Wisconsin Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way
PO Box 8366
Madison WI 53708-8366

Phone: 608-266-2112
Web: http://dsps.wi.gov
Email: dsps@wisconsin.gov

Tony Evers, Governor
Dawn B. Crim, Secretary

CONTROLLED SUBSTANCES BOARD
VIRTUAL/TELECONFERENCE
Virtual, 4822 Madison Yards Way, Madison
Contact: Adam Barr (608) 266-2112
July 9, 2021

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 May 14, 2021 (4-6)

C. Reminders: Conflicts of Interests, Scheduling Concerns

D. Introductions, Announcements and Recognition

E. Administrative Matters – Discussion and Consideration
1) Department, Staff, and Board Updates
2) Board Members – Term Expiration Dates

F. Guidance Document Regarding the Designation of Gabapentin as a Monitored Prescription Drug – Discussion and Consideration (7-9)

Legislative and Policy Matters – Discussion and Consideration (10)
1) Senate Bill 49/Assembly Bill 41 (Opioid Data System) **(11-24)**
2) Senate Bill 439 (Opioid Data System)
3) Senate Bill 407/Assembly Bill 430 (Reviewing PDMP Patient Records) **(25-26)**

G. Administrative Rule Matters – Discussion and Consideration (27-28)
1) Adoption Orders
   a. CR 20-058 (CSB 2.71) – Scheduling Lasmiditan **(29-31)**
   b. CR 20-075 (CSB 2.73) – Scheduling Cenobamate **(32-34)**
   c. CR 20-076 (CSB 2.74) – Scheduling Lemborexant **(35-37)**
   d. CR 20-077 (CSB 2.75) – Scheduling Epidiolex **(38-41)**
   e. CR 20-078 (CSB 2.76) – Scheduling Norfentanyl **(42-44)**
   f. CR 20-023 (CSB 2.77) – Scheduling Flualprazolam **(45-48)**

g. CR 20-080 (CSB 4.03(2) & 4.08(4)) – Designating Gabapentin as a Monitored Drug **(49-52)**

2) Affirmative Action Orders
   a. CSB 2.83 - Scheduling 10 Fentanyl Related Substances **(53-55)**
   b. CSB 2.84 - Scheduling Alfaxalone **(56)**
   c. CSB 2.85 - Excluding 6-beta-Naltrexol from Schedule II **(57)**
   d. CSB 2.86 - Scheduling Fospropofol **(58)**
   e. CSB 2.87 - Scheduling Embutramide **(59)**
   f. CSB 2.88 – Scheduling Lacosamide **(60)**
   g. CSB 2.89 – Scheduling Perampanel **(61)**
   h. CSB 2.90 Scheduling 1-1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile **(62-63)**
3) Scope Statement – CSB 2.80 – Scheduling Oliceridine **(64-65)**
4) Update Anabolic Steroids Schedule to Align with Federal Scheduling
5) Pending and Possible Rulemaking Projects **(66-69)**
   a. Pending Rule Updates

H. Prescription Drug Monitoring Program (PDMP) Update – Discussion and Consideration (70)

1) WI ePDMP Operations
   a. Recent and Upcoming Releases **(71-72)**
   b. Status of Grant Projects
      1. FY 2020 Harold Rogers PDMP
      2. Department of Justice Overdose Fatality Review & Medical College of Wisconsin DataShare Project
   c. Interstate Data Sharing **(73)**
   d. EHR Integration Status **(74)**
2) Gabapentin Reporting **(75-77)**
3) Excluding Buprenorphine/Naloxone from Metrics Calculation
4) WI PDMP Outreach **(78)**

I. COVID-19 – Discussion and Consideration

J. Board Member Reports – Discussion and Consideration

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

K. Liaison Reports

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

M. Deliberation on Special Use Authorizations – Discussion and Consideration

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

1) Introductions, Announcements, and Recognition
2) Administrative Matters
3) Election of Officers
4) Appointment of Liaisons and Alternates

5) Delegation of Authorities
6) Informational Items
7) Division of Legal Services and Compliance (DLSC) Matters
8) Education and Examination Matters
9) Credentialing Matters
10) Practice Matters
11) Legislative and Administrative Rule Matters
12) Liaison Reports
13) Appearances from Requests Received or Renewed
14) Speaking Engagements, Travel, or Public Relations Requests, and Reports
15) Consulting with Legal Counsel

O. Public Comments

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

P. Deliberation on Special Use Authorizations – Discussion and Consideration

Q. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: SEPTEMBER 10, 2021

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

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

VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
MAY 14, 2021

PRESENT: Yvonne Bellay, Subhadeep Barman *(excused at 10:30 a.m.)*, Alan Bloom, Doug Englebert, Sandy Koresch, John Weitekamp

EXCUSED: Padmaja Doniparthi, Peter Kallio, Herbert Kaske

STAFF: Adam Barr, Executive Director; Jameson Whitney, Board Legal Counsel; Kevyn Radcliffe, Administrative Rules Coordinator; Kimberly Wood, Program Assistant Supervisor-Adv.; and other DSPS Staff

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 9:30 a.m. A quorum was confirmed with six (6) members present.

ADOPTION OF AGENDA

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

APPROVAL OF MINUTES

March 12, 2021 and April 16, 2021

MOTION: Yvonne Bellay moved, seconded by Alan Bloom, to adopt the Minutes of March 12, 2021 and April 16, 2021 as published. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Adoption Orders

CR 20-048 – Scheduling Synthetic Cannabinoids

MOTION: Subhadeep Barman moved, seconded by Yvonne Bellay, to approve the Adoption Order for Clearinghouse Rule 20-048, relating to scheduling Synthetic Cannabinoids. Motion carried unanimously.

CR 20-049 – Scheduling Brexanolone and Solriamfetol

MOTION: Subhadeep Barman moved, seconded by Sandy Koresch, to approve the Adoption Order for Clearinghouse Rule 20-049, relating to scheduling Brexanolone and Solriamfetol. Motion carried unanimously.

CR 20-050 – Scheduling Cathinones

MOTION: Alan Bloom moved, seconded by Yvonne Bellay, to approve the Adoption Order for Clearinghouse Rule 20-050, relating to scheduling Cathinones. Motion carried unanimously.

CR 20-051 – Scheduling Noroxymorphone

MOTION: Subhadeep Barman moved, seconded by Sandy Koresch, to approve the Adoption Order for Clearinghouse Rule 20-051, relating to scheduling Noroxymorphone. Motion carried unanimously.

CR 20-022 – Scheduling MMB-FUBICA AND 4F-MDMB-BIANCA

MOTION: Sandy Koresch moved, seconded by Yvonne Bellay, to approve the Adoption Order for Clearinghouse Rule 20-022, relating to scheduling MMB-FUBICA AND 4F-MDMB-BIANCA. Motion carried unanimously.

CR 20-023 – Scheduling Isotonitazene and 1P-LSD

MOTION: John Weitekamp moved, seconded by Yvonne Bellay, to approve the Adoption Order for Clearinghouse Rule 20-023, relating to scheduling Isotonitazene and 1P-LSD. Motion carried unanimously.

Scope Statement Related to Scheduling Brorphine

MOTION: Subhadeep Barman moved, seconded by John Weitekamp, to approve the Scope Statement revising CSB 2.81, relating to scheduling Brorphine, 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.

Potential Scheduling Order for Serdexmethylphenidate as a Schedule IV Controlled Substance

MOTION: Subhadeep Barman moved, seconded by Alan Bloom, to delegate authority to the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession), to approve an Affirmative Action Order listing Serdexmethylphenidate as a schedule IV controlled substance pursuant to s. 961.11 (4), Stats.; absent the receipt of an objection to doing so within 30 days of the publication of the interim final order listing Serdexmethylphenidate as a schedule IV controlled substance in the federal register. Motion carried unanimously.

PRESCRIPTION DRUG MONITORING PROGRAM (PDMP) UPDATE

Excluding Buprenorphine/Naloxone from Metrics Calculation

MOTION: Subhadeep Barman moved, seconded by John Weitekamp, to pursue funding sources to allow the execution of the Buprenorphine/Naloxone metrics calculation development project in 2021. Motion carried unanimously.

(Subhadeep Barman was excused at 10:30 a.m.)

ADJOURNMENT

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

The meeting adjourned at 10:36 a.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Jon Derenne, Attorney	June 28, 2021 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?
July 9, 2021	☒ Yes ☐ No	Guidance Document Regarding the Designation of Gabapentin as a Monitored Prescription Drug

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

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

Review and consider draft guidance document for stakeholders regarding the implications of the board's implementation of CR 20-080.

11) Authorization

Jon Derenne June 28, 2021

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.

CONTROLLED SUBSTANCES BOARD

4822 Madison Yards Way
PO Box 8366
Madison WI 53708

Email: dsps@wisconsin.gov
Voice: 608-266-2112
FAX: 608-251-3032

GUIDANCE REGARDING THE DESIGNATION OF GABAPENTIN AS A MONITORED PRESCRIPTION DRUG

Background Facts

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

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

Action Taken

In response to the facts above, the CSB has adopted Clearinghouse Rule 20-080 relating to designating Gabapentin as a prescription drug having a substantial potential for abuse, and therefore a monitored prescription drug pursuant to Wis. Stat. § 961.385 (1) (ag). Gabapentin is now listed in Wis. Admin. Code § CSB 4.03 (2) as a monitored prescription drug.

Gabapentin Has Not Been Scheduled as a Controlled Substance

Gabapentin has been designated as a monitored prescription drug, not a controlled substance. A DEA registration number is not required for a practitioner to prescribe Gabapentin, nor is a DEA registration number required for a dispenser to fill a prescription for Gabapentin.

Practical Impact for Most Prescribers and Dispensers of Gabapentin

Because Gabapentin has been designated a monitored prescription drug, a practitioner now must review a patient's prescription drug history as required by Wis. Admin. Code § CSB 4.105 prior to prescribing Gabapentin. Additionally, dispensers must report into the PDMP as required under Wis. Admin. Code § CSB 4.05 when dispensing Gabapentin.

Exemptions Where the Lack of a DEA Registration Number Causes a Dispensing Reporting Error or Prevents Practitioner Access to the PDMP

A DEA registration number is currently required information for all submissions to the PDMP. Reporting of Gabapentin without a valid prescriber or pharmacy DEA registration number will trigger a submission

error and the record will not be accepted by the PDMP. As a result, a dispenser will be excused from their duties to report Gabapentin dispensing information where one of the following is true:

- The dispenser does not have a DEA registration number.
- The dispenser is attempting to report Gabapentin dispensing data where the prescribing practitioner does not have a DEA number.

Similarly, a DEA registration number is required for a practitioner to access the PDMP system. Because of this, a practitioner who does not have a DEA registration number is exempt from the general requirement to review a patient's prescription drug history report prior to prescribing Gabapentin.

Updated instructions for revising or voiding erroneous submissions of Gabapentin dispensing with missing DEA information is available in the Data Submitter Guide.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Adam Barr, Executive Director		**2) Date when request submitted:** 7/2/21 **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: 7/9/21	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Legislative and Policy Matters – Discussion and Consideration - Senate Bill 49/Assembly Bill 41 (Opioid Data System) - Senate Bill 439 (Opioid Data System) - Senate Bill 407/Assembly Bill 430 (Reviewing PDMP Patient Records)
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes ☐ No	**9) Name of Case Advisor(s), if required:**
10) Describe the issue and action that should be addressed: Discussion of pending legislation.		
11) Authorization Adam Barr — Signature of person making this request 7/2/21 — 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
2021 - 2022 LEGISLATURE

LRB-1514/1
TJD:wlj

2021 SENATE BILL 49

January 28, 2021 - Introduced by Senators TESTIN, BERNIER, FEYEN, KOOYENGA, WANGGAARD and NASS, cosponsored by Representatives PLUMER, EDMING, DITTRICH, STEFFEN, PETRYK, KRUG, SKOWRONSKI, ROZAR, MURSAU, CABRAL-GUEVARA, WICHGERS, SANFELIPPO, PETERSEN, MAGNAFICI, MOSES, BILLINGS, SUBECK, SPIROS, RAMTHUN, JAMES, OHNSTAD, ZIMMERMAN and ARMSTRONG. Referred to Committee on Health.

AN ACT ***to create*** 20.505 (1) (bg) and subchapter III of chapter 153 [precedes 153.85] of the statutes; **relating to:** opioid and methamphetamine data system and making an appropriation.

Analysis by the Legislative Reference Bureau

This bill requires the Department of Administration to issue a request for proposals, subject to approval by the Joint Committee on Finance under its passive review process, to establish and maintain an opioid and methamphetamine data system to collect, format, analyze, and disseminate information on opioid and methamphetamine use as specified in the bill. DOA must collaborate with and collect data from the Department of Health Services, the Department of Corrections, the Department of Justice, the Department of Safety and Professional Services, and the Department of Children and Families and any other applicable agencies for the opioid and methamphetamine data system. Under the bill, DOA administers the contract with a vendor to operate the opioid and methamphetamine data system, has access to the data contained in the opioid and methamphetamine data system, and works with the vendor to disseminate information and advanced analytics from the opioid and methamphetamine data system in as close to real time as possible. The opioid and methamphetamine data system must allow the state agencies that submit data to the opioid and methamphetamine data system access to the data in the opioid and methamphetamine data system as appropriate for the agency to fulfill its functions and as allowed by state and federal confidentiality laws. The bill requires DOA to submit a report to JCF summarizing the information from the opioid

and methamphetamine data system and analyzing trends in that information across years of data collection.

For further information see the state fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 20.005 (3) (schedule) of the statutes: at the appropriate place, insert the following amounts for the purposes indicated:

				2021-22	**2022-23**
20.505 Administration, department of					
(1) SUPERVISION AND MANAGEMENT					
(bg) Opioid and methamphetamine data system	GPR	C		1,500,000	–0–

SECTION 2. 20.505 (1) (bg) of the statutes is created to read:

20.505 **(1)** (bg) *Opioid and methamphetamine data system.* As a continuing appropriation, the amounts in the schedule for implementing the data system under subch. III of ch. 153.

SECTION 3. Subchapter III of chapter 153 [precedes 153.85] of the statutes is created to read:

CHAPTER 153

SUBCHAPTER III

OPIOID AND

METHAMPHETAMINE DATA

153.85 Definition; opioid and methamphetamine data. In this subchapter, "vendor" means a person awarded the contract following a request for proposals described under s. 153.87.

153.87 Opioid and methamphetamine data system. (1) Subject to sub. (3), the department of administration shall issue a request for proposals to establish and maintain an opioid and methamphetamine data system to collect, format, analyze, and disseminate information on opioid and methamphetamine use, which shall include all of the following:

(a) Hospital discharge data from visits and stays related to opioid use or overdose.

(b) Hospital discharge data from visits and stays related to methamphetamine use or overdose.

(c) Ambulance service run data related to opioid use or overdose.

(d) The number of opioid–related overdoses in the state, the number of individuals who overdose on opioids, and the opioids on which the individuals overdose.

(e) The number of methamphetamine–related overdoses in the state, the number of individuals who overdose on methamphetamines, and the forms of methamphetamines on which the individuals overdose.

(f) Death records related to opioid use or overdose.

(g) Death records related to methamphetamine use or overdose.

(h) The number of opioid treatment centers in the state, by the owner or operator of each opioid treatment center.

(i) The number of methamphetamine treatment centers in the state, by the owner or operator of each methamphetamine treatment center.

(j) The number of providers in this state that are allowed to prescribe a drug that is a combination of buprenorphine and naloxone, the patient capacity for those prescribers, the number of patients taking such a combination drug, and the number of patients who have discontinued such a combination drug due to successful completion of a treatment program.

(k) The number of methadone clinics in the state, the number of patients taking methadone, the number of patients who more than once have been on courses of methadone, the number of patients who have discontinued methadone use due to successful completion of a treatment program, and the number of patients who are receiving methadone treatment for each of the following durations:

1. Longer than 12 months.

2. Longer than 3 years.

3. Longer than 4 years.

4. Longer than 5 years.

5. Longer than 8 years.

6. Longer than 10 years.

(L) The amount of naloxone doses dispensed, the total number of naloxone doses administered, and the number of unique patients who have received doses of naloxone.

(m) The number of adults in the state who use opioids, the extent to which those adults use opioids, and the type of opioids used.

(n) The number of adults in the state who use methamphetamines, the extent to which those adults use methamphetamines, and the forms of methamphetamines used.

(o) The number of minors in the state who use opioids, the extent to which those minors use opioids, and the type of opioids used.

(p) The number of minors in the state who use methamphetamines, the extent to which those minors use methamphetamines, and the forms of methamphetamines used.

(q) The number of minors who enter the child protective services system due to opioid use by a parent or guardian, length of time those minors are in out–of–home care, and the type of reporter who notified child protective services of the needs of the minor.

(r) The number of persons who are incarcerated and who are receiving naltrexone for extended–release in injectable suspension, the number of persons who are on extended supervision or probation or on parole and who are receiving extended–release naltrexone, the total number of doses of extended–release naltrexone administered to persons who are incarcerated, on extended supervision or probation, or on parole in this state, and the length of time that persons who are incarcerated, on extended supervision or probation, or on parole are receiving extended–release naltrexone.

(s) The number of arrests and convictions related to methadone and the number related to a drug that is a combination of buprenorphine and naloxone.

(t) The number of arrests and convictions related to methamphetamines.

(2) The opioid and methamphetamine data system under sub. (1) shall identify, to the extent possible, for sub. (1) (a), (b), (c), (d), (e), (f), (g), (j), (k), (m), (n), (o), (p), and (r) the number of individuals who have each of the following forms of health care coverage:

(a) Public health care coverage under the Medical Assistance program.

(b) Public health care coverage under Medicare, a veteran or military health plan, or another public form of coverage other than Medical Assistance, including any self–insured governmental health plan.

(c) Private insurance or a private heath plan.

(d) Self–coverage or uninsured.

(3) (a) The department of administration shall submit the proposed request for proposals described under sub. (1) to the joint committee on finance before issuing the request for proposal. If the cochairpersons of the joint committee on finance do not notify the department of administration within 14 working days after the date of the submittal of the proposed request for proposals under this paragraph that the committee has scheduled a meeting for the purpose of reviewing the proposed request for proposals, the department may issue the request for proposals. If, within 14 working days after the date of the submittal of the proposed request for proposals under this paragraph, the cochairpersons of the committee notify the department of administration that the committee has scheduled a meeting for the purpose of reviewing the proposed request for proposals, the department may issue the proposed request for proposals only upon approval by the committee.

(b) At the time the department of administration submits the proposal under par. (a), the departments of health services, children and families, corrections, justice, and safety and professional services may submit to the joint committee on finance suggestions of opioid–related or methamphetamine–related information to collect, analyze, and disseminate in addition to information specified under sub. (1) to assist the agencies in analyzing the behavioral health status of the state's population, reducing relapse of opioid and methamphetamine misuse, improving patient outcomes after opioid or methamphetamine use or overdose, assisting

minors who are in out–of–home care, and monitoring health costs related to substance use.

(4) The department of administration shall collaborate with and collect data from the departments of health services, corrections, justice, safety and professional services, and children and families and any other applicable agencies for the opioid and methamphetamine data system under sub. (1).

(5) (a) The department of administration shall administer the contract with the vendor to operate the opioid and methamphetamine data system and shall have access to the data contained in the opioid and methamphetamine data system. The department of administration shall work with the vendor to disseminate information and advanced analytics from the opioid and methamphetamine data system in as close to real time as possible.

(b) The opioid and methamphetamine data system shall allow the state agencies that submit data to the opioid and methamphetamine data system access to the data in the opioid and methamphetamine data system as appropriate for the agency to fulfill its functions and as allowed by state and federal confidentiality laws.

153.89 Reports; opioid and methamphetamine data system. By January 31, 2022, and annually thereafter, the department of administration shall submit a report to the joint committee on finance summarizing the information from the opioid and methamphetamine data system under s. 153.87 (1) and analyzing trends in that information across years of data collection.

(END)

State of Wisconsin
2021 - 2022 LEGISLATURE

LRB-1282/1
TJD:wlj

2021 ASSEMBLY BILL 41

February 10, 2021 - Introduced by Representatives PLUMER, EDMING, DITTRICH, STEFFEN, PETRYK, KRUG, SKOWRONSKI, ROZAR, MURSAU, CABRAL-GUEVARA, WICHGERS, SANFELIPPO, PETERSEN, MAGNAFICI, MOSES, BILLINGS, SUBECK, SPIROS, RAMTHUN, JAMES, OHNSTAD, ZIMMERMAN and ARMSTRONG, cosponsored by Senators TESTIN, BERNIER, FEYEN, KOOYENGA, WANGGAARD and NASS. Referred to Committee on Substance Abuse and Prevention.

AN ACT ***to create*** 20.505 (1) (bg) and subchapter III of chapter 153 [precedes 153.85] of the statutes; **relating to:** opioid and methamphetamine data system and making an appropriation.

Analysis by the Legislative Reference Bureau

This bill requires the Department of Administration to issue a request for proposals, subject to approval by the Joint Committee on Finance under its passive review process, to establish and maintain an opioid and methamphetamine data system to collect, format, analyze, and disseminate information on opioid and methamphetamine use as specified in the bill. DOA must collaborate with and collect data from the Department of Health Services, the Department of Corrections, the Department of Justice, the Department of Safety and Professional Services, and the Department of Children and Families and any other applicable agencies for the opioid and methamphetamine data system. Under the bill, DOA administers the contract with a vendor to operate the opioid and methamphetamine data system, has access to the data contained in the opioid and methamphetamine data system, and works with the vendor to disseminate information and advanced analytics from the opioid and methamphetamine data system in as close to real time as possible. The opioid and methamphetamine data system must allow the state agencies that submit data to the opioid and methamphetamine data system access to the data in the opioid and methamphetamine data system as appropriate for the agency to fulfill its functions and as allowed by state and federal confidentiality laws. The bill requires DOA to submit a report to JCF summarizing the information from the opioid

and methamphetamine data system and analyzing trends in that information across years of data collection.

For further information see the state fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 20.005 (3) (schedule) of the statutes: at the appropriate place, insert the following amounts for the purposes indicated:

				2021-22	**2022-23**
20.505 Administration, department of					
(1) SUPERVISION AND MANAGEMENT					
(bg) Opioid and methamphetamine data system	GPR	C		1,500,000	–0–

SECTION 2. 20.505 (1) (bg) of the statutes is created to read:

20.505 **(1)** (bg) *Opioid and methamphetamine data system.* As a continuing appropriation, the amounts in the schedule for implementing the data system under subch. III of ch. 153.

SECTION 3. Subchapter III of chapter 153 [precedes 153.85] of the statutes is created to read:

CHAPTER 153

SUBCHAPTER III

OPIOID AND

METHAMPHETAMINE DATA

153.85 Definition; opioid and methamphetamine data. In this subchapter, "vendor" means a person awarded the contract following a request for proposals described under s. 153.87.

153.87 Opioid and methamphetamine data system. (1) Subject to sub. (3), the department of administration shall issue a request for proposals to establish and maintain an opioid and methamphetamine data system to collect, format, analyze, and disseminate information on opioid and methamphetamine use, which shall include all of the following:

(a) Hospital discharge data from visits and stays related to opioid use or overdose.

(b) Hospital discharge data from visits and stays related to methamphetamine use or overdose.

(c) Ambulance service run data related to opioid use or overdose.

(d) The number of opioid–related overdoses in the state, the number of individuals who overdose on opioids, and the opioids on which the individuals overdose.

(e) The number of methamphetamine–related overdoses in the state, the number of individuals who overdose on methamphetamines, and the forms of methamphetamines on which the individuals overdose.

(f) Death records related to opioid use or overdose.

(g) Death records related to methamphetamine use or overdose.

(h) The number of opioid treatment centers in the state, by the owner or operator of each opioid treatment center.

(i) The number of methamphetamine treatment centers in the state, by the owner or operator of each methamphetamine treatment center.

(j) The number of providers in this state that are allowed to prescribe a drug that is a combination of buprenorphine and naloxone, the patient capacity for those prescribers, the number of patients taking such a combination drug, and the number of patients who have discontinued such a combination drug due to successful completion of a treatment program.

(k) The number of methadone clinics in the state, the number of patients taking methadone, the number of patients who more than once have been on courses of methadone, the number of patients who have discontinued methadone use due to successful completion of a treatment program, and the number of patients who are receiving methadone treatment for each of the following durations:

1. Longer than 12 months.

2. Longer than 3 years.

3. Longer than 4 years.

4. Longer than 5 years.

5. Longer than 8 years.

6. Longer than 10 years.

(L) The amount of naloxone doses dispensed, the total number of naloxone doses administered, and the number of unique patients who have received doses of naloxone.

(m) The number of adults in the state who use opioids, the extent to which those adults use opioids, and the type of opioids used.

(n) The number of adults in the state who use methamphetamines, the extent to which those adults use methamphetamines, and the forms of methamphetamines used.

(o) The number of minors in the state who use opioids, the extent to which those minors use opioids, and the type of opioids used.

(p) The number of minors in the state who use methamphetamines, the extent to which those minors use methamphetamines, and the forms of methamphetamines used.

(q) The number of minors who enter the child protective services system due to opioid use by a parent or guardian, length of time those minors are in out–of–home care, and the type of reporter who notified child protective services of the needs of the minor.

(r) The number of persons who are incarcerated and who are receiving naltrexone for extended–release in injectable suspension, the number of persons who are on extended supervision or probation or on parole and who are receiving extended–release naltrexone, the total number of doses of extended–release naltrexone administered to persons who are incarcerated, on extended supervision or probation, or on parole in this state, and the length of time that persons who are incarcerated, on extended supervision or probation, or on parole are receiving extended–release naltrexone.

(s) The number of arrests and convictions related to methadone and the number related to a drug that is a combination of buprenorphine and naloxone.

(t) The number of arrests and convictions related to methamphetamines.

(2) The opioid and methamphetamine data system under sub. (1) shall identify, to the extent possible, for sub. (1) (a), (b), (c), (d), (e), (f), (g), (j), (k), (m), (n), (o), (p), and (r) the number of individuals who have each of the following forms of health care coverage:

(a) Public health care coverage under the Medical Assistance program.

(b) Public health care coverage under Medicare, a veteran or military health plan, or another public form of coverage other than Medical Assistance, including any self–insured governmental health plan.

(c) Private insurance or a private heath plan.

(d) Self–coverage or uninsured.

(3) (a) The department of administration shall submit the proposed request for proposals described under sub. (1) to the joint committee on finance before issuing the request for proposal. If the cochairpersons of the joint committee on finance do not notify the department of administration within 14 working days after the date of the submittal of the proposed request for proposals under this paragraph that the committee has scheduled a meeting for the purpose of reviewing the proposed request for proposals, the department may issue the request for proposals. If, within 14 working days after the date of the submittal of the proposed request for proposals under this paragraph, the cochairpersons of the committee notify the department of administration that the committee has scheduled a meeting for the purpose of reviewing the proposed request for proposals, the department may issue the proposed request for proposals only upon approval by the committee.

(b) At the time the department of administration submits the proposal under par. (a), the departments of health services, children and families, corrections, justice, and safety and professional services may submit to the joint committee on finance suggestions of opioid–related or methamphetamine–related information to collect, analyze, and disseminate in addition to information specified under sub. (1) to assist the agencies in analyzing the behavioral health status of the state's population, reducing relapse of opioid and methamphetamine misuse, improving patient outcomes after opioid or methamphetamine use or overdose, assisting

minors who are in out–of–home care, and monitoring health costs related to substance use.

(4) The department of administration shall collaborate with and collect data from the departments of health services, corrections, justice, safety and professional services, and children and families and any other applicable agencies for the opioid and methamphetamine data system under sub. (1).

(5) (a) The department of administration shall administer the contract with the vendor to operate the opioid and methamphetamine data system and shall have access to the data contained in the opioid and methamphetamine data system. The department of administration shall work with the vendor to disseminate information and advanced analytics from the opioid and methamphetamine data system in as close to real time as possible.

(b) The opioid and methamphetamine data system shall allow the state agencies that submit data to the opioid and methamphetamine data system access to the data in the opioid and methamphetamine data system as appropriate for the agency to fulfill its functions and as allowed by state and federal confidentiality laws.

153.89 Reports; opioid and methamphetamine data system. By January 31, 2022, and annually thereafter, the department of administration shall submit a report to the joint committee on finance summarizing the information from the opioid and methamphetamine data system under s. 153.87 (1) and analyzing trends in that information across years of data collection.

(END)

State of Wisconsin
2021 - 2022 LEGISLATURE

LRB-1214/1
JPC:kjf

2021 SENATE BILL 407

June 10, 2021 - Introduced by Senators DARLING, COWLES and MARKLEIN, cosponsored by Representatives ZIMMERMAN, CABRAL-GUEVARA, DITTRICH, EDMING, GOYKE, BROOKS, GUNDRUM, KUGLITSCH, MOSES, MURPHY, ROZAR, SPIROS, SUBECK, TAUCHEN, WICHGERS, JAMES and TUSLER. Referred to Committee on Health.

AN ACT ***to repeal*** 961.385 (2) (cs) 2. b. of the statutes; **relating to:** reviewing patient records under the prescription drug monitoring program.

Analysis by the Legislative Reference Bureau

This bill repeals an exemption from the requirement under the prescription drug monitoring program that a prescribing practitioner review a patient's records before the practitioner issues a prescription order for a monitored prescription drug to the patient. The exemption currently allows a prescribing practitioner to issue a prescription order for a monitored prescription drug without reviewing the patient's records if the prescription order is for a number of doses that is intended to last the patient three days or less and is not subject to refill. This bill repeals that exemption but does not affect any other existing exemptions from the requirement.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 961.385 (2) (cs) 2. b. of the statutes is repealed.

(END)

State of Wisconsin
2021 - 2022 LEGISLATURE

LRB-3535/1
JPC:kjf

2021 ASSEMBLY BILL 430

July 1, 2021 - Introduced by Representatives ZIMMERMAN, BROOKS, CABRAL-GUEVARA, DITTRICH, EDMING, GOYKE, GUNDRUM, JAMES, KUGLITSCH, MOSES, MURPHY, ROZAR, SPIROS, SUBECK, TAUCHEN and WICHGERS, cosponsored by Senators DARLING, COWLES and MARKLEIN. Referred to Committee on Health.

AN ACT ***to repeal*** 961.385 (2) (cs) 2. b. of the statutes; **relating to:** reviewing patient records under the prescription drug monitoring program.

Analysis by the Legislative Reference Bureau

This bill repeals an exemption from the requirement under the prescription drug monitoring program that a prescribing practitioner review a patient's records before the practitioner issues a prescription order for a monitored prescription drug to the patient. The exemption currently allows a prescribing practitioner to issue a prescription order for a monitored prescription drug without reviewing the patient's records if the prescription order is for a number of doses that is intended to last the patient three days or less and is not subject to refill. This bill repeals that exemption but does not affect any other existing exemptions from the requirement.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 961.385 (2) (cs) 2. b. of the statutes is repealed.

(END)

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:
Kevyn Radcliffe, Administrative Rules Coordinator	June 28, 2021 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:

June 28, 2021

5) Attachments:

☒ Yes
☐ No

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

Administrative Rule Matters – Discussion and Consideration

1. Adoption Orders
   a. CR 20-058 – Scheduling Lasmiditan
   b. CR 20-075 - Scheduling Cenobamate
   c. CR 20-076 - Scheduling Lemborexant
   d. CR 20-077 - Scheduling Epidiolex
   e. CR 20-078 - Scheduling Norfentanyl
   f. CR 20-023 - Scheduling Flualprazolam
   g. CR 20-080 - Designating gabapentin as a monitored drug
2. Affirmative Action Orders
   a. CSB 2.83 - Scheduling 10 Fentanyl related substances
   b. CSB 2.84 - Scheduling Alfaxalone
   c. CSB 2.85 - Excluding 6-beta- Naltrexol from Schedule II
   d. CSB 2.86 - Scheduling Fospropofol
   e. CSB 2.87 - Scheduling Embutramide
   f. CSB 2.88 – Scheduling Lacosamide
   g. CSB 2.89 – Scheduling Perampanel
   h. CSB 2.90 Scheduling 1-1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile
3. Scope Statement – CSB 2.80
4. Update anabolic steroids schedule to align with federal scheduling - Discussion
5. Pending Rules Update
6. Pending or Possible Rulemaking Projects

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

State of Wisconsin
Department of Safety & Professional Services

10) Describe the issue and action that should be addressed

11) Authorization

Kevyn Radcliffe — June 28, 2021

Signature of person making this request **Date**

Supervisor (if required) **Date**

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

Directions for including supporting documents:

1. **This form should be attached to any documents submitted to the agenda.**
2. **Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.**
3. **If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.**

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 20-058)

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.

ANALYSIS

Statutes interpreted: s. 961.22, Stats.

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

Explanation of agency authority:

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

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

Related statute or rule: s. 961.14, Stats.

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 (8), Stats. which adds lasmiditan to schedule V.

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.

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

Comparison with rules in adjacent states:

Illinois: Illinois has not 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 as required by state statute.

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

This rule schedules a drug and does not have an effect on small business. The rule draft was published on the department website for 14 days to solicit economic impact comments from small businesses. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

Kevyn Radcliffe, 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 608-266-0797; email at DSPSAdminRules@wisconsin.gov.

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.

(END OF TEXT OF RULE)

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 20-075)

ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.22, Stats.

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

Explanation of agency authority:

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

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

Related statute or rule: s. 961.22, Stats.

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.

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.

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

Comparison with rules in adjacent states:

Illinois: Illinois has not 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 report:

This rule schedules a drug and does not have an effect on small business. The rule draft was published on the department website for 14 days to solicit economic impact comments from small businesses. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

Kevyn Radcliffe, 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 608-266-0797; email at DSPSAdminRules@wisconsin.gov.

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)

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 20-076)

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

Explanation of agency authority:

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

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

Related statute or rule: s. 961.14, Stats.

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.

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.

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

Comparison with rules in adjacent states:

Illinois: Illinois has not 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 report:

This rule schedules a drug and does not have an effect on small business. The rule draft was published on the department website for 14 days to solicit economic impact comments from small businesses. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

Kevyn Radcliffe, 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 608-266-0797; email at DSPSAdminRules@wisconsin.gov.

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)

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 20-077)

ORDER

An order of the Controlled Substances Board to create CSB 2.75, relating to removing FDA approved cannabidiol from schedule V and excluding FDA approved cannabidiol from schedule I.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 961.14 and 961.22, Stats.

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

Explanation of agency authority:

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

If 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 (4g), Stats.]

Related statute or rule: s. 961.14, Stats.

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.

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.

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

Comparison with rules in adjacent states:

Illinois: Illinois 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 in schedule V and to exempt it from reverting into schedule I in light of the DEA's recent treatment of this drug.

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

This rule schedules a drug and does not have an effect on small business. The rule draft was published on the department website for 14 days to solicit economic impact comments from small businesses. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

Kevyn Radcliffe, 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 608-266-0797; email at DSPSAdminRules@wisconsin.gov.

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)

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 20-078)

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

Explanation of agency authority:

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

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

Related statute or rule: s. 961.14, Stats.

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.

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.

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

Comparison with rules in adjacent states:

Illinois: Illinois has not 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 report:

This rule schedules a drug and does not have an effect on small business. The rule draft was published on the department website for 14 days to solicit economic impact comments from small businesses. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

Kevyn Radcliffe, 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 608-266-0797; email at DSPSAdminRules@wisconsin.gov.

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)

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 20-079)

ORDER

An order of the Controlled Substances Board to create CSB 2.77 relating to scheduling of flualprazolam.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

Statutory authority: ss. 961.11 (1), (1m), (1r), and (2) and (4m), and 961.19 (2m), 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.]

In making a determination regarding a substance, the board shall consider the following:

(a) The actual or relative potential for abuse.
(b) The scientific evidence of its pharmacological effect, if known.
(c) The state of current scientific knowledge regarding the substance.
(d) The history and current pattern of abuse.
(e) The scope, duration and significance of abuse.
(f) The risk to the public health.
(g) The potential of the substance to produce psychological or physical dependence liability.
(h) Whether the substance is an immediate precursor of a substance already controlled under this chapter.

The controlled substances board may consider findings of the federal food and drug administration or the drug enforcement administration as prima facie evidence relating to one or more of the determinative factors.
After considering the factors, the controlled substances board shall make findings with respect to them and promulgate a rule controlling the substance upon finding that the substance has a potential for abuse. [s. 961.11 (1m), (1r), and (2), Stats.]

The controlled substances board may add a substance to schedule IV without making the finding required under sub. (1m) if the substance is controlled under schedule IV of 21 USC 812 (c) by a federal agency as the result of an international treaty, convention or protocol. [s. 961.19 (2m), Stats.]

Related statute or rule: s. 961.20, Stats.

Plain language analysis:

This rule schedules flualprazolam as a Schedule IV controlled substance.

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

Flualprazolam is not currently scheduled under the Controlled Substances Act.

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

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled flualprazolam as a controlled substance.

Iowa: Iowa has not scheduled flualprazolam as a controlled substance.

Michigan: Michigan has not scheduled flualprazolam as a controlled substance.

Minnesota: Minnesota has not scheduled flualprazolam as a controlled substance.

Summary of factual data and analytical methodologies:

Flualprazolam is an analog of alprazolam (an FDA approved schedule IV controlled substance), differing in chemical composition by the presence of a fluorine atom. Flualprazolam is a benzodiazepine synthesized and patented in 1970s for research purposes but was never marketed as a medicine. Flualprazolam is not used clinically.

The onset of action due to flualprazolam is reported to be 10-20 minutes after oral use with a duration of action of 6-14 hours. Flualprazolam depresses the central nervous system resulting in sedation, reduced anxiety, and loss of consciousness. Flualprazolam is similar to alprazolam which has demonstrably greater abuse liability compared to diazepam, especially for those with a personal or family substance use disorder history.

The World Health Organization released a critical review report on flualprazolam in October 2019. On March 4, 2020, the United Nations Commission on Narcotic Drugs placed flualprazolam under international control as a Schedule IV. Delaware added several

benzodiazepines, including flualprazolam, to Schedule IV due to the serious potential for abuse. Flualprazolam is on several states' law enforcement watchlists or alerts.

In 2019 and 2020, there has been an increased prevalence of flualprazolam in the United States. Law enforcement officers and medical examiners have provided information to the Controlled Substances Board indicating this substance is implicated in Wisconsin overdose cases, including those resulting in death. Alprazolam is not a schedule I controlled substance, therefore, a prosecution involving flualprazolam can't be commenced under Wisconsin's analog law (s. 961.25, Stats).

Public health concerns are similar to other benzodiazepines which are higher potency with a relatively fast time of onset. When flualprazolam is combined with opioids, this contributes to increased overdose through benzodiazepine-potentiated opioid-induced respiratory depression. In addition, flualprazolam causes disinhibition and sedation that impair driving. There have been reports of intentionally counterfeit alprazolam product containing flualprazolam entering the drug supply chain in other states.

Flualprazolam has a fast onset of action and similarities to alprazolam and has a relatively high dependence liability.

The Controlled Substances Board considered the following factors in making the determination to add flualprazolam to the controlled substance schedules in ch. 961, Stats.:

- The actual or relative potential for abuse.
- The scientific evidence of its pharmacological effect.
- The state of current scientific knowledge regarding the substance.
- The history and current pattern of abuse.
- The scope, duration and significance of abuse.
- The risk to the public health.
- The potential of the substance to produce psychological or physical dependence liability.
- Whether the substance is an immediate precursor of a substance already controlled under ch. 961, Stats.

The Controlled Substances Board makes a finding that flualprazolam has a potential for abuse.

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

The rule draft was posted on the department's website for 14 days to solicit economic impact comments from small businesses. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

Kevyn Radcliffe, 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 608-266-0797; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.77 is created to read:

CSB 2.77 Scheduling of flualprazolam. Section 961.20 (2) (ef), Stats., is created to read:

961.20 (2) (ef) flualprazolam.

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

(END OF TEXT OF RULE)

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 20-080)

ORDER

An order of the Controlled Substances Board to create CSB 4.03 (2) and 4.08 (4) relating to designating Gabapentin as a monitored drug having a substantial potential for abuse.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961. 385 (1), Stats.

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

Explanation of agency authority:

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

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

Related statute or rule: s. 961.385, Stats.

Plain language analysis:

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

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

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

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

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

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

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

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

Comparison with rules in adjacent states:

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

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

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

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

Summary of factual data and analytical methodologies:

The Prescription Drug Monitoring Program received inquiries from prescribers and law enforcement about the inclusion of gabapentin as a monitored drug. The Controlled Substances

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

The Prescription Drug Monitoring Program received inquiries from prescribers and law enforcement about the inclusion of gabapentin as a monitored drug. The Controlled Substances Board received information from those testifying at several law enforcement hearings held pursuant to 2017 Executive Order 228 and the Milwaukee Medical Examininers Office regarding the increase of the presence of gabapentin in overdose cases. The Controlled Substances Board reviewed research of the affects of gabapentin. In addition, the Controlled Substances Board took notice of the actions of several sptates, including our surrounding states, to either schedule gabapentin as a controlled substance or to designate it as a monitored drug in the prescription monitoring programs.

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

The rule draft was posted on the department's website for 14 days to solicit economic impact comments from small businesses. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

Kevyn Radcliffe, 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 608-266-0797; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

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

CSB 4.03 (2) Gabapentin.

SECTION 2. CSB 4.08 (4) is created to read:

CSB 4.08 (4) A dispenser who is not otherwise required to have a DEA registration number is not required to compile or submit dispensing data when dispensing Gabapentin.

SECTION 3. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On April 27, 2021, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing the following Fentanyl-related substances into schedule I of the federal Controlled Substances Act. The scheduling action is effective immediately.

- *N*-(1-(2-fluorophenethyl)piperidin-4-yl)-*N*-(2-fluorophenyl)propionamide (2'-fluoro *ortho*-fluorofentanyl; 2'-fluoro 2-fluorofentanyl);
- *N*-(1-(4-methylphenethyl)piperidin-4-yl)-*N*-phenylacetamide (4'-methyl acetyl fentanyl);
- *N*-(1-phenethylpiperidin-4-yl)-*N*,3-diphenylpropanamide (β'-phenyl fentanyl; *beta'*-Phenyl fentanyl; 3-phenylpropanoyl fentanyl);
- *N*-phenyl-*N*-(1-(2-phenylpropyl)piperidin-4-yl)propionamide (β-methyl fentanyl);
- *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide (*ortho*-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl);
- *N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl acetylfentanyl; 2-methyl acetylfentanyl);
- 2-methoxy-*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl);
- *N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide (*para*-methylfentanyl; 4-methylfentanyl);
- *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbenzamide (phenyl fentanyl; benzoyl fentanyl); and
- *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide (thiofuranyl fentanyl; 2-thiofuranyl fentanyl; thiophene fentanyl).

2. The Controlled Substances Board did not receive an objection to similarly treating the ten (10) Fentanyl-related substances listed in schedule I under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating the ten (10) Fentanyl-related substances listed above as controlled substances.

3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.13 and omitting the notice of proposed rulemaking, designating the ten (10) Fentanyl-related substances listed above as a schedule I controlled substances.

ORDER

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats the following ten (10) Fentanyl-related substances under chapter 961, Stats. by creating the following:

- *N*-(1-(2-fluorophenethyl)piperidin-4-yl)-*N*-(2-fluorophenyl)propionamide (2'-fluoro *ortho*-fluorofentanyl; 2'-fluoro 2-fluorofentanyl);
- *N*-(1-(4-methylphenethyl)piperidin-4-yl)-*N*-phenylacetamide (4'-methyl acetyl fentanyl);
- *N*-(1-phenethylpiperidin-4-yl)-*N*,3-diphenylpropanamide (β'-phenyl fentanyl; *beta'*-Phenyl fentanyl; 3-phenylpropanoyl fentanyl);
- *N*-phenyl-*N*-(1-(2-phenylpropyl)piperidin-4-yl)propionamide (β-methyl fentanyl);
- *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide (*ortho*-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl);
- *N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl acetylfentanyl; 2-methyl acetylfentanyl);
- 2-methoxy-*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl);
- *N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide (*para*-methylfentanyl; 4-methylfentanyl);
- *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbenzamide (phenyl fentanyl; benzoyl fentanyl); and
- *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide (thiofuranyl fentanyl; 2-thiofuranyl fentanyl; thiophene fentanyl).

CSB 2.83 Addition of ten (10) Fentanyl-related substances to schedule I. Section 961.14 (2) (nd) 21., 22., 23., 24., 25., 26., 27., 28., 29., and 30., Stats., is created to read:

961.14 (2) (nd)

21. *N*-(1-(2-fluorophenethyl)piperidin-4-yl)-*N*-(2-fluorophenyl)propionamide (2'-fluoro *ortho*-fluorofentanyl; 2'-fluoro 2-fluorofentanyl);
22. *N*-(1-(4-methylphenethyl)piperidin-4-yl)-*N*-phenylacetamide (4'-methyl acetyl fentanyl);
23. *N*-(1-phenethylpiperidin-4-yl)-*N*,3-diphenylpropanamide (β'-phenyl fentanyl; *beta'*-Phenyl fentanyl; 3-phenylpropanoyl fentanyl);
24. *N*-phenyl-*N*-(1-(2-phenylpropyl)piperidin-4-yl)propionamide (β-methyl fentanyl);
25. *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide (*ortho*-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl);
26. *N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl acetylfentanyl; 2-methyl acetylfentanyl);
27. 2-methoxy-*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl);

28. *N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide (*para*-methylfentanyl; 4-methylfentanyl);
29. *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbenzamide (phenyl fentanyl; benzoyl fentanyl); and
30. *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide (thiofuranyl fentanyl; 2-thiofuranyl fentanyl; thiophene fentanyl).

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

Dated _____

_____
Doug Englebert, Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On February 27, 2014, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Alfaxalone into schedule IV of the federal Controlled Substances Act. The scheduling action is effective March 31, 2014.

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

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

ORDER

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

CSB 2.84 Addition of Alfaxalone to schedule IV. Section 961.20 (2) (a), Stat., is repealed and recreated to read:

961.20 (2) (a) Alfaxalone.

Section 961.20 (2) (ak) is created to read:

961.20 (2) (ak) Alprazolam

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

Dated _____

_____
Doug Englebert, Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On January 24, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing 6-beta-Naltrexol from schedule II of the federal Controlled Substances Act. The scheduling action is effective January 24, 2020.

2. The Controlled Substances Board did not receive an objection to similarly removing 6-beta-Naltrexol 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 removing 6-beta-Naltrexol as a schedule II controlled substance.

3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.15 and omitting the notice of proposed rulemaking, removing 6-beta-Naltrexol as a schedule II controlled substance and excluding 6-beta-Naltrexol as a schedule II controlled substance pursuant to s. 961.16 (2) (a).

ORDER

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats 6-beta-Naltrexol under chapter 961, Stats. by creating the following:

CSB 2.85 Excluding 6-beta-Naltrexol from schedule II. Section 961.16 (2) (a), Stats., is amended to read:

961.16 (2) (a) Opium and substances derived from opium, and any salt, compound, derivative or preparation of opium or substances derived from opium. Apomorphine, dextrorphan, nalbuphine, butorphanol, naldemedine, nalmefene, naloxegol, naloxone, 6-beta-naltrexol and naltrexone and their respective salts and the isoquinoline alkaloids of opium and their respective salts are excluded from this paragraph. The following substances, and any of their salts, isomers and salts of isomers that are theoretically possible within the specific chemical designation, are included in this paragraph:

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

Dated _____ _____

Doug Englebert, Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On October 6, 2009, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Fospropofol into schedule IV of the federal Controlled Substances Act. The scheduling action is effective November 5, 2009.

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

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

ORDER

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

CSB 2.86 Addition of Fospropofol to schedule IV. Section 961.20 (2) (en), Stats., is created to read:

961.20 (2) (en) Fospropofol.

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

Dated _____

_____
Doug Englebert, Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On August 29, 2006, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Embutramide into schedule III of the federal Controlled Substances Act. The scheduling action is effective September 28, 2006.

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

3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.17 and omitting the notice of proposed rulemaking, listing Embutramide as a schedule III controlled substance.

ORDER

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

CSB 2.87 Addition of Embutramide to schedule III. Section 961.18 (3) (bm), Stats., is created to read:

961.18 (3) (bm) Embutramide.

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

Dated _____

_____
Doug Englebert, Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On May 21, 2009, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Lacosamide into schedule V of the federal Controlled Substances Act. The scheduling action is effective June 22, 2009.

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

3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.21 and omitting the notice of proposed rulemaking, listing Lacosamide as a schedule V controlled substance.

ORDER

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

CSB 2.88 Addition of Lacosamide to schedule V. Section 961.22 (10), Stats., is created to read:

961.22 (10) Lacosamide.

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

Dated _____

_____
Doug Englebert, Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On December 2, 2013, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Perampanel into schedule III of the federal Controlled Substances Act. The scheduling action is effective January 2, 2014.

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

3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.17 and omitting the notice of proposed rulemaking, listing Perampanel as a schedule III controlled substance.

ORDER

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

CSB 2.89 Addition of Perampanel to schedule III. Section 961.18 (3) (fm), Stats., is created to read:

961.18 (3) (fm) Perampanel.

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

Dated _____

_____
Doug Englebert, Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On May 17, 1978, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, into schedule II of the federal Controlled Substances Act. The scheduling action was effective June 16, 1978.

2. The Controlled Substances Board did not receive an objection to similarly listing 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, as schedule II controlled substances under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order listing 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, as a schedule II controlled substances.

3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.15 and omitting the notice of proposed rulemaking, transferring 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, from schedule I to schedule II controlled substances.

ORDER

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, under chapter 961, Stats. by repealing s. 961.14 (6) and creating the following:

CSB 2.90 Transfer of 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, immediate precursors to phencyclidine, also known as PCP, from Schedule I to schedule II. Section 961.16 (8) (c), Stats. is created to read:

961.16 (8) (c) Immediate precursors to phencyclidine, also known as PCP:
1. 1-phenylcyclohexylamine.
2. 1-piperidinocyclohexanecarbonitrile.

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

Dated _____

_____
Doug Englebert, Chair
Controlled Substances Board

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 2.80

Relating to: Scheduling oliceridine

Rule Type: Permanent

1. Finding/nature of emergency:

N/A

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

The objective of the proposed rule is to schedule oliceridine as a schedule II controlled substance under s. 961.11 (4), Stats.

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 October 30, 2020, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing oliceridine into schedule II of the federal Controlled Substances Act. The scheduling action was effective October 30, 2020.

The Controlled Substances Board did not receive an objection to similarly treat oliceridine 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 oliceridine as a controlled substance.

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

961.16 (3) (ta) Oliceridine.

The Affirmative Action order, dated December 7, 2020, took effect on December 14, 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:

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

Section 961.11(4), Stats. provides that "[i]f a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30−day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate,

without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2)."

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

Approximately 80 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 October 30, 2020, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing oliceridine into schedule II of the federal Controlled Substances Act. The scheduling action was effective October 30, 2020.

8. Anticipated economic impact of implementing the rule:

None to minimal.

Contact Person: Jon Derenne, Administrative Rules Coordinator, (608) 266-0955, DSPSAdminRules@wisconsin.gov

Approved for Publication:

_____

Chairperson

_____

Date Submitted

Effective Rules	Eff. Date
CSB 2.66 - Scheduling synthetic cannabinoids; Schedules 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 (SS 108-19; CR 20-048)	7/1/2021
CSB 2.67 - Scheduling Brexanolone and Solriamfetol (SS 12-20; CR 20-49)	7/1/2021
CSB 2.68 - Schedules N-Ethylehexedrone, a-PHP, 4-MEAP, MPHP, PV8 and 4-chloro-a-PVP (SS 011-20; CR 20-050)	7/1/2021
CSB 2.69 - Scheduling Noroxymorphone (SS 010-20; CR 20-051)	7/1/2021
CSB 2.70 - 4F-MDMB_BINACA and MMB_FUBICA (SS 047-20; CR 20-022)	6/1/2021
CSB 2.70 - 4F-MDMB_BINACA and MMB_FUBICA EmR 2017	expired 6/25/2021
CSB 2.72 - Scheduling Isotonitazene and 1P-LSD (SS 034-20; CR 20-023)	6/1/2021
CSB 2.72 - Scheduling Isotonitazene and 1P-LSD EmR 2013	expired 6/4/2021

Adoption Orders
CSB 2.71 - Scheduling Lasmiditan (SS 076-20; CR 20-058)
CSB 2.73 - Scheduling Cenobamate (SS 123-20; CR 20-075)
CSB 2.74 - Scheduling Lemborexant (SS 122-20; CR 20-076)
CSB 2.75 - Removes Epidiolex from the controlled substance schedules (SS 121-20; CR 20-077)
CSB 2.76 Scheduling Norfentanyl (SS 120-20; CR 20-078)
CSB 2.77 - Scheduling Flualprazolam (SS 126-20; CR 20-079 and EmR 2027)
CSB 4 - Designating gabapentin as a monitored drug (SS 111-19; CR 20-080)

Pending Rules			
Rule	**Source of CSB Action**	**Status**	**Next Step**
CSB 2.78 - Scheduling Crotonyl Fentanyl		6/21 Submitted to GORC on 06/21	Delegation to chair to approve Scope for implementation and to schedule a preliminary hearing
CSB 2.79 - Scheduling Remimazolam		6/21 Submitted to GORC	Delegation to chair to approve Scope for implementation and to schedule a preliminary hearing
CSB 2.80 - Scheduling Oliceridine		6/21 Submitted for publication and notice to JCRAR 7/9 present Scope to CSB for implementation	Draft rule
CSB 2.81 – Scheduling Brorphine	DEA March 1, 2021	6/21 Submitted to GORC	Send for publication
CSB 2.82 Scheduling Serdexmethylphenidate	DEA May 7, 2021		9/10 Present Scope to CSB
CSB 2.83 Scheduling 10 Fentanyl related substances	DEA May 4, 2021	7/9 Present Affirmative Action to CSB for Approval	9/10 Present Scope to CSB
CSB 2.84 – Scheduling Alfaxalone	227 report 79 FR 10985	7/9 Present Affirmative Action to CSB for Approval	9/10 Present Scope to CSB

CSB 2.85 Excluding 6-beta- Naltrexol from Schedule II	227 Report 85 FR 4215; removed as a controlled substance eff. 1/24/2020	7/9 Present Affirmative Action to CSB for Approval	9/10 Present Scope to CSB
CSB 2.86 – Scheduling Fospropofol	227 Report 74 FR 51234	7/9 Present Affirmative Action to CSB for Approval	9/10 Present Scope to CSB
CSB 2.87 – Scheduling Embutramide	227 report 71 FR 51115	7/9 Present Affirmative Action to CSB for Approval	9/10 Present Scope to CSB
CSB 2.88 – Scheduling Lacosamide	227 report 74 FR 23789	7/9 Present Affirmative Action to CSB for Approval	9/10 Present Scope to CSB
CSB 2.89 – Scheduling Perampanel	227 report 78 FR 72013	7/9 Present Affirmative Action to CSB for Approval	9/10 Present Scope to CSB
CSB 2.90 Scheduling 1-1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile	227 Report 43 FR 21324	7/9 Present Affirmative Action to CSB for Approval	9/10 Present Scope to CSB
227 Report Notes			
CSB 4.02 (8) (a)	The note attached to CSB 4.02 (8) (a) references Phar 7.095 which has been removed from the code.		LRB removed obsolete reference

s. 961.18 (7) 70 FR 74653 56 FR 5753	227 report Action will be taken to review and update s. 961.18 (7), Stats. to align with federal scheduling treatment of anabolic steriods.		Placed on 7/9 Agenda for Board discussion

Miscellaneous: Sandy Koresch reported a typographical error under s. 961.14 (4)(tb) 45, Stats. The Administrative Rule Coordinator contacted the Legislative Reference Bureau who corrected the error in both the Administrtive Code and the Statute for publication at the end of June.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Marjorie Liu Program Lead, PDMP	2) Date when request submitted: 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?
07/09/2021	☒ Yes ☐ No	Prescription Drug Monitoring Program (PDMP) Updates – Discussion and Consideration

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

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

1. WI ePDMP Operations
    a. Recent and Upcoming Releases
    b. Status of Grant Projects:
        i. FY 2020 Harold Rogers Prescription Drug Monitoring Program
        ii. DOJ Overdose Fatality Review & Medical College of Wisconsin DataShare Project
    c. Interstate Data Sharing
    d. EHR Integration Status
2. Gabapentin Reporting
3. Excluding Buprenorphine/Naloxone from Metrics Calculation
4. WI ePDMP Outreach

11) Authorization

Marjorie Liu — 06/30/2021

Signature of person making this request — Date

Supervisor (if required) — Date

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

Directions for including supporting documents:

1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

2019-2021 Development and Release Summary

Updated 6.28.2021

Release Date	Description
Pending	
HRG 2020 Component 1 **Release date TBD**	Security Enhancements • Multi-Factor Authentication • Vulnerable Password Check Law enforcement alerts and other usability enhancements
R22 **July 2021**	Pharmacy-Related Enhancements • **Missing DEA Number Error Process Updates** Administrative-Related Fixes
Completed	
R21 **May 2021**	New Design Enhancements • Proactive MC/HCP linkage renewals • Search enhancements Administrative-Related Enhancements Additional administrator tools
R20 **March 2021**	WI DOJ-Medical College of Wisconsin DataShare Project • Automatically send data extracts to DOJ-MCW • Automatically receive data extracts from DOJ-MCW Administrative-Related Enhancements • Additional improvements to query process • Additional administrator tools
R19 **September 2020**	New Design Enhancements • Enhanced MME calculation process • Ability to set map display defaults Administrative-Related Enhancements • Improvements to query approval process Search Engine Optimization Updates to non-user facing parts of the PDMP to optimize search engine results
R18 **July 2020**	New Design Enhancements • Updated layout and design of Patient Report including alerts and dispensing details, based on user feedback • Opioid naïve alert 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

Interstate Data Sharing

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

WI ePDMP Integration Services Summary

Current as of 6.28.2021

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

WI ePDMP Gabapentin Message Language & Mockups

Website Banner

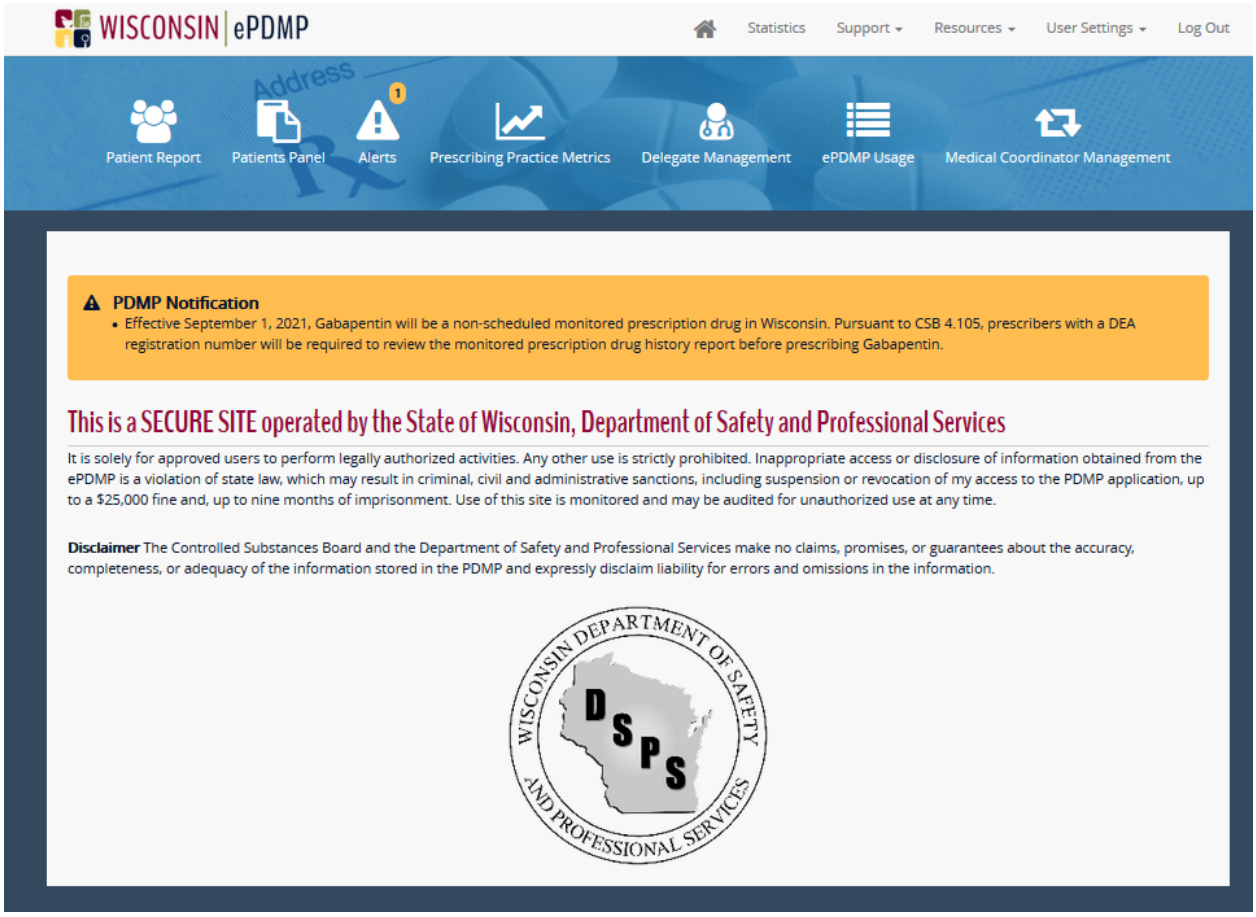
Healthcare Professional, Delegate, and Medical Coordinator account users

Pre-implementation:

Effective September 1, 2021, Gabapentin will be a non-scheduled monitored prescription drug in Wisconsin. Pursuant to CSB 4.105, prescribers with a DEA registration number will be required to review the monitored prescription drug history report before prescribing Gabapentin.

Post-implementation:

As of September 1, 2021, Gabapentin is a non-scheduled monitored prescription drug in Wisconsin. Pursuant to CSB 4.105, prescribers with a DEA registration number will be required to review the monitored prescription drug history report before prescribing Gabapentin.

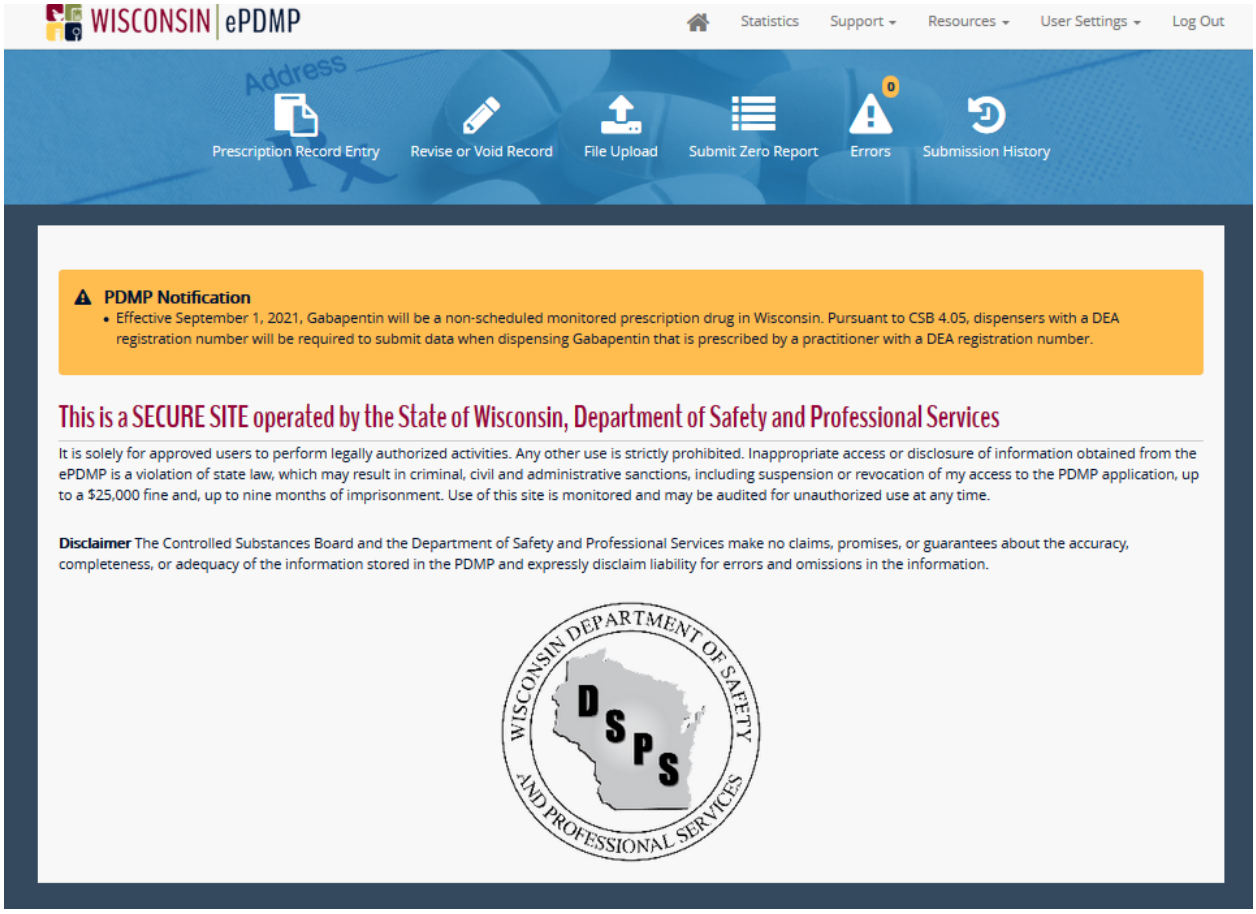


Pre-implementation:

Effective September 1, 2021, Gabapentin will be a non-scheduled monitored prescription drug in Wisconsin. Pursuant to CSB 4.05, dispensers with a DEA registration number will be required to submit data when dispensing Gabapentin that is prescribed by a practitioner with a DEA registration number.

Post-implementation:

As of September 1, 2021, Gabapentin is a non-scheduled monitored prescription drug in Wisconsin. Pursuant to CSB 4.05, dispensers with a DEA registration number will be required to submit data when dispensing Gabapentin that is prescribed by a practitioner with a DEA registration number.



Submission Error Email

Pharmacy, Submitter, and Dispensing Practitioner account users

Pre-implementation:

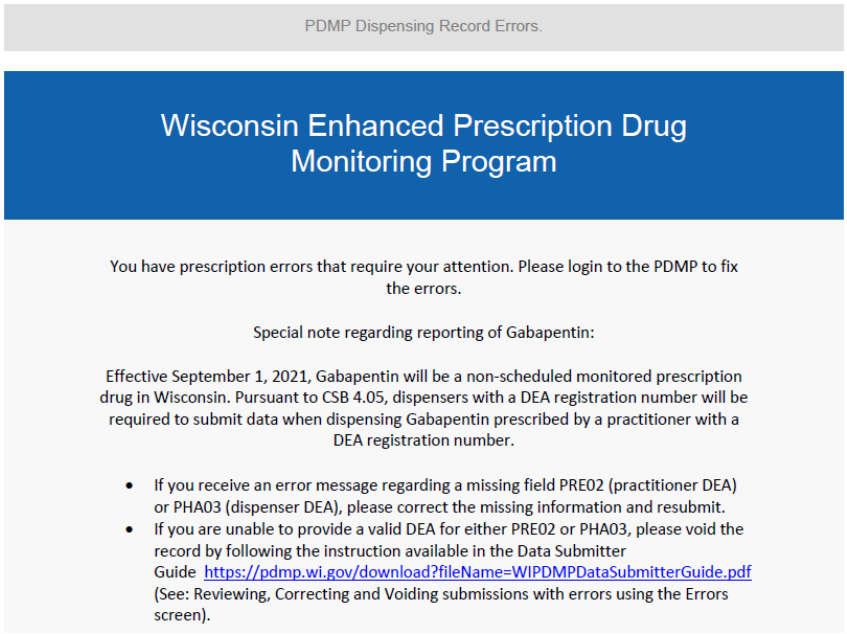
Effective September 1, 2021, Gabapentin will be a non-scheduled monitored prescription drug in Wisconsin. Pursuant to CSB 4.05, dispensers with a DEA registration number will be required to submit data when dispensing Gabapentin that is prescribed by a practitioner with a DEA registration number.

- If you receive an error message regarding a missing field PRE02 (practitioner DEA) or PHA03 (dispenser DEA), please correct the missing information and resubmit.
- If you are unable to provide a valid DEA for either PRE02 or PHA03, please void the record by following the instruction available in the Data Submitter Guide [link] (See: Reviewing, Correcting and Voiding submissions with errors using the Errors screen).

Post-implementation:

As of September 1, 2021, Gabapentin is a non-scheduled monitored prescription drug in Wisconsin. Pursuant to CSB 4.05, dispensers with a DEA registration number will be required to submit data when dispensing Gabapentin that is prescribed by a practitioner with a DEA registration number.

- If you receive an error message regarding a missing field PRE02 (practitioner DEA) or PHA03 (dispenser DEA), please correct the missing information and resubmit.
- If you are unable to provide a valid DEA for either PRE02 or PHA03, please void the record by following the instruction available in the Data Submitter Guide [link] (See: Reviewing, Correcting and Voiding submissions with errors using the Errors screen).



2021 WI PDMP Outreach Calendar

MONTH	EVENT	DESCRIPTION	DATES	NOTES
January				
February				
March				
April	Rx Drug Abuse & Heroin Summit	Panelist, PDMP & Patient Privacy	4/6/2021	Virtual Conference
	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative	4/29/2021	Quarterly Meeting. Inter-agency advisory group for OFR local sites.
May	Law Enforcement Outreach	Self-Paced PDMP Training -- Lake Delton & Fox Point Police Department		Voice-over & Animated Power Point Slides
June	PDMP Roundtable	Advocate Aurora (Kenosha)	6/9/2021	
July	North Region PDMP Webinar	Annual TTAC/BJA Regional Conference for 12 PDMPs located in the PDMP TTAC North region	7/1/2021	Virtual
	Law Enforcement PDMP participation promotion initiative	Collaborative Initiative between DSPS, DOJ & North Central HIDTA	7/8/2021	Monthly Meeting
August				
September	2021 COSSAP National Forum	Comprehensive Opioid, Stiumlant, and Substance Abuse Program (COSSAP) Annual Conference	9/28-9/30/2021	Virtual conference. Required Participations for BJA Grantees
October				
November				
December				