Wisconsin Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way
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Tony Evers, Governor
Dawn B. Crim, Secretary

CONTROLLED SUBSTANCES BOARD
Virtual, 4822 Madison Yards Way, Madison
Contact: Carl Hampton (608) 266-2112
November 13, 2020

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

AGENDA

9:30 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-3)

B. 9:30 A.M. ANNUAL HEARING WITH LAW ENFORCEMENT LEADERS, AGENCIES, AND PROSECUTORS – Discussion and Consideration

1. **Introduction**
   a. Overview of Executive Order (EO) 228
   b. Background on the Wisconsin Controlled Substances Board
2. **Overview of Scheduling Processes – Wisconsin Statutes § 961.11**
3. **Reporting Requirements for District Attorneys Regarding Controlled Substance Analogs – Wisconsin Statutes § 961.25**
4. **Receive Testimony Discussion Regarding Drug Trends**
   a. Presentations from Special Guests
   b. Presentation from the Wisconsin State Crime Lab Bureau
   c. Testimony from the Law Enforcement Community
   d. Open Discussion

C. Approval of Minutes

1. September 11, 2020 **(4-5)**
2. October 9, 2020 **(6)**

D. Administrative Matters – Discussion and Consideration

1. Department, Staff and Board Updates
2. Board Members
3. 2021 Meeting Dates

E. Administrative Rule Matters – Discussion and Consideration (7)

1. CR 20-048 Relating to Scheduling of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 **(8-16)**
2. CR 20-049 Relating to Scheduling of Brexanolone and Solriamfetol **(17-24)**
3. CR 20-050 Relating to Scheduling of N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP **(25-32)**

4. CR 20-051 Relating to Scheduling of Noroxymorphone **(33-40)**
5. Proposed Affirmative Action Order for CSB 2.78 Relating to Scheduling Crotonyl Fentanyl **(41)**
6. Proposed Affirmative Action Order for CSB 2.79 Relating to Scheduling Remimazolam **(42)**
7. Status Update on Pending CSB Rule Projects
8. December Emergency Scheduling Meeting
9. Pending and Possible Rulemaking Projects

F. Prescription Drug Monitoring Program (PDMP) Update – Discussion and Consideration (43-49)

1. WI ePDMP Operations
   a. Recent and Upcoming Releases
   b. Status of Grants
   c. Interstate Data Sharing
2. EHR Integration Status
3. Update on VA and APRIS Outreach
4. Quarterly Report Q3 2020
5. WI ePDMP Outreach Calendar

G. 42 CFR Part II Revision and Impact on PDMP – Discussion and Consideration (50-53)

H. Board Member Reports

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

I. Liaison Reports

1. State Council on Alcohol and Other Drug Abuse (SCAODA) Liaison – Subhadeep Barman

J. Special Use Authorizations – Discussion and Consideration

K. Discussion and Consideration of Items Received After Preparation of the Agenda

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

L. Public Comments

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

M. Deliberation on SUA Applications

N. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: JANUARY 15, 2021

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

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

VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
SEPTEMBER 11, 2020

PRESENT: Subhadeep Barman, Yvonne Bellay, Alan Bloom, David Bryce, Doug Englebert, Leonardo Huck, Peter Kallio, Sandy Koresch, John Weitekamp

STAFF: Christian Albouras, Executive Director; Jameson Whitney, Board Legal Counsel; Sharon Henes, Administrative Rules Coordinator; Daniel Betekhtin; Bureau Assistant; Megan Glaeser, Bureau Assistant; and other DSPS Staff

CALL TO ORDER

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

ADOPTION OF AGENDA

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

APPROVAL OF MINUTES

August 18, 2020

MOTION: Peter Kallio moved, seconded by Sandy Koresch, to approve the Minutes of August 18, 2020 as published. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

CSB 2.73 Relating to Scheduling Cenobamate

MOTION: Leonardo Huck moved, seconded by Sandy Koresch, to approve the preliminary rule draft of CSB 2.73, relating to scheduling Cenobamate, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

CSB 2.74 Relating to Scheduling Lemborexant

MOTION: Subhadeep Barman moved, seconded by Leonardo Huck, to approve the preliminary rule draft of CSB 2.74, relating to scheduling Lemborexant, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

CSB 2.75 Relating to Removing FDA Cannabidiol from Scheduling

MOTION: Subhadeep Barman moved, seconded by Peter Kallio, to approve the preliminary rule draft of CSB 2.75, relating to removing FDA Cannabidiol from Scheduling, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

CSB 2.76 Relating to Scheduling Norfentanyl

MOTION: David Bryce moved, seconded by Peter Kallio, to approve the preliminary rule draft of CSB 2.76, relating to scheduling Norfentanyl, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 10:28 a.m.

DRAFT

VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
OCTOBER 9, 2020

PRESENT: Yvonne Bellay, Alan Bloom, Padmaja Doniparthi, Doug Englebert, Peter Kallio, Sandy Koresch

EXCUSED: Subhadeep Barman, Leonardo Huck, John Weitekamp

STAFF: Carl Hampton, Administrator-Division of Policy Development; Jameson Whitney, Board Legal Counsel; Sharon Henes, Administrative Rules Coordinator; Kimberly Wood, Program Assistant Supervisor-Adv.; Daniel Betekhtin; Bureau Assistant; and other DSPS Staff

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 8:03 a.m. A quorum was confirmed with six (6) members present.

ADOPTION OF AGENDA

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

ADMINISTRATIVE RULE MATTERS

CSB 2.77 Relating to Flualprazolam

MOTION: Padmaja Doniparthi moved, seconded by Peter Kallio, to approve the emergency rule relating to scheduling flualprazolam, for emergency rule submission to the governor, publication in an official newspaper and for the permanent rule posting of economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 8:27 a.m.

DRAFT

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Jon Derenne, Administrative Rules Coordinator	November 3, 2020
	Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

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

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
November 13, 2020	☒ Yes ☐ No	1. CR 20-048 (CSB 2.66) Relating to Scheduling of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, And FUB-144 2. CR 20-049 (CSB 2.67) Relating to Scheduling of Brexanolone And Solriamfetol 3. CR 20-050 (CSB 2.68) Relating to Scheduling of N-Ethylhexedrone, A-PHP, 4-MEAP, MPHP, PV8 and 4-Chloro-A-PVP 4. CR 20-051(CSB 2.69) Relating to Scheduling of Noroxymorphone 5. Proposed Affirmative Action Order for CSB 2.78 Relating to Scheduling Crotonyl Fentanyl 6. Proposed Affirmative Action Order for CSB 2.79 Relating to Scheduling Remimazolam 7. Status Update on Pending CSB Rule Projects 8. December Emergency Scheduling Meeting 9. Pending and Possible Rulemaking Projects

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

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

1-4. Review clearinghouse report and discuss any necessary changes to the rule draft prior to submission to GORC for review.

5-6. Consider proposed affirmative action orders for drugs recently scheduled by the DEA.

7. Update on status of CSB 2.70 (scheduling MMB-FUBICA and 4F-MDMB-BINACA), 2.71 (scheduling Lasmiditan), 2.72 (scheduling isotonitazene and 1P-LSD), 2.73 (scheduling cenobamate), 2.74 (scheduling Lemborexant), 2.75 (unscheduling epidiolex), 2.76 (scheduling norfentanyl), 2.77 (scheduling flualprazolam), 4 (designating Gabapentin as a monitored drug).

8. On October 30, 2020 the DEA scheduled oliceridine as a schedule II. The board should consider adding a meeting in early December to consider an affirmative action order.

11) Authorization

Jon Derenne November 3, 2020

Signature of person making this request — Date

Supervisor (if required) — Date

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

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda 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.

LCRC
FORM 2

WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit S. Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

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

CLEARINGHOUSE RULE **20-048**

AN ORDER to create CSB 2.66, relating to scheduling of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144.

Submitted by **CONTROLLED SUBSTANCES BOARD**

10-12-2020 RECEIVED BY LEGISLATIVE COUNCIL.
11-03-2020 REPORT SENT TO AGENCY.

MSK:BL

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

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

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.66 relating to scheduling of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

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

Explanation of agency authority:

The controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227. [s. 961.11 (1), Stats.]

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

Related statute or rule: s. 961.14, Stats.

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

On December 28, 2018, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 into Schedule I of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as schedule I controlled substances under ch. 961, Stats., based upon the federal scheduling. The Controlled Substances Board took affirmative action on February 4, 2019 to similarly treat 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 under chapter 961 effective March 11, 2019 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.14 (4) (tb) 49. to 53., Stats., which adds 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 to schedule I.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule:

A public hearing on the statement of scope was held on January 10, 2020. No one testified at the hearing, or submitted written comments.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144.

Iowa: Iowa has scheduled 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as Schedule I controlled substances.

Michigan: Michigan has not scheduled 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144.

Minnesota: Minnesota has not scheduled 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144.

Summary of factual data and analytical methodologies:

The methodology was to schedule 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 to conform with the federal Controlled Substances Act.

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

This rule schedules drugs and does not have an effect on small business.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by November 13, 2020 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.66 is created to read:

CSB 2.66 Addition of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 to schedule I. Section 961.14 (4) (tb) 49., 50., 51., 52., and 53., Stats., is created to read:

961.14 (4) (tb) 49. Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, commonly known as 5F-EDMB-PINACA.
50. Methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate, commonly known as 5F-MDMB-PICA.

51. N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide, commonly known as FUB-AKB48, FUB-APINACA or AKB48 N-(4-FLUOROBENZYL).
52. 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide, commonly known as 5F-CUMYL-PINACA or SGT-25.
53. (1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone, commonly known as FUB-144.

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
10/7/2020

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.66 - Addition of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 to schedule I.

4. Subject
Scheduling of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144.

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

6. Chapter 20, Stats. Appropriations Affected

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

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

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0.00

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 United States Department of Justice, Drug Enforcement Administration scheduled 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as a schedule I controlled substance effective December 18, 2018. The Wisconsin Controlled Substances Board took affirmative action on February 4, 2019 to similarly treat 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as schedule I controlled substance effective March 11, 2019. The Board is currently promulgating a final rule.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
This rule was posted for economic comments and none were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule schedules synthetic cannabinoids and does not have an economic or fiscal impact on businesses or the State's economy as a whole.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is for the federal and state controlled substances acts to be in conformity and alleviate confusion. In addition, it is in the best interest of Wisconsin citizens to schedule 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 drugs as controlled substances.

16. Long Range Implications of Implementing the Rule
5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144. will be treated as a schedule I controlled substance.

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
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FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

17. Compare With Approaches Being Used by Federal Government

The federal government has scheduled 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as a schedule I controlled substance.

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

Iowa has scheduled 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as Schedule I controlled substances.

Illinois, Michigan, and Minnesota have not yet scheduled 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as Schedule I controlled substances.

19. Contact Name	20. Contact Phone Number
Sharon Henes	(608) 261-2377

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

WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit S. Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

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

CLEARINGHOUSE RULE **20-049**

AN ORDER to create CSB 2.67, relating to scheduling of brexanolone and solriamfetol.

Submitted by **CONTROLLED SUBSTANCES BOARD**

10-12-2020 RECEIVED BY LEGISLATIVE COUNCIL.
11-03-2020 REPORT SENT TO AGENCY.

SG:BL

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

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

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.67 relating to scheduling of brexanolone and solriamfetol.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

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

Explanation of agency authority:

The controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227. [s. 961.11 (1), Stats.]

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

Related statute or rule: s. 961.20, Stats.

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

On June 17, 2019, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing brexanolone and solriamfetol into Schedule IV of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating brexanolone and solriamfetol as schedule IV controlled substances under ch. 961, Stats., based upon the federal scheduling. The Controlled Substances Board took affirmative action on July 17, 2019 to similarly treat brexanolone and solriamfetol under chapter 961 effective July 22, 2019 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.20 (2) (ap) and (2m) (g), Stats. which adds brexanolone and solriamfetol to schedule IV.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled brexanolone or solriamfetol.

Iowa: Iowa has scheduled brexanolone and solriamfetol as Schedule IV controlled substances.

Michigan: Michigan has not scheduled brexanolone or solriamfetol.

Minnesota: Minnesota has not scheduled brexanolone or solriamfetol.

Summary of factual data and analytical methodologies:

The methodology was to schedule brexanolone and solriamfetol to conform with the federal Controlled Substances Act.

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

This rule schedules drugs and does not have an effect on small business.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by November 13, 2020 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.67 is created to read:

CSB 2.67 Addition of Brexanolone and Solriamfetol to schedule IV. Section 961.20 (2) (p) and (2m) (g), Stats., are created to read:

961.20 (2) (ap) Brexanolone.
(2m) (g) Solriamfetol.

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
10/7/2020

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.67

4. Subject
Scheduling of brexanolone and solriamfetol.

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

6. Chapter 20, Stats. Appropriations Affected

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

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

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0.00

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 United States Department of Justice, Drug Enforcement Administration scheduled brexanolone and solriamfetol as schedule IV controlled substances effective June 17, 2019. The Wisconsin Controlled Substances Board took affirmative action on July 17, 2019 to similarly treat brexanolone and solriamfetol under chapter 961 effective July 22, 2019 to allow for publication in the Administrative Register. The Board is currently promulgating a final rule.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
This rule was posted for economic comments and none were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule schedules brexamolone and solriamfetol and does not have an economic or fiscal impact on businesses or the State's economy as a whole.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is for the federal and state controlled substances acts to be in conformity and alleviate confusion. In addition, it is in the best interest of Wisconsin citizens to schedule brexanolone and solriamfetol as schedule IV controlled substances.

16. Long Range Implications of Implementing the Rule
Brexanolone and solriamfetol will be treated as a schedule IV controlled substances.

17. Compare With Approaches Being Used by Federal Government

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

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

The federal government has scheduled brexanolone and solriamfetol as a schedule IV controlled substances.

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

Iowa has scheduled brexanolone and solriamfetol as Schedule IV controlled substances. Illinois, Michigan and Minnesota have not scheduled brexanolone or solriamfetol.

19. Contact Name	20. Contact Phone Number
Sharon Henes	(608) 261-2377

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 S. Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

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

CLEARINGHOUSE RULE **20-050**

AN ORDER to create CSB 2.68, relating to scheduling of N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP.

Submitted by **CONTROLLED SUBSTANCES BOARD**

10-12-2020 RECEIVED BY LEGISLATIVE COUNCIL.
11-03-2020 REPORT SENT TO AGENCY.

MSK:BL

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

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

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.68 relating to scheduling of N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

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

Explanation of agency authority:

The controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227. [s. 961.11 (1), Stats.]

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

Related statute or rule: s. 961.14, Stats.

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

On July 18, 2019, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP into Schedule I of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP as a schedule I controlled substances under ch. 961, Stats., based upon the federal scheduling. The Controlled Substances Board took affirmative action on August 12, 2019 to similarly treat N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP under chapter 961 effective August 19, 2019 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.14 (7) (L) 35. to 40., Stats., which adds N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP to schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP.

Iowa: Iowa has scheduled N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP as Schedule I controlled substances.

Michigan: Michigan has not scheduled N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP.

Minnesota: Minnesota has scheduled MPHP and PV8 has Schedule I controlled substances. Minnesota has not scheduled N-Ethylhexedrone, a-PHP, 4-MEAP, and 4-chloro-a-PVP.

Summary of factual data and analytical methodologies:

The methodology was to schedule N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP to conform with the federal Controlled Substances Act.

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

This rule schedules drugs and does not have an effect on small business.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by November 13, 2020 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.68 is created to read:

CSB 2.68 Addition of N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP to schedule I. Section 961.14 (7) (L) 35. to 40., Stats., is created to read:

961.14 (7) (L) 35. N-Ethylhexedrone.
36. alpha-pyrrolidinohexanophenone, commonly known as a-PHP.
37. 4-methyl-alpha-ethylaminopentiophenone, commonly known as 4-MEAP.
38. 4'-methyl-alpha-pyrrolidinohexiophenone, commonly known as MPHP.
39. alpha-pyrrolidinoheptaphenone, commonly known as PV8.
40. 4'-chloro-alpha-pyrrolidinovalerophenone, commonly known as 4-chloro-a-PVP.

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
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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
10/7/2020

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.68

4. Subject
Scheduling of N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP.

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

6. Chapter 20, Stats. Appropriations Affected

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

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

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0.00

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 United States Department of Justice, Drug Enforcement Administration scheduled N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP as a schedule I controlled substance effective July 18, 2019. The Wisconsin Controlled Substances Board took affirmative action on August 12, 2019 to similarly treat N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP as schedule I controlled substances effective August 19, 2019. The Board is currently promulgating a final rule.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
This rule was posted for economic comments and none were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule schedules cathinones and does not have an economic or fiscal impact on businesses or the State's economy as a whole.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is for the federal and state controlled substances acts to be in conformity and alleviate confusion. In addition, it is in the best interest of Wisconsin citizens to schedule N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP drugs as controlled substances.

16. Long Range Implications of Implementing the Rule
N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP. will be treated as schedule I controlled substance.

17. Compare With Approaches Being Used by Federal Government

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

The federal government has scheduled N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP. as schedule I controlled substances.

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

Iowa and Minnesota have scheduled N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP as Schedule I controlled substances. Illinois and Michigan have not scheduled N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP.

19. Contact Name	20. Contact Phone Number
Sharon Henes	(608) 261-2377

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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

WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit S. Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

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

CLEARINGHOUSE RULE **20-051**

AN ORDER to create CSB 2.69, relating to scheduling of noroxymorphone.

Submitted by **CONTROLLED SUBSTANCES BOARD**

10-12-2020 RECEIVED BY LEGISLATIVE COUNCIL.
11-03-2020 REPORT SENT TO AGENCY.

SG:BL

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

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

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.69 relating to scheduling of noroxymorphone.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, Stats.

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

Explanation of agency authority:

The controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227. [s. 961.11 (1), Stats.]

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

Related statute or rule: s. 961.16, Stats.

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

On August 16, 2019, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing noroxymorphone into Schedule II of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating noroxymorphone as a schedule II controlled substance under ch. 961, Stats., based upon the federal scheduling. The Controlled Substances Board took affirmative action on November 4, 2019 to similarly treat noroxymorphone under chapter 961 effective November 11 2019 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.16 (2) (a) 10m., Stats. which adds noroxymorphone to schedule II.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled noroxymorphone.

Iowa: Iowa has not scheduled noroxymorphone.

Michigan: Michigan has not scheduled noroxymorphone.

Minnesota: Minnesota has not scheduled noroxymorphone.

Summary of factual data and analytical methodologies:

The methodology was to schedule noroxymorphone to conform with the federal Controlled Substances Act.

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

This rule schedules a drug and does not have an effect on small business.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by November 13, 2020 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.69 is created to read:

CSB 2.69 Addition of Noroxymorphone to schedule II. Section 961.16 (2) (a)10m., Stats., is created to read:

961.16 (2) (a) 10m. Noroxymorphone.

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
10/7/2020

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.69

4. Subject
Scheduling of noroxymorphone

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

6. Chapter 20, Stats. Appropriations Affected

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

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

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0.00

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 United States Department of Justice, Drug Enforcement Administration scheduled noroxymorphone as a schedule II controlled substance effective August 16, 2019. The Wisconsin Controlled Substances Board took affirmative action on November 4, 2019 to similarly treat noroxymorphone as a schedule II controlled substance effective November 11, 2019. The Board is currently promulgating a final rule.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
This rule was posted for economic comments and none were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule schedules noroxymorphone and does not have an economic or fiscal impact on businesses or the State's economy as a whole.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is for the federal and state controlled substances acts to be in conformity and alleviate confusion. In addition, it is in the best interest of Wisconsin citizens to schedule noroxymorphone as a controlled substance.

16. Long Range Implications of Implementing the Rule
Noroxymorphone will be treated as a schedule II controlled substance.

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

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

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Illinois, Iowa, Michigan and Minnesota have not scheduled noroxymorphone as a controlled substance.

19. Contact Name	20. Contact Phone Number
Sharon Henes	(608) 261-2377

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

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

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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

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

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

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

5. Describe the Rule's Enforcement Provisions

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

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On October 2, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing Crotonyl Fentanyl into schedule I of the federal Controlled Substances Act. The scheduling action is effective October 2, 2020.

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

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. 961.13 and omitting the notice of proposed rule making, designating Crotonyl Fentanyl as a schedule I controlled substance.

ORDER

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

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

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

This order shall take effect on November 23, 2020 to allow for 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 RULE-MAKING	:	AFFIRMATIVE ACTION
PROCEEDINGS BEFORE THE	:	ORDER OF THE
CONTROLLED SUBSTANCES BOARD	:	CONTROLLED SUBSTANCES BOARD

FINDINGS

1. On October 6, 2020, the Department of Justice, Drug Enforcement Administration published an interim final rule in the Federal Register placing Remimazolam into schedule IV of the federal Controlled Substances Act. The scheduling action is effective October 6, 2020.

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

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 rule making, designating Remimazolam as a schedule IV controlled substance.

ORDER

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

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

961.20 (2) (mo) Remimazolam

This order shall take effect on November 23, 2020 to allow for publication in the Administrative Register. The order expires upon promulgation of a final rule.

Dated _____

_____
Doug Englebert, Chair
Controlled Substances Board

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Marjorie Liu Program & Policy Analyst, PDMP	11/03/2020 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**

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

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
11/13/2020	☒ **Yes** ☐ **No**	Prescription Drug Monitoring Program (PDMP) Update

7) Place Item in:	8) Is an appearance before the Board being scheduled?	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. Status of Grants
   c. Interstate Data Sharing
2. EHR Integration Status
3. Update on VA and APRIS Outreach
4. Quarterly Report Q3 2020
5. WI ePDMP Outreach Calendar

11) Authorization

Signature of person making this request	Date
Marjorie Liu	*11/3/2020*
Signature of person making this request	**Date**
Supervisor (if required)	**Date**
Executive Director signature (indicates approval to add post agenda deadline item to agenda)	**Date**

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda 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.

2019-2020 Development and Release Summary

Updated 11.04.2020

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

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

WI ePDMP Interstate Data Exchange Summary

Current as of 11.04.2020

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

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

WI ePDMP Integration Services Summary

Current as of 09.04.2020

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

2020 – WI ePDMP Outreach Calendar

	JULY	AUGUST	SEPTEMBER
1			
2			
3			
4			
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10			
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18			Tribal Clinic/Health Center Outreach--Peter Christensen Health Center
19			
20			
21			
22			
23			
24			Tribal Clinic/Health Center Outreach—Forest County Potawatomi Health & Wellness Center
25			
26			
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31			

2020 – WI ePDMP Outreach Calendar

	October	November	December
1			
2			
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16		Webinar: Wisconsin Overdose Fatality Review Project	
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28			
29	Tribal Clinic/Health Center Outreach—Ho Chunk Nation		
30			
31			

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 & Policy Analyst, PDMP	11/03/2020 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**

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

Controlled Substances Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
11/13/2020	☒ Yes ☐ No	42 CFR Part II Revision and Impact on PDMP

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	Yes (Fill out Board Appearance Request) x No	

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

The 42 CFR Part II revisions concerning PDMP:

1. Non-OTP (opioid treatment program) and non-central registry treating providers are now eligible to query a central registry, in order to determine whether their patients are already receiving opioid treatment through a member program.
2. OTPs are permitted to enroll in a state prescription drug monitoring program (PDMP), and permitted to report data into the PDMP when prescribing or dispensing medications on Schedules II to V, consistent with applicable state law.

Part 2 continues to prohibit law enforcement's use of SUD patient records in criminal prosecutions against patients, absent a court order. Part 2 also continues to restrict the disclosure of SUD treatment records without patient consent.

Action Item: CSB approval of WI PDMP policy and operational changes to accommodate the rule changes.

11) Authorization

Signature of person making this request	Date
Marjorie Liu	*11/3/2020*
Signature of person making this request	**Date**
Supervisor (if required)	**Date**
Executive Director signature (indicates approval to add post agenda deadline item to agenda)	**Date**

Directions for including supporting documents:

1. This form should be attached to any documents submitted to the agenda.
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3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

HHS.Gov Press Release 7/13/2020

Fact Sheet: SAMHSA 42 CFR Part 2 Revised Rule

The 42 CFR Part 2 regulations (Part 2) serve to protect patient records created by federally assisted programs for the treatment of substance use disorders (SUD). Part 2 has been revised to further facilitate better coordination of care in response to the opioid epidemic while maintaining its confidentiality protections against unauthorized disclosure and use.

What Has Not Changed Under the New Part 2 Rule: The revised rule does not alter the basic framework for confidentiality protection of substance use disorder (SUD) patient records created by federally assisted SUD treatment programs. Part 2 continues to prohibit law enforcement's use of SUD patient records in criminal prosecutions against patients, absent a court order. Part 2 also continues to restrict the disclosure of SUD treatment records without patient consent, other than as statutorily authorized in the context of a bona fide medical emergency; or for the purpose of scientific research, audit, or program evaluation; or based on an appropriate court order.

What Has Changed Under the New Part 2 Rule: The revised rule modifies several major sections of Part 2, as follows:

Provision	What Changed?	Why Was This Changed?
Applicability and Re-Disclosure	Treatment records created by non-Part 2 providers based on their own patient encounter(s) are explicitly not covered by Part 2, unless any SUD records previously received from a Part 2 program are incorporated into such records. Segmentation or holding a part of any Part 2 patient record previously received can be used to ensure that new records created by non-Part 2 providers will not become subject to Part 2.	To facilitate coordination of care activities by non-part-2 providers.
Disposition of Records	When an SUD patient sends an incidental message to the personal device of an employee of a Part 2 program, the employee will be able to fulfill the Part 2 requirement for "sanitizing" the device by deleting that message.	To ensure that the personal devices of employees will not need to be confiscated or destroyed, in order to sanitize in compliance with Part 2.
Consent Requirements	An SUD patient may consent to disclosure of the patient's Part 2 treatment records to an entity (e.g., the Social Security Administration), without naming a specific person as the recipient for the disclosure.	To allow patients to apply for benefits and resources more easily, for example, when using online applications that do not identify a specific person as the recipient for a disclosure of Part 2 records.

Provision	What Changed?	Why Was This Changed?
Disclosures Permitted w/ Written Consent	Disclosures for the purpose of "payment and health care operations" are permitted with written consent, in connection with an illustrative list of 18 activities that constitute payment and health care operations now specified under the regulatory provision.	In order to resolve lingering confusion under Part 2 about what activities count as "payment and health care operations," the list of examples has been moved into the regulation text from the preamble, and expanded to include care coordination and case management activities.
Disclosures to Central Registries and PDMPs	Non-OTP (opioid treatment program) and non-central registry treating providers are now eligible to query a central registry, in order to determine whether their patients are already receiving opioid treatment through a member program. OTPs are permitted to enroll in a state prescription drug monitoring program (PDMP), and permitted to report data into the PDMP when prescribing or dispensing medications on Schedules II to V, consistent with applicable state law.	To prevent duplicative enrollments in SUD care, duplicative prescriptions for SUD treatment, and adverse drug events related to SUD treatment.
Medical Emergencies	Declared emergencies resulting from natural disasters (e.g., hurricanes) that disrupt treatment facilities and services are considered a "bona fide medical emergency," for the purpose of disclosing SUD records without patient consent under Part 2.	To ensure clinically appropriate communications and access to SUD care, in the context of declared emergencies resulting from natural disasters.
Research	Disclosures for research under Part 2 are permitted by a HIPAA-covered entity or business associate to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule (re: Research on Human Subjects).	To facilitate appropriate disclosures for research, by streamlining overlapping requirements under Part 2, the HIPAA Privacy Rule and the Common Rule.
Audit and Evaluation	Clarifies specific situations that fall within the scope of permissible disclosures for audits and/or program evaluation purposes.	To resolve current ambiguity under Part 2 about what activities are covered by the audit and evaluation provision.

Provision	What Changed?	Why Was This Changed?
Undercover Agents and Informants	Court-ordered placement of an undercover agent or informant within a Part 2 program is extended to a period of 12 months, and courts are authorized to further extend the period of placement through a new court order.	To address law enforcement concerns that the current policy is overly restrictive to some ongoing investigations of Part 2 programs.