinghouse Review

Controlled Substances Board
Rule Projects (updated 02/26/24)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.004	Scheduling Zuranolone	Scope Statement Reviewed at 3/8/24 Meeting	Scope Submitted for Governor Approval and for Publication
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.005	Scheduling 9 Fentanyl Related Substances	Scope Statement Reviewed at 3/8/24 Meeting	Scope Submitted for Governor Approval and for Publication
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.006	Scheduling 5 Synthetic Cannabinoids	Scope Statement Reviewed at 3/8/24 Meeting	Scope Submitted for Governor Approval and for Publication
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.007	Scheduling ADB-BUTINANCA, α-PiHP, and 3- MMC	Affirmative Action Order Under Legal Counsel Review	Affirmative Action Order Submitted for Publication
Not Assigned Yet	095-22	05/21/2025	CSB 4	National Provider Identifier Requirement	Public Hearing Held at 3/8/24 Meeting	Board Review of Final Rule Draft and Legislative Report
Not Assigned Yet	055-23	02/07/2026	CSB 4	Monitored Prescription Drug History Reports	Fiscal Estimate	Clearinghouse Review
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 4	Mail Delivered Prescriptions	Preliminary Hearing on Statement of Scope at 3/8/24 Meeting	Scope Implementation

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**	02/27/2024 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?
03/08/2024	☒ 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. Recent and Upcoming Releases
    b. EHR Integration Status
2. WI PDMP Outreach

11) Authorization

Marjorie Liu — Feb 27, 2024

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.

2021-2024 Development and Release Summary

Updated 02.26.2024

Release Date	Description
Pending	
R33.4 **February**	DEA File Updates LicensE Update – State License Validation Training Materials Update File Processing support EHR support
Completed	
R33.3 **January 2024**	LicensE Update – New User Registration LicensE Update – User Login Validation PDMP UI Page Text Updates • Home Page • Contact Us • Patient History Detail File Processing Support EHR Support
R33.2 **January 2024**	Pharmacy Users fixes • Zero reports • Revise/Correct/Void File Processing support EHR support
R33.1 **November 2023**	Statistics dashboard “utilization” page updates PMPi states data exchange updates Admin Manage Alerts Timeout Patient Matching Updates
R33.0 **November 2023**	Geocoding Address2 Line rejection Updated Submitter Guide
R32.5 **October 2023**	File processing support

R32.4 **October 2023**	EHR Support
R32.3 **October 2023**	EHR Support
R32.2 **October 2023**	EHR Support
R32.1 **October 2023**	Iframe support Epic
R32 **October 2023**	HRG 2020 Grant Release
R31 **March 2023**	Iframe support Epic
R30 **February 2023**	Iframe support Prescriber Practice Metric UI Text updates Maintenance Updates
R29 **October 2022**	Updated mapping tool Adjusted language for expired temporary licenses Modified file processing
R28 **July 2022**	Adding language related to Buprenorphine Alert Override • Minor text changes to submission error emails • Minor language changes around alert messaging Maintenance Updates
Harold Rogers Grant 2021 **Promotional Materials** **May 2022**	Promotional Materials for free EHR Integrations Maintenance Updates
R26 **April 2022**	Buprenorphine Alert Override • Ability to override prescriber facing alerts, metrics, and MME calculations for certain drugs. Maintenance Updates

	RxCheck 3.0 Upgrades
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

WI ePDMP Integration Services Summary

Current as of 02.26.2024

Pending Health Systems and EHR Platforms	Status			Notes
QuadMed, LLC	Implementation in progress			
Connected Health Systems (approx. 57% of monthly patient queries)	**Free Pricing Model**	**Implementation Date**	**Est. Total # of Users**	**Notes**
Advent Health	Y	03/05/2023		
Allina Health	Y	09/18/2023		
Ascension Wisconsin				
Aspirus Health Care				
Aurora Health Care				
Children's Hospital of Wisconsin	Y	09/01/2022	300	
Clark County	Y			
Clean Slate	Y	09/01/2022	26	
CompuGroup Medical	Y	09/26/2023		
DrFirst				
Froedtert & the Medical College of Wisconsin				Pending signed Free agreement
GHC of South Central Wisconsin				
Gundersen Health System				Pending signed Free agreement
HealthPartners				
HSHS / Prevea Health	Y	01/01/2023		
M Health Fairview	Y	08/01/2022	30	
Marshfield Clinic	Y	09/01/2022	100	
Mayo Clinic				
Mercy Health	Y	08/01/2022	766	
Monroe Clinic				
NOVO Health Technology Group	Y	02/01/2023		
Ochin	Y	12/21/2022	100	Epic
ProHealth Care				

SSM Health				
Thedacare				Pending signed Free agreement
UnityPoint				
UW Health				
Wisconsin Statewide Health Information Network	Y	09/01/2022	3500	

DrFirst Facilities	
Alay Health Team	Rogers Memorial Hospital
ASSOCIATED MENTAL HEALTH CONSULTANTS	Sauk Prairie Memorial Hospital
Behavioral Health Svcs of Racine Co.	Synergy Medical Services, LLC
Door County Memorial Hospital	Third Eye Health
Dr. Colleen Worth, DNP, APNP	Watertown Rainbow Hospice
FAMILY PSYCHIATRIC CARE, LLC	Wauwatosa Children's Clinic
Fort Healthcare	Watertown Regional Medical Center
GI Associates LLC	
Heartland Hospice	
Lake Superior Community Health Center	
Linc Health Clinic	
Lifestance Health WI	
Marshfield Clinic Health System	
Mile Bluff Medical Center	
Milwaukee Medical Associate, SC	
Mindful Healing and Wellness LLC	
Oak Medical	
Oral Surgery Associates of Milwaukee	
Orthopedic Hospital of Wisconsin	
PAIN MANAGEMENT AND TREATMENT CTR	
Pediatrics Associates	
Reka Furedi MD	
Richland Hospital	
Red Oak Counseling	
Regional Medical Center	

2024 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	1/11/2024	Virtual; Quarterly Meeting
February				
March				
April	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	4/11/2024	Virtual; Quarterly Meeting
May	2024 PMP InterConnect Steering Committee Meeting	Participant; Annual national meeting for PDMP administrators organized by National Association of Boards of Pharmacy (NABP)	5/7-5/9/2024	San Antonio, TX
June	PMPi Steering Committee Meeting	Participant; national meeting for state PDMPs connecting via PMPi data exchange hub	6/24-6/25/2024	Mount Prospect, IL
July	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	7/11/2024	Virtual; Quarterly Meeting
August				
September	Sauk County Overdose Fatality Review Team Meeting	Presenter, PDMP overview, updates, and utilization for Overdose Fatality Review	9/25/2024	Virtual
October	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	10/10/2024	Virtual; Quarterly Meeting
	NASCSA Conference (National Association of State Controlled Substances Authorities)	Participant; annual national meeting organized by NASCSA for government controlled substances authority, PDMP and healthcare professionals	10/28-10/31/2024	Greenville, South Carolina
November				
December				