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

TELECONFERENCE/VIRTUAL
CONTROLLED SUBSTANCES BOARD
Room N208, 4822 Madison Yards Way, 2nd Floor, Madison
Contact: Christian Albouras (608) 266-2112
May 8, 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. Approval of Minutes (4-5)
1. March 13, 2020

C. Administrative Matters - Discussion and Consideration
1. Department, Staff and Board Updates
2. Board Members

D. Prescription Drug Monitoring Program (PDMP) Update – Discussion and Consideration
1. WI e PDMP Operations
   a. Recent and Upcoming Releases
   b. Interstate Data Sharing
2. EHR Integration Status Update
3. Update on VA and APRIS Impact
4. WI ePDMP Outreach Calendar

E. Legislative and Policy Matters – Discussion and Consideration

F. Administrative Rule Matters – Discussion and Consideration (6-7)
1. Adopt CR 19-010 Relating to Scheduling NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA **(8-10)**
2. Adopt CR 19-011 Relating to Scheduling N-Ethylopentylone **(11-13)**
3. Adopt CR 19-012 Relating to Scheduling Approved Cannabidiol Drugs **(14-16)**
4. Affirmative Action Scheduling Cenobamate **(17)**
5. Affirmative Action Scheduling Lemborexant **(18)**
6. CSB 2.71 Scope Relating to Scheduling Lasmiditan **(19-20)**
7. CSB 2.66 Relating to Scheduling 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 **(21-24)**
8. CSB 2.67 Relating to Scheduling Brexanolone and Solriamfetol **(25-27)**

9. CSB 2.68 Relating to Scheduling N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP **(28-30)**
10. CSB 2.69 Relating to Scheduling Noroxymorphone **(31-33)**
11. CSB 4 Relating to Designating Gabapentin as a monitored drug **(34-36)**
12. Pending or Possible Rulemaking Projects

G. Board Member Reports
1. Medical Examining Board – Timothy Westlake
2. Dentistry Examining Board – Leonardo Huck
3. Board of Nursing – Peter Kallio
4. Pharmacy Examining Board – John Weitekamp

H. Liaison Reports

I. Special Use Authorizations (SUA) – Discussion and Consideration

J. 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 Policy Matters
12. Administrative Rule Matters
13. Liaison Reports
14. Appearances from Requests Received or Renewed
15. Speaking Engagements, Travel, or Public Relations Requests, and Reports
16. Consulting with Legal Counsel

K. 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.).

L. Deliberation on SUA Applications
1. Tina Nichols – Lakeshore Humane Society, Inc. **(37-69)**

M. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: JULY 10, 2020

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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. In order 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. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
MARCH 13, 2020

PRESENT: Subhadeep Barman, Yvonne Bellay, Doug Englebert *(via Skype)*, Leonardo Huck, Peter Kallio, Sandy Koresch *(arrived via Skype at 9:48 a.m., excused at 11:32 a.m.)*, John Weitekamp

EXCUSED: Alan Bloom, Timothy Westlake

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

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 9:45 a.m. A quorum was confirmed with six (6) board members present.

ADOPTION OF AGENDA

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

APPROVAL OF MINUTES

MOTION: Subhadeep Barman moved, seconded by Leonardo Huck, to approve the Minutes of January 10, 2020 as published. Motion carried unanimously.

PRESCRIPTION DRUG MONITORING PROGRAM (PDMP) UPDATE

Update on VA and APRIS Impact

MOTION: Peter Kallio moved, seconded by Yvonne Bellay, to delegate Doug Englebert, Peter Kallio, Timothy Westlake, and Department staff as necessary to inquire into the Veterans Health Administration PDMP Integration Project, communicate with vendors regarding contract specifics, compliance with statute and rule, and other relevant issues, and take action as appropriate. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Scheduling Request from Walworth County Relating to Isotonitazene

MOTION: Peter Kallio moved, seconded by Subhadeep Barman, to approve the Scope Statement creating CSB 2.72, relating to scheduling Isotonitazene, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. The Board authorizes the Chairperson to approve the emergency rule for

submission to the Governor's office and publication. Motion carried unanimously.

Scheduling Request from Calumet County Relating to 1P-LSD

MOTION: Subhadeep Barman moved, seconded by Yvonne Bellay, to approve the Scope Statement creating CSB 2.72, relating to scheduling 1P-LSD, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. The Board authorizes the Chairperson to approve the emergency rule for submission to the Governor's office and publication. Motion carried unanimously.

Scheduling Lasmiditan by Affirmative Action

MOTION: Peter Kallio moved, seconded by John Weitekamp, to schedule by affirmative action Lasmiditan as a Schedule V controlled substance. The order shall take effect on March 23, 2020 to allow for publication in the Administrative Register. Motion carried unanimously.

(Sandy Koresch was excused at 11:32 a.m.)

ADJOURNMENT

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

The meeting adjourned at 11:55 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:
Sharon Henes Administrative Rules Coordinator	27 April 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?
8 May 2020	☐ Yes ☐ No	**Administrative Rule Matters** 1. Adopt CR 19-010 Relating to Scheduling NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA 2. Adopt CR 19-011 Relating to Scheduling N-Ethylopentylone 3. Adopt CR 19-012 Relating to Scheduling Approved Cannabidiol Drugs 4. Affirmative Action Scheduling Cenobamate 5. Affirmative Action Scheduling Lemborexant 6. CSB 2.71 Scope Relating to Scheduling Lasmiditan 7. CSB 2.66 Relating to Scheduling 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 8. CSB 2.67 Relating to Scheduling Brexanolone and Solriamfetol 9. CSB 2.68 Relating to Scheduling N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP 10. CSB 2.69 Relating to Scheduling Noroxymorphone 11. CSB 4 Relating to Designating Gabapentin as a monitored drug 12. Updates on Pending or Possible Rulemaking Projects

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:

State of Wisconsin
Department of Safety & Professional Services

11) Authorization	
Sharon Henes	*mm/dd/yy*
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	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 19-010)

ORDER

An order of the Controlled Substances Board to create CSB 2.63 relating to scheduling of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

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

Explanation of agency authority:

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

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

Related statute or rule: s. 961.14, Stats.

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

On July 10, 2018, the Department of Justice, Drug Enforcement Administration published its temporary scheduling order in the Federal Register placing NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA into Schedule I of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA as schedule I controlled substances under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on August 10, 2018 to similarly treat NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA under chapter 961 effective August 13, 2018 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) 44., 45., 46., 47., and 48., Stats. which adds NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA to schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA.

Iowa: Iowa has not scheduled NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA.

Michigan: Michigan has not scheduled NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA.

Minnesota: Minnesota has not scheduled NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA.

Summary of factual data and analytical methodologies:

The methodology was to schedule NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA 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 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.

TEXT OF RULE

SECTION 1. CSB 2.63 is created to read:

CSB 2.63 Addition of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA to schedule I. Section 961.14 (4) (tb) 44., 45., 46., 47., and 48., Stats., are created to read:

961.14(4)(tb) 44. Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate, commonly known as NM2201
45. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide, commonly known as 5F-AB-PINACA
46. 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide, commonly known as 4-CN-CUMYL-BUTINACA
47. Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate, commonly known as MMB-CHMICA
48. 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide, commonly known as 5F-CUMYL-P7AICA

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

(END OF TEXT OF RULE)

Dated _____

_____
Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 19-011)

ORDER

An order of the Controlled Substances Board to create CSB 2.64 relating to scheduling of N-Ethylpentylone.

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 August 31, 2018, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing N-Ethylpentylone into Schedule I of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating N-Ethylpentylone as a schedule I controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on October 3, 2018 to similarly treat N-Ethylpentylone under chapter 961 effective October 8, 2018 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) 34., Stats. which adds N-Ethylpentylone to schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled N-Ethylpentylone.

Iowa: Iowa has not scheduled N-Ethylpentylone.

Michigan: Michigan has not scheduled N-Ethylpentylone.

Minnesota: Minnesota has not scheduled N-Ethylpentylone.

Summary of factual data and analytical methodologies:

The methodology was to schedule N-Ethylpentylone 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 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.

TEXT OF RULE

SECTION 1. CSB 2.64 is created to read:

CSB 2.64 Addition of N-Ethylpentylone to schedule I. Section 961.14 (7) (L) 34., Stats., is created to read:

961.14 (7) (L) 34. N-Ethylpentylone, commonly known as ephylone.

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

(END OF TEXT OF RULE)

Dated _____ _____

Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 19-012)

ORDER

An order of the Controlled Substances Board to create CSB 2.65 relating to scheduling of approved cannabidiol drugs.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.22, Stats.

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

Explanation of agency authority:

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

If cannabidiol is rescheduled or deleted as a controlled substance under federal law, the controlled substances board shall similarly treat cannabidiol under this chapter as soon as practically possible but no later than 30 days from the date of publication in the federal register of a final order rescheduling or deleting cannabidiol or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h). The board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r), and (2) or s. 961.13, 961.15, 961.17, 961.19, or 961.21, a final rule, for which notice of proposed rule making is omitted, rescheduling or deleting cannabidiol. [s. 961.11 (4g), Stats.]

Related statute or rule: s. 961.14, Stats.

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

On September 28, 2018, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing Food and Drug Administration approved drug products that contain cannabidiol into Schedule V of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board took affirmative action on October 9, 2018 to similarly treat Food and Drug Administration approved drug products that contain cannabidiol under chapter 961 effective October 15, 2018 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.22 (7), Stats. which adds Food and Drug Administration approved drug products that contain cannabidiol to schedule V.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled Food and Drug Administration approved drug products that contain cannabidiol.

Iowa: Iowa scheduled Food and Drug Administration approved drug products that contain cannabidiol as schedule V controlled substances.

Michigan: Michigan has not scheduled Food and Drug Administration approved drug products that contain cannabidiol.

Minnesota: Minnesota scheduled Food and Drug Administration approved drug products that contain cannabidiol as schedule V controlled substances.

Summary of factual data and analytical methodologies:

The methodology was to schedule scheduled Food and Drug Administration approved drug products that contain cannabidiol as schedule V controlled substances to conform with the federal Controlled Substances Act.

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

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 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.

TEXT OF RULE

SECTION 1. CSB 2.65 is created to read:

CSB 2.65 Addition of approved cannabidiol drugs to schedule V. Section 961.22 (7), Stats., is created to read:

961.22 (7) APPROVED CANNABIDIOL DRUGS. A drug product in finished dosage formulation that has been approved by the United States food and drug administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.

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

(END OF TEXT OF RULE)

Dated _____ _____

Chair
Controlled Substances Board

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 10, 2020, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register placing cenobamate into schedule Vof the federal Controlled Substances Act. The scheduling action is effective March 10, 2020.

2. The Controlled Substances Board did not receive an objection to similarly treating cenobamate as a schedule V under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating cenobamate 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. 961.21 and omitting the notice of proposed rule making, designating cenobamate as a schedule V controlled substance.

ORDER

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

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

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

This order shall take effect on May 18, 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 PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	AFFIRMATIVE ACTION ORDER OF THE CONTROLLED SUBSTANCES BOARD

FINDINGS

1. On April 7, 2020, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register placing lemborexant into schedule IV of the federal Controlled Substances Act. The scheduling action is effective April 7, 2020.

2. The Controlled Substances Board did not receive an objection to similarly treating lemborexant 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 lemborexant 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 lemborexant as a schedule IV controlled substance.

ORDER

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

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

961.20 (20) (2) (eqm) Lemborexant.

This order shall take effect on May 18, 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

STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 2.71

Relating to: Scheduling of Lasmiditan

Rule Type: Permanent

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

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

The objective of the rule is to schedule lasmiditan as Schedule V controlled substance. The Controlled Substances Board determines the scheduling of lasmiditan as a Schedule V controlled substance is in the best interest of the citizens of Wisconsin.

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

On January 31, 2020, the United States Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register placing lasmiditan into Schedule V of the federal Controlled Substances Act. The scheduling action was effective January 31, 2020. The Controlled Substances Board did not receive an objection to similarly treat lasmiditan as a Schedule V controlled substance under ch. 961, Stats within 30 days of the date of publication in the Federal Register of the final order designating lasmiditan as a controlled substance.

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

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

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

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

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

961.11 (1) 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.

961.11(4) 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).

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

25 hours

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

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

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

On January 31, 2020, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing lasmiditan into Schedule V of the federal Controlled Substances Act. The scheduling action was effective on January 31, 2020.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

_____
Authorized Signature

_____
Date Submitted

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.66 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 July 10, 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
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 July 10, 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
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 July 10, 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
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 July 10, 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
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 4.03 (2) relating to designating drugs having substantial potential abuse Gabapentin as a drug.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.385 (1) (ag), Stats.

Statutory authority: ss. 961.385 (1) (ag) and (2), Stats.

Explanation of agency authority:

"Monitored prescription drug" means a substance indentifed in s. 961.16, 961.18, 961.20, or 961.22 or a drug identified by the board by rule as having a substantial potential for abuse. [s. 961.385 (1) (ag), Stats.

The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs. [s. 961.385 (2) (c), Stats.]

Related statute or rule: s. 961.385, Stats.

Plain language analysis:

Gabapentin is not a scheduled controlled substance. Gabapentin closely resembles pregabalin, a Schedule V controlled substance, in its chemical structure and pharmaceological activity.

Gabapentin is a prescription medication approved by the Federal Food and Drug Administration for the treatment of neuropathic pain and epileptic disorders. In recent years however, gabapentin has been increasingly encountered by law enforcement, documented in national crime lab reports, reported to poison control centers, and diverted for illicit use. The Researched Abuse, Diversion and Addivtive – Related Surveillance (RADARS) indicates as increase in gabapentin diversion. The Drug Abuse Warning Network (DAWN) indicates a rise of emergency department visit rates for gabapentin.

The Controlled Substance Board and the Prescription Drug Monitoring Program (PDMP) staff has received requests by health care practitioners and law enforcement to have gabapentin included in the PDMP. Prescribers have indicated it is beneficial to be aware of a patient having a prescription for Gabapentin prior to prescribing an opioid because when combined with opioids there is an increase risk of respiratory depression and opioid-related mortality increases significantly. Gabapentin is highly sought after for illicit use due to its potentiating opioids affect.

This rule designates Gabapentin as a drug having substantial potential for abuse. This designation would make Gabapentin as a monitored drug in the PDMP.

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

There are no federal regulations regarding drugs monitored through state prescription drug monitoring programs. Gabapentin is not a federal controlled substance.

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

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

Comparison with rules in adjacent states:

Illinois: Illinois has designated Gabapentin as a monitored drug in the prescription monitoring program.

Iowa: Iowa's prescription monitoring program designates reportable drugs as controlled substances administered or dispensed by a practitioner or opioid antagonist dispsend by a practitioner o administered by a first responder. There is no provision for designating drugs, such as Gabapentin, as a reportable drug. Iowa has not scheduled Gabapenin as a controlled substance.

Michigan: Michigan has scheduled Gabapentin as a Schedule V controlled substance. Michigan's prescription monitoring program requires all Schedule II-V controlled substances to be monitored.

Minnesota: For purposes of the prescription monitoring program, Minnesota includes Gabapentin in the definition of controlled substances and it is a monitored drug. Gabapentin is not scheduled as a controlled substances.

Summary of factual data and analytical methodologies:

The Prescription Drug Monitoring Program received inquiries from prescribers and law enforcement about the inclusion of gabapentin as a monitored drug. The Controlled Substances Board received information from those testifying at several law enforcement hearings held

pursuant to 2017 Executive Order 228 and the Milwaukee Medical Examininers Office regarding the increase of the presence of gabapentin in overdose cases. The Controlled Substances Board reviewed research of the affects of gabapentin. In addition, the Controlled Substances Board took notice of the actions of several states, including our surrounding states, to either schedule gabapentin as a controlled substance or to designate it as a monitored drug in the prescription monitoring programs.

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis 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, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on * to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 4.03 (2) is created to read:

CSB 4.03 (2) Gabapentin.

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

(END OF TEXT OF RULE)
