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

VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD
Virtual, 4822 Madison Yards Way, Madison
Contact: Christian Albouras (608) 266-2112
September 11, 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 of August 18, 2020 (4-5)

C. Introductions, Announcements and Recognition – Discussion and Consideration

D. Administrative Matters – Discussion and Consideration
1. Department, Staff and Board Updates
2. Board Members

E. Prescription Drug Monitoring Program (PDMP) Update – Discussion and Consideration (6-9)
1. WI e PDMP Operations
   a. Recent and Upcoming Releases
   b. Interstate Data Sharing
   c. Metrics Notifications Work Group Update
2. EHR Integration Status Update
3. Update on VA and APRIS Impact
4. WI ePDMP Outreach Calendar
5. Update on Staffing

F. Administrative Rule Matters – Discussion and Consideration (10)
1) CSB 2.73 Relating to Scheduling Cenobamate **(11-13)**
2) CSB 2.74 Relating to Scheduling Lemborexant **(14-16)**
3) CSB 2.75 Relating to Removing FDA Approved Cannabidiol from Scheduling **(17-20)**
4) CSB 2.76 Relating to Scheduling Norfentanyl **(21-23)**
5) Pending or Possible Rulemaking Projects

G. Board Member Reports
1) Medical Examining Board

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

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

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: NOVEMBER 13, 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 at 608-266-2112 or the Meeting Staff at 608-266-5439.

VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
AUGUST 18, 2020

PRESENT: Yvonne Bellay, Alan Bloom, Doug Englebert, Peter Kallio, Sandy Koresch, John Weitekamp

EXCUSED: Subhadeep Barman, Leonardo Huck

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

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 1:00 p.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.

APPROVAL OF MINUTES OF JULY 10, 2020

MOTION: Peter Kallio moved, seconded by John Weitekamp, to approve the Minutes of July 10, 2020 as published. Motion carried unanimously.

PUBLIC HEARING ON CLEARINGHOUSE RULE 20-022 RELATING TO SCHEDULING MMB-FUBICA AND 4F-MDMB-BINACA

MOTION: Yvonne Bellay moved, seconded by Sandy Koresch, to accept all Clearinghouse comments for Clearinghouse Rule CR# 20-022, relating to scheduling MMB-FUBICA and 4F-MDMB-BINACA. Motion carried unanimously.

MOTION: Peter Kallio moved, seconded by Yvonne Bellay, to authorize the Chairperson to approve the Legislative Report and Draft for Clearinghouse Rule CR# 20-022, relating to scheduling MMB-FUBICA and 4F-MDMB-BINACA, for submission to the Governor's Office and Legislature. Motion carried unanimously.

PUBLIC HEARING ON CLEARINGHOUSE RULE 20-023 RELATING TO SCHEDULING ISOTONITAZENE AND 1P-LSD

MOTION: Alan Bloom moved, seconded by Yvonne Bellay, to authorize the Chairperson to approve the Legislative Report and Draft for Clearinghouse Rule CR# 20-

023, relating to scheduling Isotonitazene and 1P-LSD, for submission to the Governor's Office and Legislature. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Scope CSB 2.77 Relating to Scheduling Flualprazolam

MOTION: Peter Kallio moved, seconded by John Weitekamp, to approve the Scope Statement creating CSB 2.77, relating to scheduling flualprazolam, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on the Scope Statement, the Chairperson is authorized to approve the required notice of hearing. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 1:16 p.m.

2019-2020 Development and Release Summary

Updated 09.04.2020

Release Date	Description
Pending	
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
Completed	
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 09.04.2020

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, WV, Military Health System

Metrics Notification Workgroup Updates

- Three prescribing practice thresholds have been administered: Opioid, Benzo, and Stimulant prescription orders percentile all set at 95%.
- First notifications will be sent out in October.
- Based on a test run in August, 709 prescribers received the "elevated metrics" email notification for opioids, 666 for Benzodiazepine, and 573 for stimulants.

WI ePDMP Integration Services Summary

Current as of 09.04.2020

Pending Health Systems and EHR Platforms	
	Advanced Pain Management (Contracted- In Development)
	ADVENT (In Discussion)
	Athena (In Discussion)
	Essentia (In Discussion/Contracting)
	Prairie Clinic (In Discussion)
Connected Health Systems (approx. 50% of monthly patient queries)	
1	Ascension Wisconsin
2	Aspirus Health Care
3	Aurora Health Care
4	Children's Hospital of Wisconsin
5	Froedtert & the Medical College of Wisconsin
6	GHC of South Central Wisconsin
7	Gundersen Health System
8	**HealthPartners**
9	HSHS / Prevea Health
10	Marshfield Clinic
11	Mayo Clinic
12	MercyHealth
13	Monroe Clinic
14	ProHealth Care
15	SSM Health
16	Thedacare
17	UnityPoint
18	UW Health
19	Wisconsin Statewide Health Information Network

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	28 August 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 September 2020	☐ Yes ☐ No	Administrative Rule Matters 1. CSB 2.73 Relating to Scheduling Cenobamate 2. CSB 2.74 Relating to Scheduling Lemborexant 3. CSB 2.75 Relating to Removing FDA Approved Cannabidiol from Scheduling 4. CSB 2.76 Relating to Scheduling Norfentanyl 5. 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:

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

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.73 relating to scheduling of cenobamate.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.22, Stats.

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

Explanation of agency authority:

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. 961.22, Stats.

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

On March 10, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing cenobamate into Schedule V of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating cenobamate as a schedule V controlled substance under ch. 961, Stats., based upon the federal scheduling. The Controlled Substances Board took affirmative action on May 8, 2020 to similarly treat cenobamate under chapter 961 effective May 18, 2020 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 (9), Stats., which adds cenobamate to schedule V.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled cenobamate.

Iowa: Iowa has not scheduled cenobamate.

Michigan: Michigan has not scheduled cenobamate.

Minnesota: Minnesota has not scheduled cenobamate.

Summary of factual data and analytical methodologies:

The methodology was to schedule cenobamate 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 2.73 is created to read:

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

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

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 2.74 relating to scheduling of lemborexant.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

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

Explanation of agency authority:

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 April 7, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing lemborexant into Schedule IV of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating lemborexant as a schedule IV controlled substance under ch. 961, Stats., based upon the federal scheduling. The Controlled Substances Board took affirmative action on May 8, 2020 to similarly treat lemborexant under chapter 961 effective May 18, 2020 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) (eqm), Stats., which adds lemborexant to schedule IV.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled lemborexant.

Iowa: Iowa has not scheduled lemborexant.

Michigan: Michigan has not scheduled lemborexant.

Minnesota: Minnesota has not scheduled lemborexant.

Summary of factual data and analytical methodologies:

The methodology was to schedule lemborexant 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 2.74 is created to read:

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

961.20 (2) (eqm) Lemborexant.

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 2.75 relating to scheduling of FDA approved cannabidiol.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 961.14 and 961.22, Stats.

Statutory authority: s. 961.11 (1) and (4) (g), 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 or nabiximols is rescheduled or deleted as a controlled substance under federal law, the controlled substances board shall similarly treat cannabidiol or nabiximols 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 nabiximols 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 or nabiximols. [s. 961.11 (4) (g), Stats.]

Related statute or rule: s. 961.14, Stats.

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

On June 5, 2020, the Department of Justice, Drug Enforcement Administration provided a letter to the Controlled Substances Board indicating that as a result of the Agricultural Improvement Act of 2018, the Federal Drug Administration approved drug product Epidiolex is no longer controlled under the federal Controlled Substances Act.

The Agricultural Improvement Act of 2018 defines the term "hemp" to "mean the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol (also known as Δ9-THC) concentration of not more than 0.3 percent on a dry weight basis." (7 U.S.C. § 1639o.). The Agricultural Improvement Act of 2018 also amended the Controlled Substances Act by excluding "hemp" from the definition of marihuana under 21 U.S.C. § 802 (16) and the listing of tetrahydrocannabinols under 21 U.S.C. § 812 (c).

The prescription drug product Epidiolex is a cannabis derivative with a Δ9-THC concentration of not more than 0.3% on a dry weight basis. Therefore, as a result of the Department of Justice, Drug Enforcement Administration letter and the Agricultural Improvement Act, the drug product Epidiolex is no longer controlled under the federal Controlled Substances Act.

On August 21, 2020, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register removing drug products approved by the U.S. Food and Drug Administration that contain cannabidiol derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols from schedule V.

Plain language analysis:

The Controlled Substances Board took affirmative action on June 23, 2020 to similarly treat U.S. Food and Drug Administration approved cannabidiol under chapter 961 effective June 29, 2020 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule repeals s. 961.22 (7), Stats., removing Food and Drug Administration approved cannabidiol from Schedule V.

In addition, this rule creates s. 961.14 (4) (t) 4., Stats., creating an exception from Schedule I (under tetrahydrocannabinols) for an FDA approved cannabidiol derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols. This exception is created so that the repeal of FDA approved cannabidiol from Schedule V does not revert these substances to inclusion in Schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois does not schedule Food and Drug Administration approved cannabidiol.

Iowa: Iowa schedules Food and Drug Administration approved cannabidiol as Schedule V controlled substances.

Michigan: Michigan does not schedule Food and Drug Administration approved cannabidiol.

Minnesota: Minnesota does not schedule Food and Drug Administration approved cannabidiol.

Summary of factual data and analytical methodologies:

The methodology was to remove cannabidiol from scheduling.

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 2.75 is created to read:

CSB 2.75 Exclusion of Approved Cannabidiol Drugs from schedule I and deleting from schedule V. **(1)** Section 961.14 (4) (t) 4., Stats., is created to read:

961.14 (4) (t) 4. 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.

(2) Section 961.22 (7), Stats., is repealed.

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

(END OF TEXT OF RULE)

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 2.76 relating to scheduling of norfentanyl.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, Stats.

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

Explanation of agency authority:

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 April 17, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing norfentanyl into Schedule II of the federal Controlled Substances Act effective May 18, 2020.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating norfentanyl as a schedule II controlled substance under ch. 961, Stats., based upon the federal scheduling. The Controlled Substances Board took affirmative action on June 23, 2020 to similarly treat norfentanyl under chapter 961 effective June 29, 2020 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule renumbers and amends 961.16 (8) (b) (intro.), Stats., and creates 961.16 (8) (b) 2. which adds norfentanyl to schedule II.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled norfentanyl.

Iowa: Iowa has not scheduled norfentanyl.

Michigan: Michigan has not scheduled norfentanyl.

Minnesota: Minnesota has not scheduled norfentanyl.

Summary of factual data and analytical methodologies:

The methodology was to schedule norfentanyl 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 2.76 is created to read:

CSB 2.76 Addition of norfentanyl to schedule II. **(1)** Section 961.16 (8) (b), Stats., is renumbered 961.16 (8) (b) (intro.) and amended to read:
961.16 (8) (b) An immediate precursor to fentanyl, including all of the following:
1. 4-anilino-N-phenethyl-4-piperidine, commonly known as ANPP.

(2) Section 961.16 (8) (b) 2., Stats. is created to read:
2. N-phenyl-N-(piperidin-4-yl)propionamide, commonly known as norfentanyl.

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)
