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**
**Virtual, 4822 Madison Yards Way, Madison**
**Contact: Christian Albouras (608) 266-2112**
**July 10, 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**
1. May 8, 2020 **(4-7)**
2. June 23, 2020 **(8-9)**

**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 (10-11)**
1. Adopt CR 19-156 (CSB 4) Relating to Operation of Prescription Drug Monitoring Program **(12-14)**
2. Adopt CR 19-157 (CSB 3) Relating to Special Use Authorizations **(15-22)**
3. Scope: CSB 2.73, Relating to Scheduling Cenobamate **(23-24)**
4. Scope: CSB 2.74, Relating to Scheduling Lemborexant **(25-26)**
5. Scope: CSB 2.75, Relating to FDA Approved Cannabidiol **(27-28)**
6. Scope: CSB 2.76, Relating to Scheduling Norfentanyl **(29-30)**
7. CSB 2.71, Relating to Scheduling Lasmiditan **(31-33)**
8. Flualprazolam

9. 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: AUGUST 18, 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.

**TELECONFERENCE/VIRTUAL**
**CONTROLLED SUBSTANCES BOARD**
**MEETING MINUTES**
**MAY 8, 2020**

**PRESENT:** Yvonne Bellay, Alan Bloom, Doug Englebert, Leonardo Huck, Peter Kallio, Sandy Koresch (*joined at 9:47 a.m.)*, John Weitekamp, Timothy Westlake

**EXCUSED:** Subhadeep Barman

**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 9:31 a.m. A quorum was confirmed with six (6) board members present.

## ADOPTION OF AGENDA

**MOTION:** Leonardo Huck moved, seconded by Peter Kallio, to adopt the Agenda as published. Motion carried unanimously.

## APPROVAL OF MINUTES

**MOTION:** Peter Kallio moved, seconded by Timothy Westlake, to approve the Minutes of March 13, 2020 as published. Motion carried unanimously.

*(Sandy Koresch joined at 9:47 a.m.)*

## ADMINISTRATIVE RULE MATTERS

**Adopt CR 19-010 Relating to Scheduling NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA**

**MOTION:** Peter Kallio moved, seconded by John Weitekamp, to approve the Adoption Order for Clearinghouse Rule 19-010, relating to scheduling NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA. Motion carried unanimously.

**Adopt CR 19-011 Relating to Scheduling N-Ethylopentylone**

**MOTION:** Alan Bloom moved, seconded by Timothy Westlake, to approve the Adoption Order for Clearinghouse Rule 19-011, relating to scheduling N-Ethylopentylone. Motion carried unanimously.

**Adopt CR 19-012 Relating to Scheduling**

**MOTION:** Peter Kallio moved, seconded by Sandy Koresch, to approve the Adoption Order for Clearinghouse Rule 19-012, relating to scheduling Approved Cannabidiol Drugs. Motion carried unanimously.

**Affirmative Action Scheduling Cenobamate**

**MOTION:** Yvonne Bellay moved, seconded by Timothy Westlake, to schedule by affirmative action as a schedule V controlled substance. The order shall take effect on May 18, 2020, to allow for publication in the Administrative Register. Motion carried unanimously.

**Affirmative Action Scheduling Lemborexant**

**MOTION:** Sandy Koresch moved, seconded by Yvonne Bellay, to schedule by affirmative action Lemborexant as a schedule IV controlled substance. The order shall take effect on May 18, 2020, to allow for publication in the Administrative Register. Motion carried unanimously.

**CSB 2.71 Scope Relating to Scheduling Lasmiditan**

**MOTION:** Peter Kallio moved, seconded by Yvonne Bellay, to approve the Scope Statement revising CSB 2.71, relating to scheduling Lasmiditan, 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. Motion carried unanimously.

**CSB 2.66 Relating to Scheduling 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144**

**MOTION:** Sandy Koresch moved, seconded by John Weitekamp, to approve the preliminary rule draft of CSB 2.66, relating to scheduling 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

**CSB 2.67 Relating to Scheduling Brexanolone and Solriamfetol**

**MOTION:** Alan Bloom moved, seconded by Yvonne Bellay, to approve the preliminary rule draft of CSB 2.67, relating to scheduling Brexanolone and Solriamfetol, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

**CSB 2.68 Relating to Scheduling N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP**

**MOTION:** Peter Kallio moved, seconded by Sandy Koresch, to approve the preliminary rule draft of CSB 2.68, relating to scheduling N-Ethylhexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

**CSB 2.69 Relating to Scheduling Noroxymorphone**

**MOTION:** Alan Bloom moved, seconded by Yvonne Bellay, to approve the preliminary rule draft of CSB 2.69, relating to scheduling Noroxymorphone, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

**CSB 4 Relating to Designating Gabapentin as a Monitored Drug**

**MOTION:** John Weitekamp moved, seconded by Yvonne Bellay, to approve the preliminary rule draft of CSB 4, relating to designating Gabapentin as a monitored drug for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

## CONVENE TO CLOSED SESSION

**MOTION:** Timothy Westlake moved, seconded by Leonardo Huck, 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 closing disciplinary investigations with administrative warnings (ss. 19.85(1)(b), 440.205 and 961.385(2)(c) 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.). Doug Englebert, Chairperson, read aloud the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Yvonne Bellay-yes; Alan Bloom-yes; Doug Englebert-yes; Leonardo Huck-yes; Peter Kallio-yes; Sandy Koresch-yes; John Weitekamp-yes; and Timothy Westlake-yes. Motion carried unanimously.

The Board convened to Closed Session at 10:50 a.m.

## DELIBERATION ON SUA APPLICATIONS

**Tina Nichols – Lakeshore Humane Society, Inc.**

**MOTION:** Yvonne Bellay moved, seconded by Peter Kallio, to grant a Special Use Authorization permit to Tina Nichols with the following limitations that the board deems necessary for the protection of the public health and safety: the permit holder shall submit reports of their use and inventory to the board every three months. The reports shall be reviewed by a licensed veterinarian and shall be signed by the holder of the DEA registration number. Failure to submit this report shall be considered a deviation from the permit under CSB 3.08 and may result in immediate revocation of the permit. Reason for

limitation: CSB 3.045(1), an act constituting a violation under CSB 3.08(1). Motion carried unanimously.

**RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION**

**MOTION:** Peter Kallio moved, seconded by Yvonne Bellay, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 11:17 a.m.

**VOTE ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION, IF VOTING IS APPROPRIATE**

**MOTION:** Peter Kallio moved, seconded by Leonardo Huck, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

*(Be advised that any recusals or abstentions reflected in the closed session motions stand for the purposes of the affirmation vote.)*

**ADJOURNMENT**

**MOTION:** Peter Kallio moved, seconded by Timothy Westlake, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 11:22 a.m.

**CONTROLLED SUBSTANCES BOARD**
**MEETING MINUTES**
**JUNE 23, 2020**

**PRESENT:** Yvonne Bellay, Alan Bloom, Doug Englebert, Peter Kallio *(arrived at 1:18 p.m.)*, Sandy Koresch, John Weitekamp, Timothy Westlake

**EXCUSED:** Subhadeep Barman, Leonardo Huck

**STAFF:** Christian Albouras, Executive Director; Jameson Whitney, Board Legal Counsel; Sharon Henes, Administrative Rules Coordinator; Kimberly Wood, Program Assistant Supervisor-Advanced; Daniel Betekhtin; Bureau Assistant, and other DSPS Staff

## CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 1:05 p.m. A quorum was confirmed with six (6) board members present.

## ADOPTION OF AGENDA

***Amendments to the Agenda:***

**MOTION:** Alan Bloom moved, seconded by John Weitekamp, to adopt the Agenda as published. Motion carried unanimously.

## ADMINISTRATIVE RULE MATTERS

**Scheduling Norfentanyl by Affirmative Action**

**MOTION:** Timothy Westlake moved, seconded by Alan Bloom, to schedule by affirmative action Norfentanyl as a Schedule II controlled substances. The order shall take effect on June 29, 2020 to allow for publication in the Administrative Register. Motion carried unanimously.

**Deleting Federal Drug Administration (FDA) Approved Cannabidoil Drugs from the Controlled Substances Schedules by Affirmative Action**

**MOTION:** Alan Bloom moved, seconded by John Weitekamp, to remove from scheduling by affirmative action Federal Drug Administration approved cannabidiol drugs. The order shall take effect on June 29, 2020 to allow for publication in the Administrative Register. Motion carried unanimously.

*Peter Kallio arrived at 1:18 p.m.*

## RECOGNITION

**MOTION:** John Weitekamp moved, seconded by Peter Kallio, to recognize and thank Timothy Westlake for his years of dedicated service to the Controlled Substances Board and the State of Wisconsin. Motion carried unanimously.

## ADJOURNMENT

**MOTION:** Timothy Westlake moved, seconded by Alan Bloom, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 1:25 p.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<br>Administrative Rules Coordinator | 24 June 2020<br>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? |
|---|---|---|
| 10 July 2020 | ☒ Yes<br>☐ No | **Administrative Rule Matters**<br>1. Adopt CR 19-156 (CSB 4) Relating to Operation of Prescription Drug Monitoring Program<br>2. Adopt CR 19-157 (CSB 3) Relating to Special Use Authorizations<br>3. Scope: CSB 2.73 Relating to Scheduling Cenobamate<br>4. Scope: CSB 2.74 Relating to Scheduling Lemborexant<br>5. Scope: CSB 2.75 Relating to FDA Approved Cannibidoil<br>6. Scope: CSB 2.76 Relating to Scheduling Norfentanyl<br>7. CSB 2.71 Relating to scheduling Lasmiditan<br>8. Flualprazolam<br>9. 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<br>☐ Closed Session | ☐ Yes<br>☐ No | |

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

**11) Authorization**

*Sharon Henes* — *24 June 2020*

**Signature of person making this request** — **Date**

**Supervisor (if required)** — **Date**

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

# State of Wisconsin
# Department of Safety & Professional Services

**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

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| | | |
|---|---|---|
| IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD | : | ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 19-156) |

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ORDER

An order of the Controlled Substances Board **to amend** CSB 4.11 (9) and **to create** CSB 4.04 (2) (gb) and (gd), 4.09 (1) (c) and (d) and 4.093 (2m), relating to operation of prescription drug monitoring program.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:** s. 961.385, Stats.

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

**Explanation of agency authority:**

The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs. The section goes on to state several items the board shall do, including defining what constitutes suspicious or critically dangerous conduct or practices for purposes of the rules promulgated under s. 961.385 (2) (c), Stats.

**Related statute or rule:** s. 961.385, Stats.

**Plain language analysis:**

Section 1 requires the drug dosage units and partial fill indicator to be submitted to the prescription drug monitoring program.

Section 2 clarifies that healthcare professionals may access monitored prescription drug history reports about a patient for scientific research purposes if the patient is a direct patient of the healthcare professional and the patient has given informed consent. In addition, the proposed rule clarifies that a healthcare professional may access monitored prescription drug history reports about a patient for purposes of conducting an overdose fatality review.

Section 3 allows department staff who are charged with investigations to be able to access audit trails related to the log of monitored prescription drug history reports and prescription drug monitoring program data disclosed and a log of requests for prescription drug monitoring program data or monitored prescription drug history reports even when no information was disclosed.

Section 4 clarifies research purposes to be for scientific research purposes and that the Controlled Substances Board may require evidence of institutional review board approval for the research.

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

**Comparison with rules in adjacent states:**

**Illinois**: Illinois does not require submission of the drug dosage unit or partial fill indicator. Illinois does not authorize access for practitioner scientific research.

**Iowa**: Iowa does not require submission of the drug dosage unit or partial fill indicator. Iowa does not authorize access for practitioner scientific research. Summary, statistical, or aggregate data to public or private entities for statistical, public research, public policy, or educational purposes.

**Michigan**: Michigan does not require submission of drug dosage units or partial fill indicator. Data may be provided to employees or agents of the Department of Licensing and Regulatory Affairs. Michigan does not authorize access for scientific research.

**Minnesota:** Minnesota requires the submission of drug dosage units and partial fill indicator. Personnel of the Minnesota Board of Pharmacy may have access to audit trails. Minnesota does not authorize access for scientific research.

**Summary of factual data and analytical methodologies:**

The Controlled Substances Board reviewed the rule to make clarifications and updates based upon stakeholder feedback.

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

This rule was posted for economic comments and none were received.

**Fiscal Estimate and Economic Impact Analysis:**

The Fiscal Estimate and Economic Impact Analysis is attached.

**Effect on small business**:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at 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.

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TEXT OF RULE

SECTION 1. CSB 4.04 (2) (gb) and (gd) is created to read:

**CSB 4.04 (2)** (gb) The drug dosage units.
(gd) The partial fill indicator.

SECTION 2. CSB 4.09 (1) (c) and (d) are created to read:

**CSB 4.09 (1)** (c) Scientific research purposes if all of the following requirements are met:

1. The patient is a direct patient of the healthcare professional.
2. The healthcare professional has obtained informed consent from the patient to access monitored prescription drug history reports for scientific research purposes.

(d) Purposes of conducting an overdose fatality review.

SECTION 3. CSB 4.093 (2m) is created to read:

**CSB 4.093 (2m)** Department staff who are charged with investigating dispensers, dispenser delegates, pharmacists, pharmacist delegates, practitioners, and practitioner delegates may access the audit trails related to s. CSB 4.12 (3) (f) and (g).

SECTION 4. CSB 4.11 (9) is amended to read:

**CSB 4.11 (9)** The board may disclose PDMP data without personally identifiable information that could be reasonably used to identify any patient, healthcare professional, practitioner delegate, pharmacist delegate, or dispenser for public health and scientific research purposes. The board may require evidence of institutional review board approval.

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

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(END OF TEXT OF RULE)

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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 19-157) |

ORDER

An order of the Controlled Substances Board **to renumber and amend** CSB 3.04 (7); **to amend** CSB 3.02 (4), 3.03 (2), 3.04 (1) (a) and (note), (b), (c), and (d), (3) (intro) and (b), (4) (a) (intro.) and (5) (a) (intro.); **and to create** CSB 3.03 (2m), 3.042, and 3.08 (1) (f) and (g) relating to special use authorizations.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

**Statutes interpreted:** s. 961.335, Stats.

**Statutory authority:** s. 961.335 (8), Stats.

**Explanation of agency authority:**

The controlled substances board may promulgate rules relating to the granting of special use permits including, but not limited to, requirements for the keeping and disclosure of records, filing of applications and suspension or revocation of permits. [s. 961.335 (8), Stats.]

**Related statute or rule:** s. 961.335, Stats.

**Plain language analysis:**

Section 1 updates the rule to reflect current drafting standards by removing the phrase “but are not limited to.”

Sections 2 and 3 separates the current CSB 3.03 (2) into two separate subsections to create clarity. Special use authorizations are issued to individuals only. If a permit is issued to an individual who is designated by a college or university, or research unit, the students, laboratory technicians, research specialists or chemical analysts under the individual’s supervision do not need to obtain a special use authorization.

Section 4 updates language and creates clarity. This section removes “checklists” from the application and updates the note to reflect the current address. The reference to s. 961.335 is removed because the statute does not state the fee is $25; rather it says up to $25. The current

rule creates difficulty in applying for a special use authorization because it requires proof an application is submitted to the federal Drug Enforcement Administration and the Drug Enforcement Administration will not accept an application without proof the individual has a special use authorization. To resolve this situation, the proposed rule requires an affidavit that the individual intends to file an application with the Drug Enforcement Administration. Lastly this section removes proof of compliance with the requirements for security and instead requires a plan for security.

Section 5 clarifies that individuals providing euthanasia at humane shelters shall provide the documentation in the application including their completion of a board-approved euthanasia by injection course. In addition, for dog trainers and animal control applicants, it removes the phrase "unless other documentation is required by the board" to clarify that the letter is the requirement.

Section 6 moves the board's discretion to request an appearance to the general application requirements to create clarity.

Section 7 creates the storage requirements. Controlled substances shall be stored in a safe or steel cabinet. The safe or cabinet must be bolted or cemented to the floor if it is less than 750 pounds so that it can't be readily removed. It must meet requirements for forced entry and housed in a room which is locked during non-use hours. Other secure storage areas may be approved by the Controlled Substances Board if the storage will protect the controlled substances from theft and unauthorized use. The controlled substances must be locked up unless in use by the authorized user.

Sections 8, 9, 10 and 11 amends language to reflect the acronym "SUA" and defined term "SUA permit" for consistency throughout the rule.

Section 12 clarifies that it is a violation to not obtain a drug enforcement administration registration or if there is a violation of a state or federal law relating to controlled substances.

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

The federal government requires security controls for non-practitioners storing controlled substances. The drugs are to be stored in a safe or steel cabinet with the following specifications: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques. If the safe or steel cabinet weighs less than 750 pounds, it must be bolted or cemented to the floor or wall in a way that it can't be readily removed. The room must limit access during working hours and provide security after working hours.

**Comparison with rules in adjacent states:**

**Illinois**: In Illinois, every person who, or proposes to, manufacture, distribute, or dispense any controlled substances; engages in chemical analysis, research, or instructional activities which utilize controlled substances; purchases, stores, or administers euthanasia drugs, provides canine

odor detection services; must obtain a registration issued by the Department of Financial and Professional Regulation. Registered persons may possess, manufacture, distribute, or dispense controlled substances, or administer euthanasia drugs to the extent authorized by their registration. Registration is site-specific, so persons operating at more than one site must have a separate registration for each. A registration to manufacture, distribute, or dispense a controlled substance or purchase, store, or administer euthanasia drugs may be denied, refused renewal, suspended or revoked if a person does any of the following: provided false or fraudulent material information in any application; has been convicted of a felony related to any controlled substance; has had their federal DEA registration suspended or revoked; has been convicted of bribery, perjury or other infamous crime; violated any provision of the controlled substances act; or failed to provide effective controls against the diversion of controlled substances in other than legitimate medical, scientific or industrial channels. [Ill. Admin. Code 77 § 3100]

**Iowa**:

In Iowa, researchers, analytical laboratories, animal shelters, dog training facilities, and teaching institutions are required to apply for a controlled substances registration permit with the Pharmacy Board. Registration applies to one site only, so persons operating at more than one site must have separate registrations for each. Registered persons may possess, manufacture, distribute, dispense, or conduct research using controlled substances to the extent authorized by their registration only and in conformity with the other provisions of Iowa's controlled substances registration law. A registration to manufacture, distribute, dispense, prescribe, import or export, conduct research or instructional activities or conduct chemical analysis with controlled substances may be denied if the board determines that the issuance of the registration would be inconsistent with the public interest. In determining the public interest, the board shall consider the following factors: maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels; compliance with applicable state and local law; any convictions related to any controlled substance; past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion; furnishing false or fraudulent material in any application for registration; suspension or revocation of the federal DEA registration; and any other factors relevant to and consistent with the public health and safety. [Iowa Admin. Code r. 657-10]

**Michigan**:

In Michigan, an individual in charge of a licensed dog pound or animal shelter, must obtain both a Drug Enforcement Agency (DEA) controlled substance registration and a Michigan controlled substance license for the limited purpose of buying, possessing, or administering a commercially prepared, premixed solution of sodium pentobarbital to practice euthanasia on animals. Michigan officers or state employees are exempted from licensure if that person is engaged in the enforcement of a state or local law relating to controlled substances and who is duly authorized to possess controlled substances in the course of that person's duties. Licensed researchers and manufacturers of a controlled substance may conduct research with those substances, perform chemical analysis, manufacture the substance, distribute the substance to other persons who are licensed or authorized, and conduct instructional activities with the

substances. Certain activities involving schedule 1 controlled substances may require a separate license. The license shall be granted unless the issuance of the license would be inconsistent with the public interest. In determining the public interest, the following shall be considered: maintenance of effective controls against diversion to other than legitimate and professionally recognized therapeutic, scientific, or industrial channels; compliance with applicable state and local law; conviction relating to a controlled substance; past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion; furnishing false or fraudulent material in an application for a controlled substance license; suspension or revocation of the federal DEA registration; and any other factor relevant to and consistent with the public health and safety. [Mich. Admin. Code r. 338]

**Minnesota:**

In Minnesota, any qualified person may use controlled substances in the course of a bona fide research project but cannot administer or dispense such drugs to human beings unless such drugs are prescribed, dispensed and administered by a person lawfully authorized to do so. Researchers involved in the use of controlled substances must apply annually for registration with the state Board of Pharmacy. Registration requires that the registrant have policies and procedures for effective controls against theft and diversion of all stocked inventory, unauthorized access, substance waste, and returns. The board may deny, suspend, revoke, or refuse to renew any registration based upon the following: fraud or deception in connection with securing the registration; habitual indulgence in the use of narcotics, stimulants, or depressant drugs or habitual indulgence in intoxicating liquors in a manner which could cause conduct endangering public health; unprofessional conduct or conduct endangering public health; gross immorality; conviction of theft of drugs or the unauthorized use, possession or sale thereof; and violation of the provisions of the rules of the board. [Minn. R 6800.4400]

**Summary of factual data and analytical methodologies:**

The Controlled Substances Board reviewed the chapter for statutory compliance and obsolete practices. The Controlled Substances Board also took into consideration obstacles encountered by individuals who apply and hold special use authorizations.

**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.

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TEXT OF RULE

SECTION 1. CSB 3.02 (4) is amended to read:

**CSB 3.02 (4)** "Special use" means to manufacture, obtain, possess, use, administer, or dispense a controlled substance for purposes that include~~, but are not limited to,~~ scientific research, instructional activities, chemical analysis, drug-detecting animal training, and euthanasia in humane shelters.

SECTION 2. CSB 3.03 (2) is amended to read:

**CSB 3.03 (2)** An SUA permit may be issued to an individual only. ~~Entities are not eligible to receive an SUA permit, except that an individual may be designated and authorized to receive the permit for a college or university department, research unit, or similar administrative organization unit. Students, laboratory technicians, research specialists, or chemical analysts under the designee's supervision may possess and use the substances named in the designee's permit for the authorized purposes without obtaining an individual permit.~~

SECTION 3. CSB 3.03 (2m) is created to read:

**CSB 3.03 (2m)** A SUA permit may be issued to an individual who is designated and authorized to receive a SUA permit for a college or university department, research unit, or similar administrative organizational unit. Students, laboratory technicians, research specialists, or chemical analysts under the individual's supervision, may, without obtaining a SUA permit, possess and use a controlled substance, for the purposes authorized in the permit received for the department or unit.

SECTION 4. CSB 3.04 (1) (a), (a) (note), (b) (c), and (d) are amended to read:

**CSB 3.04 (1)** (a) Submit a completed application ~~and any required checklists using forms provided by the board~~. A complete application shall include a detailed description of the anticipated uses for each identified controlled substance in Schedules I to V of ch. 961, Stats., including each identified controlled substance by name and schedule and the protocols for such uses.

Note: Application forms ~~and checklists~~ are available ~~upon request to the board office at 1400 E. Washington Ave.~~ on the department's website at dsps.wi.gov, or by request from the Department of Safety and Professional Services, P.O. Box 8935, Madison, Wisconsin 53708, or ~~online at http://dsps.wi.ogv, under "Professions", then "Controlled Substance Special Use Authorization."~~ by calling (608) 266-2112.

(b) Pay the applicable permit fee of $25 ~~as set forth in s. 961.335, Stats~~. No fee for an SUA permit may be charged to an employee of a state agency or institution if the permit is necessary to perform employment functions.

(c) Provide ~~proof~~ an affidavit which states that the applicant ~~has submitted~~ intends to file an application for registration with the federal drug enforcement administration.

(d) Provide ~~proof of the applicant's compliance with the board's requirements~~ a plan for maintaining the physical security of the controlled substances identified in the application.

SECTION 5. CSB 3.04 (3) (intro.), (a) and (b), (4) (a) (intro.), and (5) (a) (intro.) are amended to read:

**CSB 3.04 (3)** In addition to sub. (1), individuals providing euthanasia at humane shelters shall also provide all of the following:

(a) Estimates as to the number of animals to be euthanized during the 1 year the SUA permit is in effect and dosage per animal.

(b) Documentation of the individual's completion of a board-approved euthanasia by injection course ~~by each staff member performing euthanasia~~.

**(4)** (a) ~~Unless other documentation is required by the board, a~~ A letter from the sheriff or chief of police, in the jurisdiction where the controlled substances are stored, that includes all of the following for dog training purposes:

**(5)** (a) ~~Unless other documentation is required by the board, a~~ A letter from the sheriff or chief of police, in the jurisdiction where the controlled substances are stored, that includes all of the following for euthanasia purposes:

SECTION 6. CSB 3.04 (7) is renumbered to CSB 3.04 (1) (g) and amended to read:

**CSB 3.04 (1)** (g) ~~The~~ Appear before the board ~~may request an appearance before the board~~ if requested by the board ~~additional information is required~~.

SECTION 7. CSB 3.042 is created to read:

**CSB 3.042 Storage. (1)** Individuals holding a SUA permit shall store controlled substances in a safe or steel cabinet or box that meets all of the following requirements:

(a) Bolted or cemented to the floor or wall in such a way that it cannot be readily removed if the safe or steel cabinet or box weighs less than 750 pounds.

(b) Is able to withstand attempts at forced entry by individuals using common tools for a period of 10 minutes or lock manipulation for 20 hours. Fire resistance is not required.

(c) Is housed in a room which is locked during non-use hours.

**(2)** Notwithstanding sub. (1), a central safe used for other security purposes may be used if the controlled substances are locked in metal boxes sufficient to prevent casual access by others authorized to use the safe. Other secure storage areas may be approved by the board if the manner in which the controlled substances are stored will protect the controlled substances from theft and unauthorized use.

**(3)** Controlled substances shall be kept locked except when they are in active use by the authorized individual or under the supervision of an authorized individual under s. CSB 3.03 (2m).

SECTION 8. CSB 3.045 (intro.) is amended to read:

**CSB 3.045. Limited special use authorization.** The board may grant a limited SUA permit or deny a SUA permit based upon consideration of public health and safety including any of the following reasons:

SECTION 9. CSB 3.06 (1) (intro.), (a), and (b), (2) and (3) are amended to read:

**CSB 3.06 Amendment. (1)** A SUA permit shall be effective only for the individual, substances, and project specified on its face and for additional projects which derive directly from the state project. An individual holding a valid SUA permit may apply for an amendment to the permit by filing a written request with the board indicating the justification for the amendment and by paying a $5 fee. The board may approve a request to amend a permit for any of the following reasons:

(a) A change to the original SUA permit holder.

(b) The addition of new individuals to the SUA permit who are participating int eh functions for which the authorization was approved.

**(2)** An application for an amendment shall be submitted to the department and approved by the board prior to a SUA permit holder operating under the terms of the amendment.

**(3)** Individuals applying for an amendment shall provide any other information or documentation requested by the board including information and documentation related to previous ~~special use authorization~~ SUA permits.

SECTION 10. CSB 3.07 (1) (intro.), (a), and (b), (2) and (3) are amended to read:

**CSB 3.07 Record-keeping; records retention; disclosure. (1)** A SUA permit holder shall maintain updated and accurate records of all of the following:

(a) The purchase of controlled substances pursuant to the SUA permit, including receipts.

(b) The disbursement, use, and disposition of all controlled substances authorized by the SUA permit.

**(2)** A SUA permit holder shall retain the records described in sub. (1) for 4 years after the expiration of the ~~special use authorization~~ SUA permit.

**(3)** A SUA permit holder shall provide copies of the original records upon request of the board or the department of safety and professional services, except for those that are protected from disclosure by s. 961.335(7), Stats.

SECTION 11. CSB 3.08 (1) (a) and (2) are amended to read:

**CSB 3.08 (1)** (a) Any deviation from the SUA permit's specifications related to controlled substances, schedules of drugs, or amounts authorized.

**(2)** Any violation of a special use authorization permit may, in the board's discretion, result in the suspension or revocation of the ~~special use authorization~~ SUA permit.

SECTION 12. CSB 3.08 (1) (f) and (g) are created to read:

**CSB 3.08 (1)** (f) Failure to obtain a drug enforcement administration registration.

(g) A violation of state or federal law relating to controlled substances.

SECTION 13. 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.

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(END OF TEXT OF RULE)

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This Proposed Order of the Controlled Substances Board is approved for submission to the Governor and Legislature.

Dated _____ _____

Chair
Controlled Substances Board

# STATEMENT OF SCOPE

## Controlled Substances Board

**Rule No.:** CSB 2.73

**Relating to:** Scheduling of Cenobamate

**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 cenobamate as a Schedule V controlled substance. The Controlled Substances Board determines the scheduling of cenobamate 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 March 10, 2020, the United States Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register placing cenobamate into Schedule V of the federal Controlled Substances Act. The scheduling action was effective March 10, 2020. The Controlled Substances Board did not receive an objection to similarly treat cenobamate as a Schedule V controlled substance under ch. 961, Stats within 30 days of the date of publication in the Federal Register of the interim final order designating cenobamate as a controlled substance.

Pursuant to s. 961.11 (4), Stats., the Controlled Substances Board took affirmative action to similarly treat cenobamate under ch. 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)*

The Affirmative Action order, dated May 8, 2020, took effect on May 18, 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 March 10, 2020, the United States Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register placing cenobamate into Schedule V of the federal Controlled Substances Act. The scheduling action was effective on March 10, 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

# STATEMENT OF SCOPE

## Controlled Substances Board

**Rule No.:** CSB 2.74

**Relating to:** Scheduling of lemborexant

**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 lemborexant as a Schedule V controlled substance. The Controlled Substances Board determines the scheduling of lemborexant 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 April 7, 2020, the United States Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register placing lemborexant into Schedule I of the federal Controlled Substances Act. The scheduling action was effective April 7, 2020. The Controlled Substances Board did not receive an objection to similarly treat lemborexant as a Schedule I controlled substance under ch. 961, Stats within 30 days of the date of publication in the Federal Register of the interim final order designating lemborexant as a controlled substance.

Pursuant to s. 961.11 (4), Stats., the Controlled Substances Board took affirmative action to similarly treat lemborexant under ch. 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 (2) (eqm) Lemborexant.*

The Affirmative Action order, dated May 8, 2020, took effect on May 18, 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 April 7, 2020, the United States Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register placing lemborexant into Schedule V of the federal Controlled Substances Act. The scheduling action was effective on April 7, 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

# STATEMENT OF SCOPE

## Controlled Substances Board

**Rule No.:** CSB 2.75

**Relating to:** Removing FDA approved cannabidiol from schedule V and excluding from Schedule I

**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 remove U.S. Food and Drug Administration approved cannabidiol from Schedule V and exclude from Schedule I.

**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 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 ∆9-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 ∆9-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.

The Department of Justice, Drug Enforcement Administration intends to issue a final rule to conform with the Agricultural Improvement Act of 2018 that would formally remove 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.

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

***CSB 2.75 Exclusion of Approved Cannabidiol Drugs from schedule I****. (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) is repealed.*

The Affirmative Action order, dated June 23, 2020, took effect on June 29, 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(4g)** Notwithstanding sub. (4), 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.

**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 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. Epidiolex is the only Federal Drug Administration approved drug product.

**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

# STATEMENT OF SCOPE

## Controlled Substances Board

**Rule No.:** CSB 2.76

**Relating to:** Scheduling of Norfentanyl

**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 norfentanyl as a Schedule II controlled substance. The Controlled Substances Board determines the scheduling of norfentanyl as a Schedule II 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 April 17, 2020, the United States 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. The scheduling action was effective May 18, 2020. The Controlled Substances Board did not receive an objection to similarly treat norfentanyl as a Schedule II controlled substance under ch. 961, Stats within 30 days of the date of publication in the Federal Register of the final order designating norfentanyl as a controlled substance.

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

***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.*

The Affirmative Action order, dated June 23, 2020, took effect on June 29, 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 April 17, 2020, the United States 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. The scheduling action was effective on May 18, 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

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

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PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.71 relating to scheduling of lasmiditan.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:** s. 961.22, 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 January 31, 2020, the 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.

**Plain language analysis:**

The Controlled Substances Board did not receive an objection to treating lasmiditan as a schedule V controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on March 13, 2020 to similarly treat lasmiditan under chapter 961 effective March 23, 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 (3), Stats. which adds lasmiditan to schedule V.

**Comparison with rules in adjacent states:**

**Illinois**: Illinois has not scheduled lasmiditan.

**Iowa**: Iowa has not scheduled lasmiditan.

**Michigan**: Michigan has not scheduled lasmiditan.

**Minnesota:** Minnesota has not scheduled lasmiditan.

**Summary of factual data and analytical methodologies:**

The methodology was to schedule lasmiditan 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 September 11, 2020 to be included in the record of rule-making proceedings.

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TEXT OF RULE

SECTION 1. CSB 2.71 is created to read:

**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]

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.

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(END OF TEXT OF RULE)

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