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

VIRTUAL/TELECONFERENCE CONTROLLED SUBSTANCES BOARD

Virtual, 4822 Madison Yards Way, Madison Contact: Adam Barr (608) 266-2112 May 13, 2022

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. OR IMMEDIATELY FOLLOWING THE REFERRAL CRITERIA WORK GROUP MEETING

OPEN SESSION - CALL TO ORDER - ROLL CALL

- A. Adoption of Agenda (1-3)
- B. Approval of Minutes March 11, 2022 (4-5)
- 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
 - a. Alton, Troy
 - b. Barman, Subhadeep -5/1/2019
 - c. Bellay, Yvonne
 - d. Bloom, Alan -5/1/2020
 - e. Englebert, Doug
 - f. Ferguson, Kris
 - g. Koresch, Sandy
 - h. Weitekamp, John
 - 3) Alternate Members
 - a. Rosemary Dolatowski
 - b. Herbert Kaske
 - c. Michael Parish
 - d. Emily Zentz

F. Administrative Rule Matters – Discussion and Consideration

- 1) Preliminary Rule Draft CSB 2.91, Relating to Scheduling 4,4 Dimethylaminorex **(6-9)**
- 2) Pending and Possible Rulemaking Projects (10-11)

- G. Legislature Agenda Request: Status of Kratom Discussion and Consideration (12-14) (22-24)
- H. Planning for the 2022 Annual Law Enforcement Hearing Discussion and Consideration
- I. Prescription Drug Monitoring Program (PDMP) Update Discussion and Consideration (15)
 - 1) WI ePDMP Operations
 - a. CSB 2022 Q1 Report
 - b. Recent and Upcoming Releases (16-18)
 - c. Status of Grant Projects:
 - 1. FY 2020 Harold Rogers Prescription Drug Monitoring Program
 - 2. FY 2021 Harold Rogers Prescription Drug Monitoring Program
 - 3. Buprenorphine Exclusion Project
 - d. Interstate Data Sharing (19-20)
 - e. EHR Integration Status
 - 2) WI ePDMP Outreach (21)

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. COVID-19 Discussion and Consideration
- **N.** Deliberation on Special Use Authorizations Discussion and Consideration
- **O.** 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

P. 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.).

- **Q.** Deliberation on Special Use Authorizations Discussion and Consideration
- **R.** Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

- **S.** Vote on Items Considered or Deliberated Upon in Closed Session if Voting is Appropriate
- **T.** Open Session Items Noticed Above Not Completed in the Initial Open Session

ADJOURNMENT

NEXT MEETING: JULY 15, 2022

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

VIRTUAL/TELECONFERENCE CONTROLLED SUBSTANCES BOARD MEETING MINUTES MARCH 11, 2022

PRESENT: Troy Alton, Subhadeep Barman, Yvonne Bellay, Alan Bloom, Doug Englebert, Peter

Kallio, Sandy Koresch, Michael Parish, John Weitekamp

EXCUSED: Kris Ferguson

STAFF: Tom Ryan, Acting Executive Director; Jameson Whitney, Legal Counsel; Nilajah

Hardin, Administrative Rules Coordinator; Katlin Schwartz, Bureau Assistant; Kimberly Wood, Program Assistant Supervisor-Adv.; and other DSPS Staff

Michael Parish served as the Medical Examining Board Representative at this meeting.

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 9:34 a.m. A quorum was confirmed with nine (9) members present.

ADOPTION OF AGENDA

MOTION: Alan Bloom moved, seconded by Yvonne Bellay, to adopt the Agenda as

published. Motion carried unanimously.

APPROVAL OF MINUTES OF JANUARY 14, 2022

MOTION: Michael Parish moved, seconded by Sandy Koresch, to adopt the Minutes of

January 14, 2022 as published. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Final Rule Draft and Legislative Report

MOTION: Subhadeep Barman moved, seconded by Peter Kallio, to approve the Legislative Report and Draft for the following rules:

- Clearinghouse Rule 22-011 (CSB 2.78), relating to Scheduling Crotonyl Fentanyl,
- Clearinghouse Rule 22-014 (CSB 2.79), relating to Scheduling Remimazolam,
- Clearinghouse Rule 22-016 (CSB 2.81), relating to Scheduling Brorphine,

for submission to the Governor's Office and Legislature. Motion carried unanimously.

Preliminary Rule Draft

MOTION: Subhadeep Barman moved, seconded by John Weitekamp, to approve the following preliminary rule drafts:

- CSB 2.82, Relating to Scheduling Serdexmethylphenidate,
- CSB 2.83, Relating to Scheduling 10 Fentanyl Related Substances,
- CSB 2.84, Relating to Scheduling Alfaxalone,
- CSB 2.85, Relating to Excluding 6-beta-natrexol,
- CSB 2.86, Relating to Scheduling Fospropofol,
- CSB 2.87, Relating to Scheduling Embutramide,
- CSB 2.88, Relating to Scheduling Lacosamide,
- CSB 2.89, Relating to Scheduling Perampanel,
- CSB 2.90, Relating to Transferring 1-phenylcyclohexylamine and 1piperidinocyclohexanecarbonitrile,

for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

REPORT FROM THE REFERRAL CRITERIA WORK GROUP

MOTION: Peter Kallio, moved, seconded by Alan Bloom, to accept the

> recommendations of the Referral Criteria Work Group and refer the specified providers to the appropriate examining boards for further proceedings. Motion carried unanimously.

ADJOURNMENT

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

Motion carried unanimously.

The meeting adjourned at 10:25 a.m.

State of Wisconsin Department of Safety & Professional Services AGENDA REQUEST FORM

1) Name and title of pers	son submitting the	request:	2) Date whe	n request submitted:	
		04/28/22			
Nilajah Hardin, Administrative Rules Coordinator		Items will be considered late if submitted after 12:00 p.m. on the deadline			
2) Name of Board Com	mittee Courail Co	-4:·	date which is	8 business days before the meeting	
3) Name of Board, Com		ctions:			
Controlled Substances		0.11	. 9 1 (91 .	Lead and the second	
4) Meeting Date:	5) Attachments:			d on the agenda page? rs – Discussion and Consideration	
05/13/22				oraft – CSB 2.91, Relating to Scheduling 4,4'-	
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	∐ No	2. Pending	g or Possible	Rulemaking Projects	
7) Die ee Herre in .	0) In an ann ann	maa hafaya tha Daa	ud balası	O) Name of Coop Advisor(a) if required.	
7) Place Item in:		nce before the Boa		9) Name of Case Advisor(s), if required:	
	scheduled? (If yes, please complete Appearance Request for Non-DSPS Staff)			N/A	
☐ Closed Session			,		
10) Describe the issue and action that should be addressed:					
Attachments:	ila action that sho	ulu be auulesseu.			
Preliminary Rule Dr	aft – CSB 2.91				
Rule Projects Chart					
Copies of all current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx					
Copies of all current	Board Rule Projec	as Can be viewed	nere: <u>nttps:/</u>	/dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx	
11)		Authoriza	tion		
Monato al	1.1			04/28/22	
Signature of person mal	king this request			Date	
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Supervisor (if required)				Date	
oupervisor (in required)				Duto	
Executive Director signs	Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date				
	<u> </u>	· · · · · · · · · · · · · · · · · · ·	ayenua ueau	line item to agenda) Date	
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda.					
				ne Policy Development Executive Director.	
				ignature to the Bureau Assistant prior to the start of a	
meeting.		_			

STATE OF WISCONSIN CONTROLLED SUBSTANCES BOARD

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IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE

PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD

CONTROLLED SUBSTANCES BOARD : ADOPTING RULES

: (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.91 relating to 4,4'-Dimethylaminorex.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, Stats.

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

Explanation of agency authority:

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)."

Related statute or rule: s. 961.16, Stats.

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

On August 12, 2021, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing 4,4'-Dimethylaminorex into schedule I of the federal Controlled Substances Act. The scheduling action is effective September 13, 2021.

Plain language analysis:

This rule schedules 4,4'-Dimethylaminorex as a schedule I controlled substance.

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 4,4'-Dimethylaminorex as a schedule I controlled substance.

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

CSB 2.91 Addition of 4,4'-Dimethylaminorex to schedule I. Section 961.14 (7) (cm), Stats., is created to read:

961.14 (7) (cm) 4,4'-Dimethylaminorex.

The Affirmative Action order, dated September 16, 2021, took effect on September 27, 2021, when it was published in the Administrative Register and expires upon promulgation of a final rule.

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: $\rm\,N/A$

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled 4,4'-Dimethylaminorex as a controlled substance.

Iowa: Iowa has not scheduled 4,4'-Dimethylaminorex as a controlled substance.

Michigan: Michigan has not scheduled 4,4'-Dimethylaminorex as a controlled substance.

Minnesota: Minnesota has not scheduled 4,4'-Dimethylaminorex as a controlled substance.

Summary of factual data and analytical methodologies:

The methodology was to schedule 4,4'-Dimethylaminorex to conform with the federal Controlled Substances Act.

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

The rule schedules 4,4'-Dimethylaminorex as a Schedule I controlled substance which will not have any effect on small business.

Fiscal Estimate:

The proposed rule will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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:

Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by (date) to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.91 is created to read:

CSB 2.91 Addition of 4,4'-Dimethylaminorex to schedule I. Section 961.14 (7) (cm), Stats., is created to read:

961.14 (7) (cm) 4,4'-Dimethylaminorex.

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)

Controlled Substances Board Rule Projects (updated 04/28/2022)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
22-011	070-21	02/29/2024	CSB 2.78	Scheduling Crotonyl Fentanyl	Submitted to the Legislature on 04/14/2022	Legislative Review After 01/03/2023
22-014	071-21	02/29/2024	CSB 2.79	Scheduling Remimazolam	Submitted to the Legislature on 04/14/2022	Legislative Review After 01/03/2023
21-098	061-21	12/28/2023	CSB 2.80	Scheduling Oliceridine	Legislative Review	Adoption Order Anticipated for Board Review at 07/15/22 Meeting
22-016	072-21	02/29/2024	CSB 2.81	Scheduling Brorphine	Submitted to the Legislature on 04/14/2022	Legislative Review After 01/03/2023
22-032	088-21	04/18/2024	CSB 2.82	Scheduling Serdexmethylphenidate	Clearinghouse Review	Board Review of Final Rule Draft and Legislative Report at 07/15/22 Meeting
22-033	089-21	04/18/2024	CSB 2.83	Scheduling 10 Fentanyl Related Substances	Clearinghouse Review	Board Review of Final Rule Draft and Legislative Report at 07/15/22 Meeting
22-034	090-21	04/18/2024	CSB 2.84	Scheduling Alfaxalone	Clearinghouse Review	Board Review of Final Rule Draft and Legislative Report at 07/15/22 Meeting
22-035	091-21	04/18/2024	CSB 2.85	Excluding 6-beta-Naltrexol	Clearinghouse Review	Board Review of Final Rule Draft and Legislative Report at 07/15/22 Meeting
22-036	092-21	04/18/2024	CSB 2.86	Scheduling Fospropofol	Clearinghouse Review	Board Review of Final Rule Draft and Legislative Report at 07/15/22 Meeting
22-037	093-21	04/18/2024	CSB 2.87	Scheduling Embutramide	Clearinghouse Review	Board Review of Final Rule Draft and Legislative Report at 07/15/22 Meeting

Controlled Substances Board Rule Projects (updated 04/28/2022)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
22-039	094-21	04/18/2024	CSB 2.88	Scheduling Lacosamide	Clearinghouse Review	Board Review of Final Rule Draft and Legislative Report at 07/15/22 Meeting
22-038	095-21	04/18/2024	CSB 2.89	Scheduling Perampanel	Clearinghouse Review	Board Review of Final Rule Draft and Legislative Report at 07/15/22 Meeting
22-040	096-21	04/18/2024	CSB 2.90	Transferring 1- phenylcyclohexylamine and 1- piperidinocyclohexanecarbonitrile , Immediate Precursors to Phencyclidine, Also Known as PCP	Clearinghouse Review	Board Review of Final Rule Draft and Legislative Report at 07/15/22 Meeting
Not Assigned Yet	015-22	08/28/2024	CSB 2.91	Scheduling 4,4'- Dimethylaminorex	Board Review of Preliminary Rule Draft at 05/13/22 Meeting	Post for EIA Comment and Submission to Clearinghouse for Review

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:			
Adam Barr, Executive Director on behalf of Representative		5/3/2022					
Dave Murphy et al.		Items will be considered late if submitted after 12:00 p.m. on the					
3) Name of Board, Com	nittee Co	nuncil Sections:		deadline date whic	h is 8 business days before the meeting		
,	-	Julicii, Sections.					
	Controlled Substances Board						
4) Meeting Date:	5) Attac		•		tled on the agenda page?		
5/13/2022	⊠ Ye				t: Status of Kratom – Discussion and		
T) D1 1/ 1	□ No	<u> </u>	Conside				
7) Place Item in:		8) Is an appearanc scheduled? (If yes,			9) Name of Case Advisor(s), if applicable:		
		Appearance Reques					
☐ Closed Session			_	,			
		│ □ Yes │ 図 No					
10) Describe the issue a	nd action	1 —	raccad:				
,					ial review of existing research and provide the		
legislature with guidance natural form should be s asked to promulgate a r	e or act uscheduled	inilaterally if appropi d in Wisconsin. If the entiating MG and 7H	riate. Sp e board -MG fou	ecifically, the board concludes natural kr ind in natural kratom	is asked to determine whether kratom in its atom should not be scheduled, the board is from that contained in other substances, so		
that natural kratom wou	ld not vio	late the Wisconsin (Controll	ed Substances Act.			
11)		Αι	uthoriza	tion			
Adam Barr					5/3/2022		
Signature of person ma	king this	request			Date		
Supervisor (Only require	ed for no	st agenda deadline it	tems)		Date Date		
Cuportion (Ciny require	ой тог ро	or agonaa acaamic ii			24.0		
- " D: (:							
Executive Director signa	Executive Director signature (Indicates approval for post agenda deadline items) Date						
Directions for including							
1. This form should be saved with any other documents submitted to the <u>Agenda Items</u> folders.							
 Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a 							
meeting.							



April 28, 2022

Wisconsin Controlled Substances Board DSPS PO Box 8366 Madison, WI 53708-8366

Dear Chairperson Engelbart and Members:

The kratom tree is a member of the coffee family and native to Southeast Asia. The kratom leaf in its pure, natural form has been used for centuries for pain relief, alertness, and general well-being in that part of the world. More recently, it has been used as a natural alternative to prescription drugs used for pain relief and anxiety and has been shown to be especially helpful to individuals who experience adverse reactions to prescription medications. The crisis in drug overdoses in the United States has stimulated research into the uses of kratom and other alternative pain management options. This research has shown kratom to have lower addiction and abuse profiles, while showing promising results for users. Unfortunately, nearly a decade ago, kratom was made illegal to possess or use in Wisconsin due to a provision that was included in a bill intended to address the synthetic drug problem. We believe this was done without adequate research and understanding of kratom in its natural form. Therefore, we ask the Board to review the research and provide guidance as to whether natural kratom merits scheduling.

For background, 2013 Wisconsin Act 351 changed the concept of scheduling an analog of a synthetic drug and replaced it with an actual description of the chemical structure of prohibited substances. Two chemical structures included in the long list were mitragynine (MG) and 7-hydroxymitragynine (7H-MG). MG and 7H-MG are alkaloids that are found naturally in the kratom leaf and have acceptable safety profiles in that form. Unfortunately, the change in law made *any substance* with MG or 7H-MG in it illegal, and as a result made natural kratom illegal also. We do not believe it was the intent of the Legislature to ban natural kratom; rather the inclusion of these particular alkaloids was intended to address concerns related to synthesized and adulterated products *marketed* as kratom. We agree that substances that are synthesized or adulterated with MG or 7H-MG are dangerous and should be scheduled. Kratom, however, in its natural form should not be treated in the same manner.

Since 2013, there has been significant research and discussion on natural kratom and the scientific basis for the decision to schedule kratom here and in the few states where it was indirectly banned, as well as at the federal level. Hundreds of peer-reviewed studies have now been conducted by researchers worldwide, including research sponsored by the National Institute on Drug Abuse (NIDA). These studies confirm that natural kratom is not like opioids in its safety and addiction profile and is actually a harm reduction tool that can enhance public health.

In 2015 and 2018, the Controlled Substances Board had discussions in open session regarding the issue of kratom's scheduling in Wisconsin, but no further action was taken. In August 2018, the US Department of Health and Human Services (HHS) rescinded its recommendation that FDA and DEA begin the process of scheduling MG and 7H-MG, due to insufficient evidence as well as emerging research

suggesting that *scheduling* kratom could actually create "an unknown and potentially substantial risk to *public health*" because it would no longer be available to the millions of Americans that use it. Most recently, 2021 Assembly Bill 599 and Senate Bill 958 were introduced in the Wisconsin Legislature which would legalize and regulate the use and sale of natural kratom while keeping synthesized and adulterated kratom products scheduled. AB 599 was given a public hearing and was approved by the standing committee with a bipartisan 9-2 vote.

As a result of the recent evidence, research, and public interest regarding kratom that has been made public since the enactment of 2013 Act 351, we believe it is appropriate for the Board to conduct its own impartial review of existing research and provide the legislature with guidance or act unilaterally if appropriate. We ask the following:

- 1) That the CSB use its authority under Wis. Stats. Ch. 961.11 to make a determination using the criteria provided in Wis. Stats. Ch. 961(1m) and (1r) as to whether or not kratom in its natural form should be scheduled in Wisconsin; and
- 2) If natural kratom does not meet the criteria under Wis. Stats. Ch. 961(1m), that the CSB promulgate a rule that would differentiate MG and 7H-MG found in natural kratom from MG and/or 7H-MG contained in other substances so that natural kratom would not violate Wis. Stats. Ch. 961.17(7)(mk) and (ml) of the Wisconsin Controlled Substances Act.

Thank you for your consideration of these requests. We request that the Board please let us know how it intends to proceed.

Sincerely,

Rep. Dave Murphy

56th Assembly District

Sen Jon Erpenbach 27th Senate District

Rep. Dora Drake 11th Assembly District

Rep. Michael Schraa 53rd Assembly District Sen. Mary Felzkowski

12th Senate District

Rep. Rob Brooks 60th Assembly District

Rep. Dan Knodl

24th Assembly District

Rep. Christine Sinicki

20th Assembly District

Speaker Robin Vos

63rd Assembly District

Rep. Jonathan Brostoff

19th Assembly District

Rep. John Macco

88th Assembly District

¹ https://www.kratomscience.com/wp-content/uploads/2021/01/dhillon-8.16.2018-response-letter-from-ashradm-giroir4.pdf

State of Wisconsin Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when reque	2) Date when request submitted:			
Marjorie Liu	5/3/2022	5/3/2022			
Program Lead, PDMP		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 tit	tled on the agenda page?			
5/13/2022		g Program (PDMP) Updates – Discussion and			
□ No	Consideration				
7) Place Item in: 8) Is an appearance scheduled? (If yes	ce before the Board being	9) Name of Case Advisor(s), if required:			
Open Session Appearance Requ	rest for Non-DSPS Staff)				
Closed Session Yes					
□ Tes ⊠ No					
10) Describe the issue and action that should be add	Iressed:	L			
1. WI ePDMP Operations					
a. CSB 2022 Q1 Report					
b. Recent and Upcoming Releases					
c. Status of Grant Projects:					
i. FY 2020 Harold Rogers P	Prescription Drug Monitoring	Program			
ii. FY 2021 Harold Rogers P	ii. FY 2021 Harold Rogers Prescription Drug Monitoring Program				
iii. Buprenorphine Exclusion Project					
d. Interstate Data Sharing					
e. EHR Integration Status					
2. WI ePDMP Outreach					
	uthorization				
Marjorie Liu		5/3/2022			
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 s	submitted to the agenda				
Post Agenda Deadline items must be authorized by		y Development Executive Director.			
3. If necessary, provide original documents needing	Board Chairperson signature	e to the Bureau Assistant prior to the start of a			

2020-2022 Development and Release Summary

Updated 04.28.2022

Release Date	Description	
Pending		
Harold Rogers Grant 2021 Promotional Materials May 2022	EHR Integration Page Updates Integration Interest Form Minor Maintenance Updates	
Harold Rogers Grant 2020 Component 3 Release date TBD	Ability for users to change the order in which the sections of the patient report are presented. Adding a Buprenorphine History Alert section to the patient report.	
Harold Rogers Grant 2020 Component 2 Release date TBD	Infrastructure and technology stack changes to improve performance in the following areas: • Patient Matching • Dispensing Matching • Reporting Statistics	
Completed		
R26 April 2022	 Buprenorphine Exclusion Ability to override prescriber facing alerts, metrics, and MME calculations for certain drugs. Maintenance Updates RxCheck 3.0 Upgrades 	
Harold Rogers Grant 2020 Component 1 December 2021	Security Enhancements Two-Factor Authentication Compromised Email Address Check Patient Report and other User Experience Updates	
R25 November 2021	Maintenance Updates	
R24 August 2021	Text Updates • Gabapentin related text changes to the Submitter Error Email. Security-Related Enhancements	
R23 July 2021	Text Updates • Gabapentin related text changes to the Submitter Error Email.	

R22 July 2021	Pharmacy-Related Enhancements • Missing DEA Number Error Process Updates Administrative-Related Enhancements
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
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Interstate Data Sharing

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

WI ePDMP Integration Services Summary

Current as of 04.28.2022

Pending Health Systems and EHR Platforms
Advent Health (In Discussion/Contracting)
Marshfield EHR System Change (In Discussion/Contracting)
Wisconsin Statewide Health Information Network (Converting to New Platform)
Bluestone Physician Services (In Discussion/Contracting)
Clean Slate (In Development)
Connected Health Systems (approx. 57% of monthly patient queries)
Ascension Wisconsin
Aspirus Health Care
Aurora Health Care
Children's Hospital of Wisconsin
DrFirst Fort Healthcare (go-live in June 2022), Heartland Hospice, Lifestance Health WI, Oak Medical, Wauwatosa Children's Clinic
Froedtert & the Medical College of Wisconsin
GHC of South Central Wisconsin
Gundersen Health System
HealthPartners

HSHS / Prevea Health
M Health Fairview
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

2022 WI PDMP Outreach Calendar

MONTH	EVENT	DESCRIPTION	DATES	NOTES
January	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	1/13/2022	Quarterly meeting
February				
March				
	DOJ Law Enforcement (LE) Bulletin	Updated FAQ for LE alert reporting	WILENET April Issue	
April	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	4/14/2022	Quarterly meeting
	Rx Drug Abuse & Heroin Summit	Participant; national conference led by multidisciplinary experts for stakeholders addressing the opioid crisis	4/18-4/21/2022	Atlanta, GA
May	RxCheck Governance Board Bi-Annual Meeting	Participant; annual meeting for state PDMP administrators	5/12/2022	Virtual
June				
luk	RxCheck Governance Board North-Region Meeting	Participant; regional meeting for PDMP administrators Organized by PDMP Training and Technical Assistance Center	TBD	In-Person
July	PMPi Steering Committee Annual Meeting	Participant; annual meeting for PDMP administrators organized by National Association of Boards of Pharmacy	7/27-7/28/2022	Mount Prospect, IL
August				
September	RxCheck Governance Board Bi-Annual Meeting	Participant; Annual meeting for state PDMP administrators	TBD	In-Person
October				
November				
December				

MARK POCAN

2ND DISTRICT, WISCONSIN

COMMITTEE ON APPROPRIATIONS
COMMITTEE ON EDUCATION & LABOR
JOINT ECONOMIC COMMITTEE
SENIOR WHIP



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May 10, 2022

Wisconsin Controlled Substances Board Department of Safety and Professional Services PO Box 8366 Madison, WI 53708

Dear Chairperson Engelbart and Members:

As a long-time supporter of legalizing the manufacture, distribution, delivery, and possession of kratom, I write to request your review of research pertaining to kratom and guidance as to whether or not it merits scheduling.

As a Member of Congress, I have worked with federal representatives in both parties to continue the research and legal use of kratom due to its promising help in a number of health conditions as well as its ability to help many people overcome addiction. I've been moved by the many, many personal stories of the benefits of kratom from people across the nation.

According to the Wisconsin Legislative Reference Bureau: "Under current law, kratom is classified as a Schedule I controlled substance and if a person manufactures, distributes, or delivers kratom, [they are] guilty of a misdemeanor." Last legislative session, AB 599 attempted to reverse this unfounded restriction by removing kratom from the schedule of controlled substances while legalizing the manufacture, distribution, delivery, and possession of kratom, subject to certain limitations. This legislative outcome would have been consistent with the emerging view in Washington, D.C. where kratom is now supported on a bipartisan basis, it will be receiving millions of dollars in new research funding, and its benefits have been recognized by the Director of the National Institute on Drug Abuse (NIDA) within the National Institutes of Health (NIH).

In a recent letter addressed to both the U.S. Ambassador to the United Nations and the Secretary of the U.S. Department of Health and Human Services², Senator Mike Lee – a Republican from Utah – and I wrote "to ask that the United States oppose any effort to add kratom and its alkaloids to the 1971 U.N. Convention on psychotropic substances as a banned substance." Additionally, we noted that "In 2016, 145,906 Americans including consumers, scientists, and state and federal lawmakers raised their voices in opposition to the Department of Health and Human Services' (HHS) proposal to schedule kratom as a controlled substance."

¹ https://docs.legis.wisconsin.gov/2021/related/proposals/ab599

² https://www.americankratom.org/mediak/news/bi-partisan-letter.html

Similar to this strong support for kratom from Members of the U.S. House of Representatives and the U.S. Senate – across party lines – the Fiscal Year 2022 Labor, Health and Human Services, Education, and Related Agencies Subcommittee appropriation legislation in the House of Representatives contained the following³:

"Kratom.—The [Appropriations] Committee recognizes that NIDA-funded research has contributed to the continued understanding of the health impacts of kratom, including its constituent compounds, mitragynine and 7-hydroxymitragynine. The Committee is aware of the potential promising results of kratom for acute and chronic pain patients who seek safer alternatives to sometimes dangerously addictive and potentially deadly prescription opioids and of research investigating the use of kratom's constituent compounds for opioid use disorder. The Committee directs NIDA to continue to invest in this important research, especially considering the increase in overdose deaths during the COVID–19 pandemic." (p. 135)

"Kratom.—The [Appropriations] Committee directs the Secretary to maintain current Agency policy to not recommend that the substances mitragynine and 7-hydroxymitragynine, known as kratom, be permanently controlled in Schedule I of the Controlled Substances Act, either temporarily or permanently [...] The Committee encourages AHRQ to continue to fund research on natural products that are used by many to treat pain in place of opioids, including kratom [...] The Committee recommends an additional \$3,000,000 for this research and directs AHRQ to make center-based grants to address research which will lead to clinical trials in geographic regions which are among the hardest hit by the opioid crisis." (p.189)

While testifying before the Appropriations Committee in the U.S. House of Representatives on May 25, 2021, Dr. Nora Volkow, the Director of NIDA, stated: "Kratom, most notably mitragynine, has many interesting properties that could be of value potentially as a medication for pain. Also, interestingly, they could hold value as treatment for addiction [...] it is so important to actually do research on this substance." HHS Secretary Becerra went one step further in a letter responding to Senator Lee and me in which he stated: "Discussions continue within HHS on mitigating actions to best address the various public health concerns presented, including potential unintended consequences that may arise from transitioning to riskier alternatives (for example fentanyl) if kratom were to be scheduled."

Clearly, Wisconsin is out of sync with the nation when it comes to kratom, and the results can be devasting. You, however, can contribute to addressing this disparity, and publish guidance that will place Wisconsin one step closer to joining the 44 states that do not restrict kratom in the way

³ https://www.congress.gov/117/crpt/hrpt96/CRPT-117hrpt96.pdf

⁴ https://appropriations.house.gov/events/hearings/fy-2022-budget-request-for-the-national-institutes-of-health

⁵ https://www.politico.com/newsletters/prescription-pulse/2022/04/12/fda-combatting-field-mice-at-white-oak-campus-00024563

our state currently does. I hope you will look favorably upon this request.

Sincerely,

Mark Pocan

Member of Congress