Wisconsin Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way
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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
May 10, 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 March 8, 2024 (4-6)**

C. Reminders: Conflicts of Interests, Scheduling Concerns

D. Introductions, Announcements and Recognition

E. **10:00 A.M. Public Hearing for Clearinghouse Rule 24-033 on CSB-4, Relating to Monitored Prescription Drug History Reports (7)**
   1) Review Public Hearing Comments and Respond to Clearinghouse Report **(8-16)**

F. Administrative Matters – Discussion and Consideration
   1) Department, Staff, and Board Updates
   2) Board Members – Term Expiration Dates
      a. Gundersen, David – 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. Alton, Troy – Dentistry Examining Board Representative
      b. Ferguson, Kris – Medical Examining Board Representative
      c. Weinman, Robert – Board of Nursing Representative

G. **Administrative Rule Matters – Discussion and Consideration (17)**
   1) Affirmative Action Order:
      a. CSB 2.008, Relating to Scheduling 2-methyl AP-237 **(18)**
   2) Preliminary Rule Draft:

a. CSB 4, Relating to Mail Delivered Prescriptions **(19-21)**

3) Final Rule Draft:
   a. CSB 2.001, Relating to Scheduling Methiopropamine **(22-30)**
   b. CSB 2.002, Relating to Excluding Fenfluramine **(31-39)**
   c. CSB 4, Relating to National Provider Identifier Requirement **(40-50)**
4) Pending and Possible Rulemaking Projects
   a. Rule Projects Chart **(51-52)**

H. **Prescription Drug Monitoring Program (PDMP) Updates – Discussion and Consideration (53)**

1) WI ePDMP Operations
   a. Recent and Upcoming Releases **(54-56)**
   b. EHR Integration Status **(57-58)**
2) WI ePDMP Outreach **(59)**

I. **Board Member Reports – Discussion and Consideration**

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

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

K. Liaison Reports

L. Deliberation on Special Use Authorizations – Discussion and Consideration

M. **Scheduling of Kratom – Informational Item (60-82)**

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: JULY 12, 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
MARCH 8, 2024

PRESENT: Subhadeep Barman, Yvonne Bellay, Alan Bloom, Cullen Eberhardy, Doug Englebert, Amanda Kane, Gregory Schmeling, John Weitekamp

EXCUSED: David Gundersen

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

Troy Alton served as the Dentistry Examining Board 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 nine (9) members present.

ADOPTION OF AGENDA

Amendments to the Agenda:

- **CHANGE** Dentistry Examining Board Representative from Troy Alton to David Gundersen
- **CHANGE** Dentistry Examining Board Alternate Representative from Matthew Bistan to Troy Alton

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

APPROVAL OF MINUTES OF JANUARY 19, 2024

MOTION: Cullen Eberhardy moved, seconded by Troy Alton, to adopt the Minutes of January 19, 2024 as published. Motion carried unanimously.

10:00 A.M. PUBLIC HEARING FOR CLEARINGHOUSE RULE 24-013 ON CSB-4, RELATING TO NATIONAL PROVIDER IDENTIFIER REQUIREMENT

Review Public Hearing Comments and Respond to Clearinghouse Report

MOTION: Yvonne Bellay moved, seconded by Troy Alton, to authorize the Chairperson (or other member) to work with DSPS staff on responding to the Clearinghouse Report and drafting the Final Rule and Legislative Report for Clearinghouse Rule 24-013 (CSB 4), Relating to National Provider Identifier Requirement. Motion carried unanimously.

10:00 A.M. PRELIMINARY HEARING ON STATEMENT OF SCOPE – SS 022-24 ON CSB-4, RELATING TO MAIL DELIVERED PRESCRIPTION

Review Preliminary Hearing Comments

MOTION: Alan Bloom moved, seconded by John Weitekamp, to affirm the Board has provided an opportunity to receive public comments concerning Scope Statement (SS) 022-24 on CSB 4, relating to Mail Delivered Prescriptions. Additionally, after consideration of all public comments and feedback, the Board approves SS 022-24 for implementation. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Scope Statement

CSB 2.004, Relating to Scheduling Zuranolone

CSB 2.005, Relating to Scheduling Nine Fentanyl Analogs

CSB 2.006, Relating to Scheduling Five Synthetic Cannabinoids

MOTION: Subhadeep Barman moved, seconded by Troy Alton, to approve the following Scope Statements for submission to the Department of Administration and Governor's Office and for publication:

- CSB 2.004, Relating to Scheduling Zuranolone
- CSB 2.005, Relating to Scheduling Nine Fentanyl Analogs
- CSB 2.006, Relating to Scheduling Five Synthetic Cannabinoids

Additionally, the Board authorizes the Chairperson to approve these Scope Statements for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on these Scope Statements, the Chairperson is authorized to approve the required notices of hearing. Motion carried unanimously.

Preliminary Rule Draft

CSB 2.003, Relating to Five Synthetic Benzodiazepine Substances

MOTION: Subhadeep Barman moved, seconded by Alan Bloom, to approve the preliminary rule draft of CSB 2.003, Relating to Five Synthetic Benzodiazepine Substances, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

Final Rule Draft

CSB 2.98, Relating to Excluding [^{18} F]FP-CIT

CSB 2.99, Relating to Scheduling Mesocarb

MOTION: Troy Alton moved, seconded by Subhadeep Barman, to approve the Legislative Report and Draft for the following rules for submission to the Governor's Office and Legislature:

- Clearinghouse Rule 24-004 on CSB 2.98, Relating to Excluding [^{18} F]FP-CIT
- Clearinghouse Rule 24-005 on CSB 2.99, Relating to Scheduling Mesocarb

Motion carried unanimously.

Adoption Order

CSB 2.92, Relating to Scheduling 35 Anabolic Steroids

CSB 2.93, Relating to Scheduling Daridorexant

CSB 2.94, Relating to Scheduling Seven Synthetic Benzimidazole-Opioids

CSB 2.95, Relating to Scheduling Ganaxolone

MOTION: Subhadeep Barman moved, seconded by Amanda Kane, to approve the Adoption Orders for the following rules:

- CSB 2.92, Relating to Scheduling 35 Anabolic Steroids
- CSB 2.93, Relating to Scheduling Daridorexant
- CSB 2.94, Relating to Scheduling Seven Synthetic Benzimidazole-Opioids
- CSB 2.95, Relating to Scheduling Ganaxolone

Motion carried unanimously.

REPORT FROM THE REFERRAL CRITERIA WORK GROUP

MOTION: Troy Alton moved, seconded by Amanda Kane, 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: Subhadeep Barman moved, seconded by Yvonne Bellay, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 10:40 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**	**04/30/24** 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?
05/10/24	☒ Yes ☐ No	**10:00 A.M. Public Hearing for Clearinghouse Rule 24-033 on CSB 4, Relating to Monitored Prescription Drug History Reports** **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 — 4/30/24

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 amend CSB 4.11 (2) (a) and (c), relating to monitored prescription drug history reports.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.385 (2) (c), Stats.

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

Explanation of agency authority:
961.385 (2) (c) states that the board shall establish by rule and have the prescription drug monitoring program "specify the persons whom a record may be disclosed and the circumstances under which the disclosure may occur. Except as otherwise provided under this section, the rule promulgated under this paragraph shall comply with s. 146.82."

Related statute or rule: None.

Plain language analysis: Wisconsin Administrative Code Chapter CSB 4 currently outlines requirements for methods of obtaining monitored prescription drug history reports. Patients are allowed to request their own history reports either in person at the Department of Safety and Professional Services or via a mailed request on a form provided by the Board. A person authorized by the patient may only request copies of those same reports in person. Without making changes under the proposed rule, a person authorized by the patient will continue to only be able to make such requests in person at the Department.

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: N/A

Comparison with rules in adjacent states:

Illinois: The Illinois Prescription Monitoring Program allows patients access to their personal prescription history based on a validation process established by administrative rules [720 Illinois Compiled Statutes Chapter 570 Section 318 (m)]. The administrative rules governing patient access to their prescription history require that the patient, parent, or guardian complete a notarized request for a personal information report of a patient's prescription history, and submit it by mail to the Illinois Prescription Monitoring Program [Illinois Administrative Coder Title 77 Chapter X Subchapter e Part 2050 Section 2080.190 (a)].

Iowa: The Iowa Prescription Monitoring Program allows patients or a patient's agent to request that individual patient's own prescription history report by submitting a request form. Request forms may be submitted in-person with a government issued photo identification or via mail if the request form is notarized and sent with a certified copy of the patient's government issued identification. A patient's agent may sign the request form in lieu of the patient if a copy the legal document establishing the agency relationship is provided. The patient's agent must also present a government issued identification for in-person requests or a certified copy of a government issued identification for mailed requests. [657 Iowa Administrative Code Chapter 37 Section 37.16 (7)].

Michigan: The administrative rules that govern the Michigan Automated Prescription System, the states electronic system for monitoring schedule II to V controlled substances, does not specify whether a report of a patient's prescription history can be disclosed, nor how a report may be obtained by a patient. [Michigan Administrative Rules R 338.3162b].

Minnesota: The Minnesota Prescription Monitoring Program allows a patient who has been prescribed a controlled substance to access the program's database to obtain information on users who have access to that patient's data records. A patient may submit a request for this information on a notarized form from the Minnesota State Board of Pharmacy's website.[Minnesota Statutes Chapter 152 Section 152.126 Subdivision 11].

Summary of factual data and analytical methodologies: The Board reviewed Wisconsin Administrative Code Chapter CSB 4 and made updates as needed.

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, 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 May 10, 2024, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 4.11 (2) (a) and (c) are amended to read:

CSB 4.11 (2) (a) Appears in person at the department with two forms of valid proof of identity, one of which is a valid government-issued photographic identification or mails to the department copies of two forms of valid proof of identity, one of which is a valid government-issued photographic identification.

(c) Makes a request for the monitored prescription drug history report on a form provided by the board. If the request is mailed, the form shall be notarized.

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

(END OF TEXT OF RULE)

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

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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

2. Date
3/28/24

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

4. Subject
Monitored Precription Drug History Reports

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

6. Chapter 20, Stats. Appropriations Affected
s. 20.165 (1) (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
The objective of the proposed rule is to allow an authorized patient representative to request monitored prescription drug history reports on behalf of a patient both in person and via mail.

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.
None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
DSPS estimates a total of $3,200 in one-time costs for implementing the provisions of this rule to support the equivalent of a 0.1 limited term employee for activities including rulemaking and coordination with PDMP program staff. The one-time costs cannot be absorbed in the currently appropriated agency budget.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit of implementing the rule is that patients authorized represeentatives will have the option to request monitored prescirption drug history reports via mail, in addition to in-person requests.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing this rule is greater patient and customer satisfaction with the Prescroption Drug Monitoring Program (PDMP) through increased accessability to monitored prescription drug history reports where allowed by law.

17. Compare With Approaches Being Used by Federal Government
None.

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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: The Illinois Prescription Monitoring Program allows patients access to their personal prescription history based on a validation process established by administrative rules [720 Illinois Compiled Statutes Chapter 570 Section 318 (m)]. The administrative rules governing patient access to their prescription history require that the patient, parent, or guardian complete a notarized request for a personal information report of a patient's prescription history, and submit it by mail to the Illinois Prescription Monitoring Program [Illinois Administrative Coder Title 77 Chapter X Subchapter e Part 2050 Section 2080.190 (a)].

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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 **24-033**

AN ORDER to amend CSB 4.11 (2) (a) and (c), relating to monitored prescription drug history reports.

Submitted by **CONTROLLED SUBSTANCES BOARD**

03-28-2024 RECEIVED BY LEGISLATIVE COUNCIL.
04-22-2024 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 ☑

Scott Grosz
Clearinghouse Director

Margit Kelley
Clearinghouse Assistant Director

Anne Sappenfield
Legislative Council Director

CLEARINGHOUSE RULE 24-033

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.]

4. Adequacy of References to Related Statutes, Rules and Forms

In the "statutes interpreted" section of the rulemaking summary, the agency should refer to s. 146.82, Stats., as that statute is an explicit limitation on the board's rulemaking authority under s. 961.385 (2) (c), Stats. Additionally, it may be useful to the typical reader to more fully explain the relationship between the two statutes in the explanation of the agency's authority, rather than simply quoting s. 961.385 (2) (c), Stats.

State of Wisconsin
Department of Safety & Professional Services
AGENDA REQUEST FORM

1) Name and title of person submitting the request:

Nilajah Hardin
Administrative Rules Coordinator

2) Date when request submitted:

04/30/24

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:

05/10/24

5) Attachments:

☒ **Yes**
☐ **No**

6) How should the item be titled on the agenda page?

Administrative Rule Matters – Discussion and Consideration

1. **Affirmative Action Order:**
   a. **CSB 2.008, Relating to Scheduling 2-methyl AP-237**
2. **Preliminary Rule Draft:**
   a. **CSB 4, Relating to Mail Delivered Prescriptions**
3. **Final Rule Draft:**
   a. **CSB 2.001, Relating to Scheduling Methiopropamine**
   b. **CSB 2.002, Relating to Excluding Fenfluramine**
   c. **CSB 4, Relating to National Provider Identifier Requirement**
4. **Pending or Possible Rulemaking Projects**
   a. **Rule Projects Chart**

7) Place Item in:

☒ **Open Session**
☐ **Closed Session**

8) Is an appearance before the Board being scheduled? *(If yes, please complete **Appearance Request** for Non-DSPS Staff)*

☐ **Yes**
☒ **No**

9) Name of Case Advisor(s), if required:

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:

- Affirmative Action Order – CSB 2.008
- Preliminary Rule Draft – CSB 4 (Mail Delivered Prescriptions)
- Legislative Report, Final Rule Draft, EIA, and Clearinghouse Report – CSB 2.001, 2.002, and 4 (NPI Requirement)
- 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 — 4/30/24

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

FINDINGS

1. On March 15, 2024, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register adding 2-methyl AP-237 to schedule I of the federal Controlled Substances Act. The scheduling action is effective April 15, 2024.

2. The Controlled Substances Board did not receive an objection to similarly listing 2-methyl AP-237 in schedule I under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order listing 2-methyl AP-237 as a schedule I controlled substance.

3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing 2-methyl AP-237 as a schedule I controlled substance.

ORDER

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats 2-methyl AP-237 under chapter 961, Stats. by creating the following:

CSB 2.003 Addition of 2-Methyl AP-237 to Schedule I. Section 961.14 (2) (qz), Stats., is created to read:

961.14 (2) (qz) 2-methyl AP-237 (1-(2-methyl-4-(3-phenylprop-2-en-1-yl)piperazin-1-yl)butan-1-one).

This order shall become effective upon publication in the Administrative Register. The order expires upon promulgation of a final rule.

Dated _____

_____
Doug Englebert, Chair
Controlled Substances Board

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 amend CSB 4.04 (2) (p), relating mail delivered prescriptions.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.11 (1b)(f) and 961.385 (2) (b), Stats.

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

Explanation of agency authority:
961.385 (2) (a), Stats. 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…"

Related statute or rule: Wisconsin Administrative Code Chapter Phar 8

Plain language analysis: Wisconsin Administrative Code Chapter CSB 4 currently outlines requirements for what data should be entered into the Wisconsin Prescription Drug Monitoring Program (PDMP) for each reportable prescription. Pursuant to s. 450.11 (1) (f), Stats., the Pharmacy Examining Board has written an exception, outlined in s. Phar 8.06 (2), that applies to the name required under s. CSB 4.04 (2) (p) when the prescription is delivered to the patient via common carrier or delivery services. As currently written, s. CSB 4.04 (2) (p) does not allow for a practitioner to make this exception. Therefore, the Controlled Substances Board has updated the requirement so that this exception can occur without causing data entry issues for the PDMP. Without making changes under the proposed rule, there will continue to be a lack of clarity and around the name that needs to be entered into the PDMP per s. CSB 4.04 (2) (p).

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: The Controlled Substances Board held a Preliminary Hearing on Statement of Scope for this project on March 8, 2024. No public comments were received.

Comparison with rules in adjacent states:

Illinois: The Illinois Prescription Monitoring Program does not specify that the person to whom the drug was dispensed must provide identification and that the name on the identification must be recorded into the system. There also does not appear to be an exception to data entry when a prescription is delivered via mail. However, the recipient's name, address, date of birth, and gender are required for each reportable prescription [720 Illinois Compiled Statutes Chapter 570 Section 316].

Iowa: The Iowa Prescription Monitoring Program does not specify that the person to whom the drug was dispensed must provide identification and that the name on the identification must be recorded into the system. There also does not appear to be an exception to data entry when a prescription is delivered via mail. Outside of the prescriber's name and Drug Enforcement Administration (DEA) registration number, only the patient's name and various pieces of information are required for each reportable prescription [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 specify that the person to whom the drug was dispensed must provide identification and that the name on the identification must be recorded into the system. There also does not appear to be an exception to data entry when a prescription is delivered via mail. However, there is a provision that allows for the dispensing prescriber to presume that the identification provided by the patient or their representative is correct [Michigan Administrative Rules R 338.3162b].

Minnesota: The Minnesota Prescription Monitoring Program does not specify that the person to whom the drug was dispensed must provide identification and that the name on the identification must be recorded into the system. There is an exception where the dispenser is not required to submit data to the program for a prescription that is mailed or delivered from Minnesota to another state, as long as the data is reported to the prescription drug monitoring program of that state. Various pieces of dispenser, patient, and prescriber data are required for each reportable prescription [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 and made updates as needed based on a recommendation from the Wisconsin Pharmacy Examining Board.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at 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 a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 4.04 (2) (p) is amended to read:

CSB 4.04 (2) (p) The name recorded under s. 450.11 (1b) (bm), Stats.<u>, unless exempted pursuant to s. Phar 806 (2).</u>

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 24-023**

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 Methiopropamine 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 Methiopropamine as a schedule I controlled substance. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Methiopropamine under chapter 961, Stats. by creating the following:

CSB 2.001 Addition of Methiopropamine to Schedule I. Section 961.14 (7) (t), Stats., is created to read:

> **961.14 (7) (t)** N-methyl-1-(thiophen-2-yl)propan-2-amine, commonly known as Methiopropamine.

The Affirmative Action order, dated March 24, 2023, took effect on April 3, 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 24-023)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.001, relating to scheduling Methiopropamine.

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 December 9, 2022, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register adding Methiopropamine to schedule I of the federal Controlled Substances Act. The scheduling action was effective January 9, 2023.

Plain language analysis:
This rule schedules Methiopropamine 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 Methiopropamine as a schedule I controlled substance. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Methiopropamine under chapter 961, Stats. by creating the following:

> **CSB 2.001 Addition of Methiopropamine to Schedule I**. Section 961.14 (7) (t), Stats., is created to read:
>
> > **961.14 (7) (t)** N-methyl-1-(thiophen-2-yl)propan-2-amine, commonly known as Methiopropamine.

The Affirmative Action order, dated March 24, 2023, took effect on April 3, 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 Methiopropamine as a schedule I controlled substance [720 Illinois Compiled Statutes 570/204].

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

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

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

Summary of factual data and analytical methodologies:
The methodology was to schedule Methiopropamine 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:
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 May 10, 2024, to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.001 is created to read:

CSB 2.001 Addition of Methiopropamine to Schedule I. Section 961.14 (7) (t), Stats., is created to read:

> **961.14 (7) (t)** N-methyl-1-(thiophen-2-yl)propan-2-amine, commonly known as Methiopropamine.

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
2/22/24

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.001

4. Subject
Scheduling Methiopropamine

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

6. Chapter 20, Stats. Appropriations Affected
s. 20.165 (1) (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 December 9, 2022, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register adding Methiopropamine to schedule I of the federal Controlled Substances Act. The scheduling action was effective January 9, 2023.

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.
None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule aligns Wisconsin statute with federal scheduling and classifies Methiopropamine 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 Mesthiopropamine 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 Methiopropamine as schedule I controlled substance.

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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

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

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

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

Minnesota: Minnesota has not listed Methiopropamine 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 **24-023**

AN ORDER to create CSB 2.001, relating to scheduling Methiopropamine.

Submitted by **CONTROLLED SUBSTANCES BOARD**

02-22-2024 RECEIVED BY LEGISLATIVE COUNCIL.
03-11-2024 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 ☑

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING	**:**	
PROCEEDINGS BEFORE THE	**:**	**REPORT TO THE LEGISLATURE**
CONTROLLED SUBSTANCES BOARD	**:**	**CR 24-024**

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 Fenfluramine 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, excluding Fenfluramine as a schedule IV controlled substance. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Fenfluramine under chapter 961, Stats. by creating the following:

CSB 2.002 Excluding Fenfluramine from schedule IV. Section 961.20 (4) (am), Stats. is repealed.

The Affirmative Action order, dated April 7, 2023, took effect on April 17, 2023, upon 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 24-024)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.002, relating to Excluding Fenfluramine.

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 December 23, 2022, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing Fenfluramine from schedule IV of the federal Controlled Substances Act. The scheduling action was effective on December 23, 2022.

Plain language analysis:
This rule excludes Fenfluramine 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, excluding Fenfluramine as a schedule IV controlled substance. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Fenfluramine under chapter 961, Stats. by creating the following:

> **CSB 2.002 Excluding Fenfluramine from schedule IV**. Section 961.20 (4) (am), Stats. is repealed.

The Affirmative Action order, dated April 7, 2023, took effect on April 17, 2023, upon 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 Fenfluramine listed as a schedule IV controlled substance [720 Illinois Compiled Statutes 570/210 (d) (1)].

Iowa: Iowa has Fenfluramine listed as a schedule IV controlled substance [Iowa Code 124.210 (4)].

Michigan: Michigan has Fenfluramine listed as a schedule IV controlled substance [Michigan Compiled Laws s. 333.7218 (b)].

Minnesota: Minnesota has Fenfluramine listed as a schedule IV controlled substance [Minnesota Statutes 152.02 (5) (d)].

Summary of factual data and analytical methodologies:
The methodology was to remove Fenfluramine from Schedule IV 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 May 10, 2024, to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.002 is created to read:

CSB 2.002 Excluding Fenfluramine from schedule IV. Section 961.20 (4) (am), Stats. is repealed.

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
2/22/24

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.002

4. Subject
Excluding Fenfluramine

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

6. Chapter 20, Stats. Appropriations Affected
s. 20.165 (1) (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
☐ 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 December 23, 2022, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing Fenfluramine from schedule IV of the federal Controlled Substances Act. The scheduling action was effective on December 23, 2022. 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, excluding Fenfluramine as a schedule IV controlled substance.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
The rule was posted on the Department's website for 14 days to solicit 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.
None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule aligns Wisconsin statute with federal scheduling and removes Fenfluramine as a schedule IV 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 Femfluramine will no longer be a Schedule IV controlled substance in Wisconsin.

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

17. Compare With Approaches Being Used by Federal Government

The federal government has excluded Fenfluramine as a schedule IV controlled substance.

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

Illinois: Illinois has Fenfluramine listed as a schedule IV controlled substance [720 Illinois Compiled Statutes 570/210 (d) (1)].

Iowa: Iowa has Fenfluramine listed as a schedule IV controlled substance [Iowa Code 124.210 (4)].

Michigan: Michigan has Fenfluramine listed as a schedule IV controlled substance [Michigan Compiled Laws s. 333.7218 (b)].

Minnesota: Minnesota has Fenfluramine listed as a schedule IV controlled substance [Minnesota Statutes 152.02 (5) (d)].

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)

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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 **24-024**

AN ORDER to create CSB 2.002, relating to excluding Fenfluramine.

Submitted by **CONTROLLED SUBSTANCES BOARD**

02-22-2024 RECEIVED BY LEGISLATIVE COUNCIL.
03-01-2024 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 24-013**

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:

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) (bm) and (im). Sections CSB 4.04 (2) (b) and (i) were also updated to reflect that a DEA number is only required if applicable. 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 any of the data from CSB 4.04 (2) when required. 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).

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

The Controlled Substances Board held a public hearing on March 8, 2024. No public comments were received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment: "5a. As created by the proposed rule s. CSB 4.097 (1) (i) specifies the consequences for failure to enter other data into the PDMP system as required under s. CSB 4.04 (2)?"

Response: The Board accepts this comment and agrees that the requirement in s. CSB 4.097 (1) (i) should apply to all data outlined in s. CSB 4.04 (2). Section CSB 4.097 (1) (i) has been updated accordingly.

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

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

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 24-013)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 4.02 (12s), 4.04 (2) (bm) and (im), and 4.097 (1) (i), and amend CSB 4.04 (2) (b) and (i), 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) (bm) and (im). Sections CSB 4.04 (2) (b) and (i) were also updated to reflect that a DEA number is only required if applicable. 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 any of the data from CSB 4.04 (2) when required. 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) is created to read:

CSB 4.02 (12s) "NPI number" means national provider identifier number, the unique number issued by the National Plan and Provider Enumeration System of the federal Centers for Medicare and Medicaid Services used in the U.S. to identify each health care provider.

SECTION 2. CSB 4.04 (2) (b) is amended to read:

CSB 4.04 (2) (b) The dispenser's DEA registration number, if applicable.

SECTION 3. CSB 4.04 (2) (bm) is created to read:

CSB 4.04 (2) (bm) Beginning December 1, 2025, the dispenser's NPI number.

SECTION 4. CSB 4.04 (2) (i) is amended to read:

CSB 4.04 (2) (i) The practitioner's DEA registration number, if applicable.

SECTION 5. CSB 4.04 (2) (im) is created to read:

CSB 4.04 (2) (im) Beginning December 1, 2025, the prescriber's NPI number.

SECTION 6. 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 7. CSB 4.08 (4) is repealed.

SECTION 8. CSB 4.097 (1) (i) is created to read:

CSB 4.097 (1) (i) Beginning December 1, 2025, the board may temporarily suspend access to monitored prescription drug history reports when the healthcare professional fails to enter any of the data under s. CSB 4.04 (2) where required.

SECTION 9. 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)

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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

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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].

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19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules Coordinator	(608) 267-7139

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

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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

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

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

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

5. Describe the Rule's Enforcement Provisions

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

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

Margit Kelley
Clearinghouse Assistant Director

Anne Sappenfield
Legislative Council 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.]

Controlled Substances Board
Rule Projects (updated 04/30/24)

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	Rule Effective 5/1/24	N/A
23-019	092-22	05/21/2025	CSB 2.93	Scheduling Daridorexant	Rule Effective 5/1/24	N/A
23-020	093-22	05/21/2025	CSB 2.94	Scheduling 7 Synthetic Benzimidazole-Opioids	Rule Effective 5/1/24	N/A
23-021	094-22	05/21/2025	CSB 2.95	Scheduling Ganaxolone	Rule Effective 5/1/24	N/A
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	Governor Review of Final Rule Draft	Legislative Review
24-005	054-23	02/07/2026	CSB 2.99	Scheduling Mesocarb	Governor Review of Final Rule Draft	Legislative Review
Not Assigned Yet	078-23	04/23/2026	CSB 2.001	Scheduling Methiopropamine	Final Rule Draft Reviewed at 5/10/24 Meeting	Submission for Governor's Approval and Legislative Review
Not Assigned Yet	079-23	04/23/2026	CSB 2.002	Excluding Fenfluramine	Final Rule Draft Reviewed at 5/10/24 Meeting	Submission for Governor's Approval and Legislative Review
Not Assigned Yet	001-24	07/02/2026	CSB 2.003	Transferring Flualprazolam and Scheduling 4 Other Synthetic Benzodiazepine Substances	Pending Fiscal Estimate	Clearinghouse Review

Controlled Substances Board
Rule Projects (updated 04/30/24)

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 Pending Governor Approval	Scope Submission for Publication in Administrative Register
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.005	Scheduling 9 Fentanyl Related Substances	Scope Statement Pending Governor Approval	Scope Submission for Publication in Administrative Register
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.006	Scheduling 5 Synthetic Cannabinoids	Scope Statement Pending Governor Approval	Scope Submission for Publication in Administrative Register
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	Not Assigned Yet	Not Assigned Yet	CSB 2.008	Scheduling 2-methyl AP-237	Affirmative Action Order Reviewed at 5/10/24 Meeting	Affirmative Action Order Submitted for Publication
Not Assigned Yet	095-22	05/21/2025	CSB 4	National Provider Identifier Requirement	Final Rule Draft Reviewed at 5/10/24 Meeting	Submission for Governor's Approval and Legislative Review
Not Assigned Yet	055-23	02/07/2026	CSB 4	Monitored Prescription Drug History Reports	Public Hearing Held at 5/10/24 Meeting	Board Review of Final Rule Draft and Legislative Report
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 4	Mail Delivered Prescriptions	Preliminary Rule Draft Reviewed at 5/10/24 Meeting	Submission for EIA Comment, Fiscal Estimate, and Clearinghouse Review

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**	04/30/2024 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?
05/10/2024	☒ 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 — April 30, 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.

2022-2024 Development and Release Summary

Updated 04.29.2024

Release Date	Description
Pending	
R33.7 **May 2024**	Dispenser Compliance Report Review Submitter/Dispenser Report Review
Completed	
R33.6 **April 2024**	System Updates • Pending Account Changes UI language • UAT email notification links • Controlled Substance UI language Updated error messages for Submitters RXCheck 3.1 Update and Patch Statistics Dashboard populate counties' logic EHR Support
R33.5 **March 2024**	Statistics reporting updates EHR/Epic OAuth Support File Submission Queue processing
R33.4 **February 2024**	DEA File Updates LicenseE Update – State License Validation Training Materials Update File Processing support EHR support
R33.3 **January 2024**	LicenseE Update – New User Registration LicenseE 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 Project 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

WI ePDMP Integration Services Summary

Current as of 04.29.2024

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	PDMP Administrators' National Conference	Presenter; First national meeting for PDMP administrators; organized by federal BJA-TTAC.	5/7-5/9/2024	San Antonio, TX
June	2024 PMP InterConnect Steering Committee Meeting	Participant; Annual national meeting for PDMP administrators organized by National Association of Boards of Pharmacy (NABP)	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				

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:
Greg Hubbard, American Kratom Association	4/8/2024
	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?
5/10/2024	☒ Yes ☐ No	Scheduling of Kratom – Informational Item

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 applicable:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	N/A

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

The American Kratom Association has sent materials for the agenda, "Pilot, Dose-Finding Study of Kratom Alkaloids: Study Design Updates" which the Board Chair has requested be included in the agenda packet as an informational item.

No formal appearance has been scheduled.

Public Comments may be provided by 2 Wisconsin citizens regarding the impact of the current law.

11) Authorization

Signature of person making this request	Date
Supervisor (Only required for post agenda deadline items)	Date
Executive Director signature (Indicates approval for post agenda deadline items)	Date

Directions for including supporting documents:

1. This form should be saved with any other documents submitted to the Agenda Items folders.
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.

U.S. FOOD & DRUG ADMINISTRATION

Pilot, Dose-Finding Study of Kratom Alkaloids: Study Design Updates

February 15th, 2024

Chad J. Reissig, PhD
Supervisory Pharmacologist, Controlled Substance Staff
FDA's Center for Drug Evaluation and Research

Disclaimer

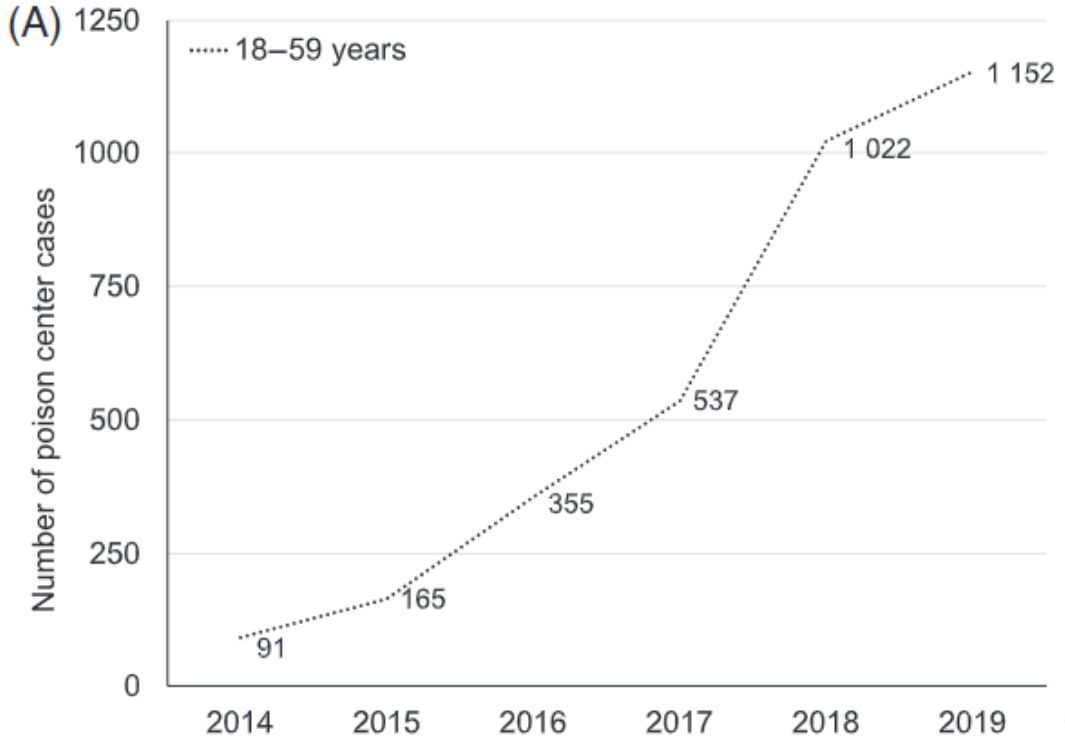
Opinions expressed in this presentation are my own and do not necessarily reflect the views and policies of the FDA

I have no conflicts of interest to report

Kratom

- According to the 2021 National Survey on Drug Use and Health (NSDUH), an estimated 0.6% of individuals (~1.7 million people) reported using kratom in the past 12 months

- Reports of kratom exposures to poison control centers have also increased 2014-2019
  - Graves et al., 2021 J. Am Geriatr Soc 69 (8): 2176-2184



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Clinical Kratom Research

- Controlled, well-designed human studies of kratom are sparse despite increasing interest and use of kratom
  - e.g., Trakulsrichai et al. (2015), Balasingam et al. (2020), Tanna et al. (2022)
- A pilot, dose-ranging and safety study was desired by FDA to gain preliminary data on kratom's effects in humans
  - Contract was awarded to AltaSciences on 9/30/2021
  - Study conducted by Vince and Associates

Study Design

- Single, ascending dose (SAD) design
  - Orally administered, botanical kratom (i.e., encapsulated, raw leaf)
  - The kratom material used in our study was from a single source and well-characterized as to composition and impurities
  - The kratom used did not have alkaloid levels found to be present in *some* marketed kratom products
  - Thus, the results might not be representative of drug effects associated with other kratom-related products in the marketplace
- Primary objective: evaluate the safety and tolerability of single, ascending, oral doses of kratom relative to placebo
- Secondary objectives:
  - To evaluate the pharmacokinetics (PK) of mitragynine, 7-hydroxy-mitragynine, paynantheine, speciogynine, mitraciliatine, corynantheidine, and speciociliatine
  - To evaluate the pharmacodynamics (PD) of kratom

Study Design - Key Inclusion Criteria

- Healthy adult male or female subjects
- Current nondependent, polydrug recreational users
  - Used opioid drugs for recreational (nontherapeutic) purposes (i.e., for psychoactive effects) at least 10 times in the subject's lifetime and at least once in the last 12 weeks from screening; and has a history of recreational use of at least 2 or more of any of the perception-altering (e.g., lysergic acid diethylamide [LSD], kratom, cannabis, dronabinol, ketamine, phencyclidine [PCP], dextromethorphan, 3,4 methylenedioxymethamphetamine [MDMA], mescaline, psilocybin, tryptamine derivatives or ring-substituted amphetamines with perception altering effects) or stimulant drugs (e.g., cocaine, amphetamine, methamphetamine, methylphenidate, methcathinone, and other synthetic cathinones) on at least 5 occasions in the subject's lifetime
- Other, standard criteria (e.g., signed ICF, use of appropriate contraceptives etc.)

Study Design - Key Exclusion Criteria

- Difficulty swallowing capsules
- Sensitivities to kratom
- Significant disease (e.g., history of significant hepatic, renal, cardiovascular, pulmonary, hematologic, neurological, psychiatric, gastrointestinal, endocrine, immunologic, ophthalmologic, or dermatologic disease)
- History of substance or alcohol moderate to severe use disorder (excluding nicotine and caffeine) within the past 2 years, as defined by the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5)

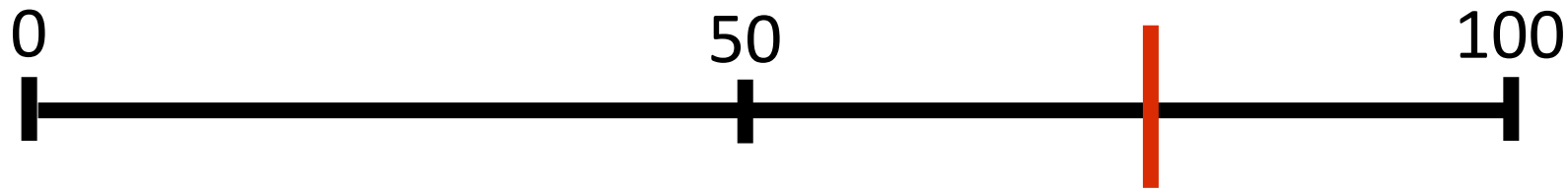
Study Design

- Study was performed under an Investigational New Drug (IND) application
  - Botanical kratom was obtained from Sun Distribution, Super Organics
  - Subjects were dosed using 500 mg, light blue, gelatin capsules (size 00) manufactured under GMP
  - Kratom was administered under “fed” conditions after a high fat meal

Study Design - Pharmacodynamic endpoints

- Drug liking VAS including maximum (peak/Emax) ratings

Do you like the drug effect?



Neither like nor dislike

No, not at all

Yes, very much

Study Design - Pharmacodynamic endpoints

- Drug liking VAS including maximum (peak/Emax) ratings
- Overall Drug Liking VAS (12 and 24 hr)
- Take Drug Again VAS (12 and 24 hr)
- High VAS
- Various other PD effects:
  - Good effects, bad effects, any effects, feeling drunk, drowsiness, relaxation/agitation, Bowdle VAS
- ARCI
- Pupillometry
- PD endpoints were assessed repeatedly after capsule administration

Study Design - Safety Endpoints

- Safety will be evaluated through the assessment of adverse events (AEs), vital signs (blood pressure, pulse, respiratory rate, oxygen saturation, and body temperature), electrocardiogram (ECG), physical examination findings, and Columbia Suicide Severity Rating Scale (C-SSRS)

Study Design - Pharmacokinetic endpoints

- A total of 15 blood plasma samples were obtained
- Timepoints: baseline and 0.25, 0.5, 1, 1.5, 2.0, 2.5, 3.0, 4.0, 5.0, 6.0, 8.0, 10, 12.0, 24, 48 hours
- Samples are being processed; no data currently available

Preliminary (blinded) Results

Results

- Kratom composition
  - 6 month stability data

UF Clinical and Translational Science Institute
Translational Drug Development Core
UNIVERSITY of FLORIDA

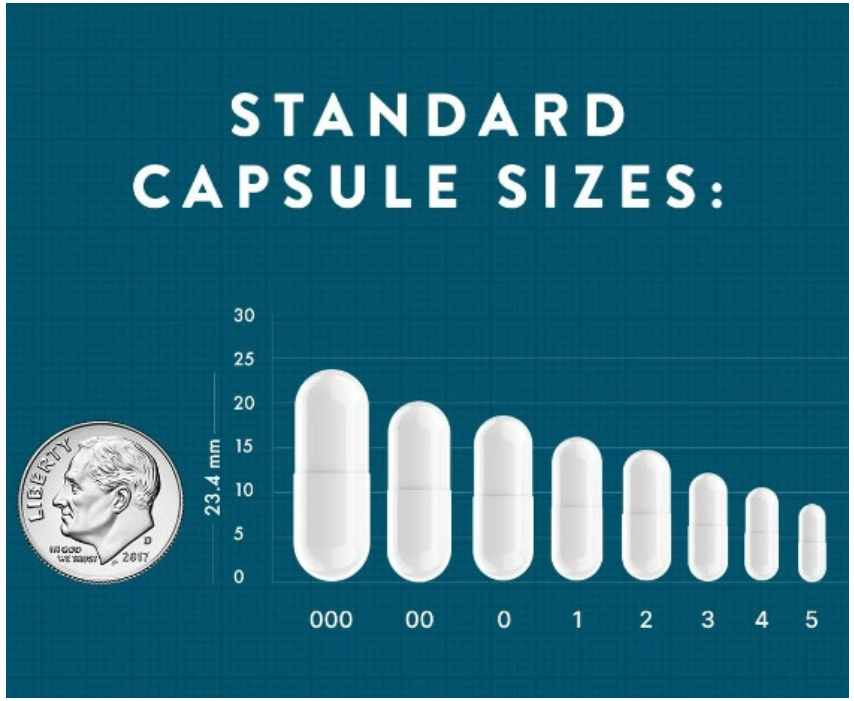
FDA

Alkaloid	Capsule content (mg)#
Mitragynine	5.07 ± 0.71
Speciogynine	0.92 ± 0.13
Speciociliatine	1.98 ± 0.26
Mitraciliatine	0.29 ± 0.04
7-Hydroxymitragynine	BLLOQ
Paynantheine	1.28 ± 0.18
Corynantheidine	0.13 ± 0.02
Corynoxine A	0.04 ± 0.01
Corynoxine B	BLLOQ
Mitraphylline	BLLOQ

*BLLOQ = below the lower limit of quantification (1 ng/mL equivalent to 32 ng/capsule)

Results

- Five (5) cohorts (n=8/cohort) were completed (**2 subjects in each cohort received placebo**)
  - Last subject(s) completed dosing on Jan 17th 2024
- Final dosing regimen was: **1, 3, 8, 10, and 12g** (500 mg capsules)



Results

- This SAD was substantially different than a traditional human abuse potential (HAP) study
- Considerations:
  - Data are still blinded
  - Small sample size
  - No qualification phase
  - No positive control comparator
  - Between-subject design

Safety

- No serious adverse events occurred in dosed subjects
- Nausea and vomiting were observed, but no more than 2 events/dose have been recorded
  - No significant changes in vital signs, ECG, or laboratory evaluations
- No study subject(s) reached “stopping criteria” that were defined as:
    - 1 kratom-related SAE
    - Moderate or severe AEs in 50% of the subjects in the cohort or more

U.S. FOOD & DRUG ADMINISTRATION

Preliminary Conclusions

Conclusions

- Data are still blinded but…
- At the doses tested, no SAEs occurred and kratom appeared to be well-tolerated in this study
  - The kratom material used in our study was taken from a single source and well-characterized as to composition and impurities. The kratom used did not have alkaloid levels found to be present in some marketed kratom products
  - Thus, the results might not be representative of drug effects associated with other kratom-containing products in the marketplace
- Further studies are need to determine kratom's comprehensive safety and tolerability profile

Next Steps…

- These pilot data are informative for future studies of kratom
- The PK data may provide additional insight on the time course effects of various kratom alkaloids
- FDA has announced a cooperative agreement for a human abuse potential (HAP) study of kratom
  - Announced 1/16/24: grants.gov/search-results-detail/351644.
  - These pilot data compliment other research activities currently ongoing by FDA; see web page at https://www.fda.gov/news-events/public-health-focus/fda-and-kratom


FDA
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