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 Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE CONTROLLED SUBSTANCES BOARD

Virtual, 4822 Madison Yards Way, Madison Contact: Tom Ryan (608) 266-2112 July 11, 2025

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

10:00 A.M.

OPEN SESSION - CALL TO ORDER - ROLL CALL

- A. Adoption of Agenda (1-3)
- B. Approval of Minutes May 9, 2025 (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
 - a. Barman, Subhadeep -5/1/2019
 - b. Bellay, Yvonne DATCP Representative
 - c. Bloom, Alan -5/1/2020
 - d. Eberhardy, Cullen AG Representative
 - e. Englebert, Doug DHS Representative
 - f. Gundersen, David Dentistry Examining Board Representative
 - g. Kane, Amanda Board of Nursing Representative
 - h. Majeed-Haqqi, Lubna Medical Examining Board Representative
 - i. Weitekamp, John Pharmacy Examining Board Representative
 - 3) Alternates
 - a. Alton, Troy Dentistry Examining Board Representative
 - b. Leuthner, Steven Medical Examining Board Representative
 - c. Weinman, Robert Board of Nursing Representative

F. Administrative Rule Matters – Discussion and Consideration (7-25)

- 1) Scope Statement:
 - a. CSB 2.012, Relating to Scheduling 7 Fentanyl-related Substances (8-9)
- 2) Preliminary Rule Draft:
 - a. CSB 2.011, Relating to Scheduling Ethylphenidate (10-12)

- 3) Adoption Order:
 - a. CSB 2.006, Relating to Scheduling 5 Synthetic Cannabinoids (13-16)
 - b. CSB 2.007, Relating to Scheduling ADB-BUTINACA, α-PiHP, and 3-MMC (17-20)
 - c. CSB 2.008, Relating to Scheduling 2-methyl AP-237 (21-23)
- 4) Pending or Possible Rulemaking Projects
 - a. Rule Projects Chart (24-25)

G. Prescription Drug Monitoring Program (PDMP) Updates – Discussion and Consideration (26-34)

H. DSPS Interdisciplinary Advisory Committee Liaison Report – Discussion and Consideration (35-41)

- 1) Draft IV Hydration Guidance Document
- 2) Future Topics

I. Board Member Reports – Discussion and Consideration

- 1) Medical Examining Board
- 2) Dentistry Examining Board
- 3) Board of Nursing
- 4) Pharmacy Examining Board
- J. Report from the Referral Criteria Work Group Discussion and Consideration
- K. Liaison Reports
- L. Speaking Engagements, Travel, or Public Relations Requests, and Reports
- 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) Public Health Emergencies
 - 14) Appearances from Requests Received or Renewed
 - 15) Speaking Engagements, Travel, or Public Relations Requests, and Reports
 - 16) 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 19, 2025

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 virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of any agenda item may be changed by the board for the convenience of the parties. The person credentialed by the board has the right to demand that the meeting at which final action may be taken against the credential be held in open session. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer or reach the Meeting Staff by calling 608-267-7213.

VIRTUAL/TELECONFERENCE CONTROLLED SUBSTANCES BOARD MEETING MINUTES MAY 9, 2025

PRESENT: Subhadeep Barman, Yvonne Bellay, Alan Bloom, Cullen Eberhardy (arrived at

10:06), Doug Englebert, Amanda Kane, Lubna Majeed-Haqqi, John Weitekamp

ABSENT: David Gundersen

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

Administrative Rules Coordinator; Brenda Taylor, Board Services Supervisor; and

other DSPS Staff

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 10:00 a.m. A quorum was confirmed with seven (7) members present.

ADOPTION OF AGENDA

MOTION: Alan Bloom moved, seconded by John Weitekamp, to adopt the Agenda as

amended. Motion carried unanimously.

APPROVAL OF MINUTES OF MARCH 14, 2025

MOTION: Yvonne Bellay moved, seconded by Subdaheep Barman, to adopt the Minutes

of March 14, 2025, as published. Motion carried unanimously.

Cullen Eberhardy arrived at 10:06 am

PRELIMINARY HEARING ON STATEMENT OF SCOPE – SS 016-25 ON CSB 2.010 (RENUMBERED TO 2.011), RELATING TO SCHEDULING ETHYLPHENIDATE

Review Preliminary Hearing Comments

MOTION: Doug Englebert moved, seconded by John Weitekamp, to the Board has

provided an opportunity to receive public comments concerning Scope Statement (SS) 016-25 on CSB 2.010 (Renumbered to 2.011), Relating to Scheduling Ethylphenidate. Additionally, after consideration of all public comments and feedback the Board approves SS 016-25 for implementation.

Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Final Rule Draft:

CSB 2.009, Relating to Scheduling 2 Synthetic Benzimidazole-Opioids

MOTION: Subhadeep Barman moved, seconded by Yvonne Bellay, to approve the

Legislative Report and Draft for Clearinghouse Rule 25-021 (CSB 2.009), Relating to Scheduling 2 Synthetic Benzimidazole-Opioids for submission to

the Governor's Office and Legislature. Motion carried unanimously.

Adoption Order:

CSB 2.98, Relating to Excluding [18F]FP-CIT

CSB 2.99, Relating to Scheduling Mesocarb

CSB 2.001, Relating to Scheduling Methiopropamine

CSB 2.002, Relating to Excluding Fenfluramine

CSB 2.003, Relating to Transferring Flualprazolam and Scheduling 4 Other Synthetic Benzodiazepine Substances

CSB 2.004, Relating to Scheduling Zuranolone

CSB 2.005, Relating to Scheduling 9 Fentanyl-related Substances

MOTION: Subhadeep Barman moved, seconded by Doug Eberhardy, to approve the

Adoption Order for the following Rules:

Clearinghouse Rule 24-004 (CSB 2.98), Relating to Excluding [¹⁸F]FP-CIT Clearinghouse Rule 24-005 (CSB 2.99), Relating to Scheduling Mesocarb

Clearinghouse Rule 24-023 (CSB 2.001), Relating to Scheduling

Methiopropamine

Clearinghouse Rule 24-024 (CSB 2.002), Relating to Excluding Fenfluramine

Clearinghouse Rule 24-048 (CSB 2.003), Relating to Transferring Flualprazolam and Scheduling 4 Other Synthetic Benzodiazepine Substances

Clearinghouse Rule 24-058 (CSB 2.004), Relating to Scheduling Zuranolone Clearinghouse Rule 24-069 (CSB 2.005), Relating to Scheduling 9 Fentanyl-related Substances

Motion carried unanimously.

CSB 4, Relating to National Provider Identifier Requirement

MOTION: Subhadeep Barman moved, seconded by John Weitekamp, to approve the

Adoption Order for Clearinghouse Rule 24-013 (CSB 4), relating to National

Provider Identifier Requirement. Motion carried unanimously.

CSB 4, Relating to Monitored Prescription Drug History Reports

MOTION: Lubna Majeed-Hagqi moved, seconded by Alan Bloom, to approve the

Adoption Order for Clearinghouse Rule 24-033 (CSB 4), relating to

Monitored Prescription Drug History Reports. Motion carried unanimously.

CSB 4, Relating to Mail Delivered Prescriptions

MOTION: John Weitekamp moved, seconded by Yvonne Bellay, to approve the

Adoption Order for Clearinghouse Rule 24-060 (CSB 4), relating to Mail

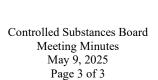
Delivered Prescriptions. Motion carried unanimously.

ADJOURNMENT

MOTION: Doug Englebert moved, seconded by Lubna Majeed-Haqqi, to adjourn the

meeting. Motion carried unanimously.

The meeting adjourned at 10:29 a.m.



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

1) Name and title of	f pers	on submitting	the request:	2) Date when request submitted:		
Nilajah Hardin				06/30/25		
Administrative Rules Coordinator				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 Substan						
4) Meeting Date:	5) A	ttachments:	6) How should the ite		n the agenda page? ssion and Consideration	
07/11/25		Yes	1. Scope Stater	nent:		
		No	a. CSB 2.0 2. Preliminary		o Scheduling 7 Fentanyl-related Substances	
			a. CSB 2.0	011, Relating t	o Scheduling Ethylphenidate	
			3. Adoption Or a. CSB 2.0		o Scheduling 5 Synthetic Cannabinoids	
			b. CSB 2.0	007, Relating t	o Scheduling ADB-BUTINACA, α-PiHP, and 3-MMC	
					o Scheduling 2-methyl AP-237 aking Projects	
			a. Rule Pr	ojects Chart		
7) Place Item in:			earance before the Boa		9) Name of Case Advisor(s), if required:	
	1		(If yes, please complete Request for Non-DSPS		N/A	
☐ Closed Session	on		ror mon bor o	Glamy		
		│				
10) Describe the is:	sue a		should be addressed:			
*				ary Rules D	rafts, and Final Rule Drafts.	
A 44 1 4						
Attachments: • Scope Sta	ıteme	nt – CSB 2.0	12			
-		ıle Draft – CS				
-		er – CSB 2.000	6-2.008			
Rule Proj	ects (Chart				
(All Board Rule Pr	roject	s can be View	ved Here if Needed: ht	tps://dsps.wi	gov/Pages/RulesStatutes/PendingRules.aspx)	
11)			Authoriza	tion		
Melajarto de	24	Harolis			6/30/25	
Signature of person	n mak	ing this reque	st		Date	
Supervisor (if required) Date						
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date						
Directions for including supporting documents:						
 This form should be attached to any documents submitted to the agenda. 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.						

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.:	CSB 2.012
Relating to:	Scheduling Seven Fentanyl-Related Substances
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 the following seven fentanyl-related substances as a schedule I controlled substance under s. 961.11 (4), Stats:

- Para-chlorofentanyl
- Ortho-chlorofentanyl
- Meta-fluorofuranyl fentanyl
- Ortho-methylcyclopropyl fentanyl
- Beta-methylacetyl fentanyl
- Tetrahydrothiofuranyl fentanyl
- Para-fluoro valeryl fentanyl

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 December 30, 2024, the Department of Justice, Drug Enforcement Administration published its temporary scheduling order in the Federal Register adding the seven fentanyl-related substances listed above to schedule I of the federal Controlled Substances Act. The scheduling action was effective December 30, 2024. The Controlled Substances Board did not receive an objection to similarly adding the seven fentanyl-related substances listed above as schedule I controlled substances under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order listing the seven fentanyl-related substances listed about as schedule I controlled substances. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats the seven fentanyl-related substances listed above under chapter 961, Stats. by creating the following:

CSB 2.012 Addition of 7 Fentanyl Related Substances to Schedule I. (1) Section 961.14 (2) (nd) 8m, 12p, 16h, 16q, 16r, 17d, and 18m are created to read:

- 961.14 (2) (nd) 8m. Beta-methylacetyl fentanyl (N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)acetamide);
- 12p. Meta-fluorofuranyl fentanyl (N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);
- 16h. Ortho-chlorofentanyl (N-(2-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);
- 16q. Ortho-methylcyclopropyl fentanyl (N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide):
- 16r. Para-chlorofentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide;
- 17d. Para-fluoro valeryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)pentanamide);
- 18m. Tetrahydrothiofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrothiophen-2-carboxamide);

Rev. 3/6/2012

The Affirmative Action order, dated March 18, 2025, took effect on March 31, 2025, upon 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 December 30, 2024, the Department of Justice, Drug Enforcement Administration published its temporary scheduling order in the Federal Register adding the seven fentanyl-related substances listed above to schedule I of the federal Controlled Substances Act. The scheduling action was effective December 30, 2024.

Contact Person: Nilajah Hardin, Administrative Rules Coordinator, DSPSAdminRules@wisconsin.gov

8. Anticipated economic impact of implementing the rule: None to minimal.

Approved for publication:	Approved for implementation:
Authorized Signature	Authorized Signature
Date Submitted	

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 2.011, relating to scheduling Ethylphenidate.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, 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. 961.14, Stats.

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

On October 22, 2024, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register adding Ethylphenidate to schedule I of the federal Controlled Substances Act. The scheduling action was effective November 21, 2024.

Plain language analysis:

This rule schedules Ethylphenidate as a schedule I controlled substance. 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 rulemaking, listing Ethylphenidate as a schedule I controlled substance. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Ethylphenidate under chapter 961, Stats. by creating the following:

CSB 2.011 Addition of Ethylphenidate to Schedule I. . Section 961.14 (7) (u), Stats., is created to read:

961.14 (7) (u) Ethyl 2-phenyl-2-(piperidin-2-yl)acetate, commonly known as Ethylphenidate.

The Affirmative Action order, dated November 27, 2024, took effect on December 16, 2024, upon publication 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: The Controlled Substances Board held a Preliminary Hearing on Statement of Scope for this project on May 9, 2025. No comments were received.

Comparison with rules in adjacent states:

Illinois: Illinois has not listed Ethylphenidate as a schedule I controlled substance [720 Illinois Compiled Statutes 570 Section 204].

Iowa: Iowa has not listed Ethylphenidate as a schedule I controlled substance [Iowa Code 124.204].

Michigan: Michigan has not listed Ethylphenidate as a schedule I controlled substance [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not listed Ethylphenidate as a schedule I controlled substance [Minnesota Statutes 152.02 (2)].

Summary of factual data and analytical methodologies:

The methodology was to schedule Ethylphenidate 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 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.

Fiscal Estimate and Economic Impact Analysis:

The fiscal estimate and economic impact analysis will be attached upon completion.

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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

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; 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 2.011 is created to read:

CSB 2.011 Addition of Ethylphenidate to Schedule I. . Section 961.14 (7) (u), Stats., is created to read:

961.14 (7) (u) Ethyl 2-phenyl-2-(piperidin-2-yl)acetate, commonly known as Ethylphenidate.

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

(END OF TEXT OF RULE)

STATE OF WISCONSIN CONTROLLED SUBSTANCES BOARD

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IN THE MATTER OF RULE-MAKING : ORDER OF THE

PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD

CONTROLLED SUBSTANCES BOARD : ADOPTING RULES

(CLEARINGHOUSE RULE 24-083)

ORDER

An order of the Controlled Substances Board to create CSB 2.006, relating to scheduling five synthetic cannabinoids.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, 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. 961.14, Stats.

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

On December 12, 2023, the Department of Justice, Drug Enforcement Administration published its temporary amendment and scheduling order in the Federal Register adding the following 6 synthetic cannabinoids to schedule I of the federal Controlled Substances Act:

- MDMB-4en-PINACA
- 4F-MDMB-BUTICA or 4F-MDMB-BICA
- ADB-4en-PINACA
- CUMYL-PEGACLONE or SGT-151
- 5F-EDMB-PICA or 5F-EDMB-2201
- MMB-FUBICA

The scheduling action was effective December 12, 2023.

Plain language analysis:

The objective of the proposed rule is to add the following five synthetic cannabinoids as a schedule I controlled substance under s. 961.11 (4), Stats:

- MDMB-4en-PINACA
- 4F-MDMB-BUTICA or 4F-MDMB-BICA
- ADB-4en-PINACA
- CUMYL-PEGACLONE or SGT-151
- 5F-EDMB-PICA or 5F-EDMB-2201

The Controlled Substances Board did not receive an objection to similarly listing five of the above synthetic cannabinoids as schedule I controlled substances under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order listing those 5 synthetic cannabinoids as schedule I controlled substances. The remaining synthetic cannabinoid, MMB-FUBICA, is already included in schedule I of ch. 961, Stats. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats the above 5 synthetic cannabinoids under chapter 961, Stats. by creating the following:

CSB 2.006 Adding 5 Synthetic Cannabinoids to Schedule I. (1) Section 961.14 (4) (tb) 54. to 58., Stats., are created to read:

961.14 (4) (tb) 54. Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate, commonly known as MDMB-4en-PINACA.

- 55. Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, commonly known as 4F-MDMB-BUTICA or 4F-MDMB-BICA.
- 56. *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxaminde, commonly known as ADB-4en-PINACA.
- 57. 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one, commonly known as CUMYL-PEGACLONE or SGT-151.
- 58. Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, commonly known as 5F-EDMB-PICA or 5F-EDMB-2201.

The Affirmative Action order, dated January 24, 2024, took effect on February 5, 2024, upon publication 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 listed the 5 synthetic cannabinoids in this rule as schedule I controlled substances. However, they do have general requirement to include any synthetic cannabinoid that is not approved by the United States Food and Drug Administration or if approved is not dispensed according to law would be considered a schedule I controlled substance [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not included the 5 synthetic cannabinoids listed in this rule as schedule I controlled substances [Iowa Code 124.204].

Michigan: Michigan has not included the 5 synthetic cannabinoids listed in this rule as schedule I controlled substances. However, they do have general requirement to include any synthetic cannabinoid that is not approved by the United States Food and Drug Administration or included in schedules II to V [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not included the 5 synthetic cannabinoids listed in this rule as schedule I controlled substances [Minnesota Statutes 152.02 (2)].

Summary of factual data and analytical methodologies:

The methodology was to add the 5 synthetic cannabinoids listed in this rule to Schedule I 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 proposed rule was 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. 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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

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; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.006 is created to read:

CSB 2.006 Adding 5 Synthetic Cannabinoids to Schedule I. (1) Section 961.14 (4) (tb) 54. to 58., Stats., are created to read:

- **961.14 (4) (tb)** 54. Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate, commonly known as MDMB-4en-PINACA.
- 55. Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, commonly known as 4F-MDMB-BUTICA or 4F-MDMB-BICA.
- 56. *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxaminde, commonly known as ADB-4en-PINACA.
- 57. 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one, commonly known as CUMYL-PEGACLONE or SGT-151.
- 58. Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, commonly known as 5F-EDMB-PICA or 5F-EDMB-2201.

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_				
		Chair	person		
			olled Substan	ces Board	

STATE OF WISCONSIN CONTROLLED SUBSTANCES BOARD

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IN THE MATTER OF RULE-MAKING : ORDER OF THE

PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD

CONTROLLED SUBSTANCES BOARD : ADOPTING RULES

(CLEARINGHOUSE RULE 24-084)

ORDER

An order of the Controlled Substances Board to create CSB 2.007, relating to scheduling ADB-BUTINACA, α-PiHP, and 3-MMC.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, 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. 961.14, Stats.

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

On December 13, 2023, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register adding the following three substances to schedule I of the federal Controlled Substances Act:

- ADB-BUTINACA
- α-PiHP or alpha-PiHP
- 3-MMC

The scheduling action is effective December 13, 2023.

Plain language analysis:

This rule schedules ADB-BUTINACA, α -PiHP, and 3-MMC as schedule I controlled substances. 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, listing ADB-BUTINACA, α -PiHP, and 3-MMC as schedule I controlled substances. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats ADB-BUTINACA, α -PiHP, and 3-MMC under chapter 961, Stats. by creating the following:

CSB 2.007 Addition of ADB-BUTINACA, Alpha-PiHP, and 3-MMC to Schedule I. (1) Section 961.14 (4) (tb) 32m. is created to read:

961.14 (4) (tb) 32m. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1*H*-indazole-3-carboxamide, commonly known as ADB-BUTINACA.

(2) Section 961.14 (7) (L) 2m. and 36m. are created to read:

961.14 (7) (L) 2m. 3-methylmethcathinone or 2-(methylamino)-1-(3-methylphenyl)propan-1-one, commonly known as 3-MMC.

36m. 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one, commonly known as alpha-PiHP.

The Affirmative Action order, dated June 4, 2024, took effect on June 17, 2024, upon publication 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 listed ADB-BUTINACA, α -PiHP, and 3-MMC as schedule I controlled substances [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not listed ADB-BUTINACA, α -PiHP, and 3-MMC as schedule I controlled substances [Iowa Code 124.204].

Michigan: Michigan has not listed ADB-BUTINACA, α-PiHP, and 3-MMC as schedule I controlled substances [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not listed ADB-BUTINACA, α-PiHP, and 3-MMC as schedule I controlled substances [Minnesota Statutes 152.02 (2)].

Summary of factual data and analytical methodologies:

The methodology was to schedule ADB-BUTINACA, α-PiHP, and 3-MMC 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 proposed rule was 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. 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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

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; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.007 is created to read:

CSB 2.007 Addition of ADB-BUTINACA, Alpha-PiHP, and 3-MMC to Schedule I. (1) Section 961.14 (4) (tb) 32m. is created to read:

961.14 (4) (tb) 32m. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1H-indazole-3-carboxamide, commonly known as ADB-BUTINACA.

(2) Section 961.14 (7) (L) 2m. and 36m. are created to read:

961.14 (7) (L) 2m. 3-methylmethcathinone or 2-(methylamino)-1-(3-methylphenyl)propan-1-one, commonly known as 3-MMC.

36m. 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one, commonly known as alpha-PiHP.

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 TEX	T OF RULE)		
Dated	Agency			
		Chairperson		
		Controlled Substances Board		

STATE OF WISCONSIN CONTROLLED SUBSTANCES BOARD

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IN THE MATTER OF RULE-MAKING : ORDER OF THE

PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD

CONTROLLED SUBSTANCES BOARD : ADOPTING RULES

(CLEARINGHOUSE RULE 24-085)

ORDER

An order of the Controlled Substances Board to create CSB 2.008, relating to scheduling 2-methyl AP-237.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, 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. 961.14, Stats.

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

On March 15, 2024, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register adding 2-methyl AP-237 to schedule I of the federal Controlled Substances Act. The scheduling action is effective April 15, 2024.

Plain language analysis:

This rule schedules 2-methyl AP-237 as a schedule I controlled substance. 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, listing 2-methyl AP-237 as a schedule I controlled substance. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats 2-methyl AP-237 under chapter 961, Stats. by creating the following:

CSB 2.008 Addition of 2-Methyl AP-237 to Schedule I. Section 961.14 (2) (qz), Stats., is created to read:

961.14 (2) (qz) 2-methyl AP-237 (1-(2-methyl-4-(3-phenylprop-2-en-1-yl)piperazin-1-yl)butan-1-one).

The Affirmative Action order, dated May 13, 2024, took effect on May 20, 2024, upon publication 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: N/A

Comparison with rules in adjacent states:

Illinois: Illinois has not listed 2-methyl AP-237 as a schedule I controlled substance [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not listed 2-methyl AP-237 as a schedule I controlled substance [Iowa Code 124.204].

Michigan: Michigan has not listed 2-methyl AP-237 as a schedule I controlled substance [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not listed 2-methyl AP-237 as a schedule I controlled substance [Minnesota Statutes 152.02 (2)].

Summary of factual data and analytical methodologies:

The methodology was to schedule 2-methyl AP-237 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 proposed rule was 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. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The fiscal estimate and economic impact 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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

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; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.008 is created to read:

CSB 2.008 Addition of 2-Methyl AP-237 to Schedule I. Section 961.14 (2) (qz), Stats., is created to read:

961.14 (2) (qz) 2-methyl AP-237 (1-(2-methyl-4-(3-phenylprop-2-en-1-yl)piperazin-1-yl)butan-1-one).

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 O	F RULE)	
Dated		Chairperson Controlled Substances Board	

Controlled Substances Board Rule Projects (updated 06/30/25)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
24-004	053-23	02/07/2026	CSB 2.98	Excluding [18 F] FP-CIT	Effective 06/01/25	N/A
24-005	054-23	02/07/2026	CSB 2.99	Scheduling Mesocarb	Effective 06/01/25	N/A
24-023	078-23	04/23/2026	CSB 2.001	Scheduling Methiopropamine	Effective 06/01/25	N/A
24-024	079-23	04/23/2026	CSB 2.002	Excluding Fenfluramine	Effective 06/01/25	N/A
24-048	001-24	07/02/2026	CSB 2.003	Transferring Flualprazolam and Scheduling 4 Other Synthetic Benzodiazepine Substances	Effective 06/01/25	N/A
24-058	048-24	11/13/2026	CSB 2.004	Scheduling Zuranolone	Effective 06/01/25	N/A
24-059	049-24	11/13/2026	CSB 2.005	Scheduling 9 Fentanyl Related Substances	Effective 06/01/25	N/A
24-083	086-24	02/05/2027	CSB 2.006	Scheduling 5 Synthetic Cannabinoids	Adoption Order Reviewed at 07/11/25 Meeting	Submission for Publication; 09/01/25 Anticipated Effective Date
24-084	087-24	02/05/2027	CSB 2.007	Scheduling ADB-BUTINANCA, α-PiHP, and 3- MMC	Adoption Order Reviewed at 07/11/25 Meeting	Submission for Publication; 09/01/25 Anticipated Effective Date
24-085	088-24	02/05/2027	CSB 2.008	Scheduling 2-methyl AP-237	Adoption Order Reviewed at 07/11/25 Meeting	Submission for Publication; 09/01/25 Anticipated Effective Date
25-021	113-24	06/02/2027	CSB 2.009	Scheduling 2 Synthetic Benzimidazole- Opioids	Legislative Review	Adoption Order Reviewed at a Future Board Meeting
Not Assigned Yet	016-25	09/10/2027	CSB 2.010 (Renumbered to 2.011)	Scheduling Ethylphenidate	Preliminary Rule Draft Reviewed at 07/11/25 Meeting	Submission for EIA Comment and Clearinghouse Review
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.011 (Renumbered to 2.012)	Scheduling 7 Fentanyl-related Substances	Scope Statement Reviewed at 07/11/25 Meeting	Drafting Rule

Controlled Substances Board Rule Projects (updated 06/30/25)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
24-013	095-22	05/21/2025	CSB 4	National Provider Identifier Requirement	Effective 07/01/25	N/A
24-033	055-23	02/07/2026	CSB 4	Monitored Prescription Drug History Reports	Effective 07/01/25	N/A
24-060	072-24	08/12/2026	CSB 4	Mail Delivered Prescriptions	Effective 07/01/25	N/A

State of Wisconsin Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of pers	on submitting the request:	2) Date when reques	2) Date when request submitted:	
Marjorie Liu		0701/2025		
Program Lead, PDMP			red late if submitted after 12:00 p.m. on the deadline ess days before the meeting	
3) Name of Board, Comn	nittee, Council, Sections:			
Controlled Substances E	Board			
4) Meeting Date:	5) Attachments:	6) How should the item be tit	led on the agenda page?	
07/11/2025		Prescription Drug Monitoring Consideration	Program (PDMP) Updates – Discussion and	
7) Place Item in: Open Session Closed Session	scheduled? (If yes	8) Is an appearance before the Board being scheduled? (If yes, please complete Appearance Request for Non-DSPS Staff) Yes 9) Name of Case Advisor(s), if required:		
10) Describe the issue a	nd action that should be add	ressed:		
1. WI ePDMP Ope	rations			
a. Recer	t and Upcoming Releases			
b. EHR li	ntegration Status			
2. WI PDMP Outre	each			
11)	Au	uthorization		
Signature of person making this request Date				
Supervisor (if required)			Date	
Marjorie Liu Jul 1, 2025				
		dd post agenda deadline item	to agenda) Date	
Directions for including		uhwitted to the seconds		
 This form should be attached to any documents submitted to the agenda. 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. 				

2023-2025 Development and Release Summary

Updated 6.30.2025

Release Date	Description
Completed	
R33.20 June 2025	Website changes adapting to NPI Requirements Automated Notification Language Updates: • Submission compliance notification when NPI is missing • Gabapentin reporting guideline updates User Portal • Healthcare Professional Account – NPI requirement pop up updates • Law enforcement/investigative unit account: NPI added to prescriber and dispenser report request screen for Data Analytics • Metrics calculations revert to DEA-based
R33.19 May 2025	Website changes adapting to NPI Requirements Data Analytics NPI Search Added to Detailed Prescriber Monitoring Report NPI Added to Opioid Prescribing Practice Summary Report Admin Portal Fixes and Updates
R33.18 April 2025	 Website Administration: On-going Formatting and Calculation cleanups for automated Reports NPI data field added to reports User Portal: NPI field added to search screen (for law enforcement, prosecutorial, and regulatory agencies)
R33.17 March 2025	 User Portal: Additional DEA fields in Prescribers account profile NPI field added in Pharmacy account profile
R33.16 February 2025	 Data Analytics Updates: MME Conversion Factors updates Buprenorphine exclusion rules applied to automated reporting of prescribing reports User Interface Updates Healthcare Professionals - MME Calculator & Addiction Resource Updates Investigators - Dispenser Report Request via User Accounts Administrative workflow updates - NPI added to Pending Account Registration Review Webpage Language Updates: Registration Page, Dashboard charts
R33.15.1	Emergency Release to fix errors for out of state queries connecting via PMPi hub

February 2025	
R33.15 January 2025	 Data Analytics Updates: New admin tool of adding additional DEA numbers to automate Detailed Prescriber Monitoring Report Formatting updates on Opioid Practice Summary Report User Interface Updates: Pharmacy Account data revise/edit screen now with multiple DEAs dropdown selection
R33.14 January 2025	Updates to online form "Report Suspected Errors in WI ePDMP Date" PDF Pharmacy additional DEA display Increased License Number Character Limits from 7 to 8 File Processing Updates - Skipping Duplicate Files
R33.13 December 2024	User Interface: • Updated Text on the Delegate Management Screen • Updated Calculations for Daily Prescribing Volume Ranking for Opioids • License Number is no Longer a Required Field for a Medical Coordinator Account Admin Portal Updates: • Added Submission Date to Prescriber Alerts Table • NDC of Dispensed Medications displayed in the prescriber Report • Updated the Prescriber Query Compliance Report
R33.12 November 2024	ePDMP Webpage Updates: Contact Us info & user registration screen for Medical Coordinator and Researcher Analytics and Reports Updates- • Prescriber Monitoring Report Charts Readability • Prescriber Address populated on Dispensing History Details Administrative Workflow Enhancement: Alert reviewing screen updates
R33.11 September 2024	Non – HCP Alert Displays on Requested Reports Detailed Prescriber Monitoring Report Rework Updated Quarterly CSB Reports Prescriber Address Visible on Patient Report Table
R33.10 August 2024	Automation of Reports: Opioid Prescribing Practice Summary Report Review Quarterly Statistics for CSB Report Review Detailed Prescriber Monitoring Report Review Prescriber Address Populated on UI EHR Support Partial Refill Review
R33.9 July 2024	Opioid Prescribing Practice Summary Report Review Text Updates in UI Updates to notification emails Prescriber Query Compliance Report update

R33.8 June 2024	Opioid Prescribing Practice Summary Report Review Quarterly CSB Report Review Compound Drug UI Statistic utilization optimizations Addition of email address to non-HCP query requests
R33.7 May 2024	Dispenser Compliance Report Review Submitter/Dispenser Report Review
R33.6 April 2024	 System Updates Pending Account Changes UI language UAT email notification links Controlled Substance UI language Updated error messages for Submitters RXCheck 3.1 Update and Patch Statistics Dashboard populate counties' logic EHR Support
R33.5 March 2024	Statistics reporting updates EHR/Epic OAuth Support File Submission Queue processing
R33.4 February 2024	DEA File Updates LicenseE Update – State License Validation Training Materials Update File Processing support EHR support
R33.3 January 2024	LicenseE Update – New User Registration LicenseE Update – User Login Validation PDMP UI Page Text Updates • Home Page • Contact Us • Patient History Detail File Processing Support EHR Support
R33.2 January 2024	Pharmacy Users fixes
R33.1 November 2023	Utilization page updates PMPi States Admin Manage Alerts Timeout Patient Matching Updates

R33.0 November 2023	Geocoding Address2 Line rejection Updated Submitter Guide	
R32.5 October 2023	File processing support	
R32.4 October 2023	EHR Support	
R32.3 October 2023	EHR Support	
R32.2 October 2023	EHR Support	
R32.1 October 2023	Iframe support Epic	
R32 October 2023	HRG 2020 Grant Release	

WI ePDMP Integration Services Summary

Updated 06.30.2025

Pending Health Systems and EHR Platforms		Notes		
Internal Medicine Associates	In discussion			
MECFS Clinic MN	In discussion			
Oak Leaf	In discussion			
CareATC	In discussion			
Connected Health Systems (61% of monthly patient queries)	Free Pricing Model	Implementation Date	Est. Total # of Users	Notes
Advent Health		03/05/2023	15	
Allina Health	Υ	09/18/2023	100	
Ascension Wisconsin				
Aspirus Health Care				
Aurora Health Care	Υ	05/08/2024	12,000	
Children's Hospital of Wisconsin	Υ	09/01/2022	300	
Clark County	Υ	11/01/2023		
Clean Slate	Υ	09/01/2022	26	
CompuGroup Medical	Υ	08/14/2024	50	
DrFirst	Υ	05/01/2025		
Froedtert & the Medical College of Wisconsin			100	Pending signed Free agreement
GHC of South Central Wisconsin	Υ	09/01/2024		
Gundersen Health System			800	Pending signed Free agreement
HealthPartners				
HSHS / Prevea Health	Υ	01/01/2023	500	
M Health Fairview	Υ	08/01/2022	30	
Marshfield Clinic	Υ	09/01/2022	100	
Mayo Clinic				
Mercy Health	Υ	08/01/2022	766	
Monroe Clinic				

NOVO Health Technology Group	Υ	02/01/2023		
Ochin	Υ	12/21/2022	100	
ProHealth Care	Υ	1/17/2025		
QuadMed, LLC	Υ	5/17/2023	40	
SSM Health				
Thedacare				Pending signed Free agreement
UnityPoint				
UW Health			4000	
Wisconsin Statewide Health Information Network	Y	09/01/2022	3500	

DrFirst Facilities			
Alay Health Team	National Medical Groups		
Associated Mental Health Consultants	Nova Integrated Care LLC		
Behavioral Health Svcs of Racine Co.	Oak Medical		
Benjamin S. Gozon MDSC D/B/A Capitol Rehabilitation Clinic	Oral Surgery Associates of Milwaukee		
Christian Family Solutions	Orthopedic Hospital of Wisconsin		
Door County Memorial Hospital	Pain Management and Treatment Center		
Dr. Colleen Worth, DNP, APNP	Pediatrics Associates		
Empower Recovery	Reka Furedi MD		
Envision ADHD Clinic	Red Oak Counseling		
FAMILY PSYCHIATRIC CARE, LLC	Regional Medical Center		
Fort Healthcare	Richland Hospital		
GI Associates LLC	Rogers Memorial Hospital		
Heartland Hospice	Sauk Prairie Memorial Hospital		
Jonathan Hoerl PMHNP	Shorewood Behavioral Health		
Kelly Pickens	Third Eye Health		
Lake Superior Community Health Center	University of Wisconsin - Milwaukee		
Linc Health Clinic	Watertown Rainbow Hospice		
Lifestance Health WI	Wauwatosa Children's Clinic		
Madison Recovery Center	Watertown Regional Medical Center		

Marshfield Clinic Health System	Yee Xiong MD
Mental Health Specialty Group PA	
Mile Bluff Medical Center	
Milwaukee Medical Associate, SC	
Mindful Healing and Wellness LLC	

2025 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	1/9/2025	Virtual; Quarterly Meeting
February				
March	Bi-Annual RxCheck Governance Board Meeting	Board Member-Participant; Interstate PDMP data exchange discussion	3/18-3/19/2025	San Diego, CA
April	Overdose Fatality Review (OFR) Local Community Meeting	PDMP Presentation; Portage County OFR Team Meeting	4/1/2025	Virtual
	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	4/10/2025	Virtual; Quarterly Meeting
May	Opioids, Stimulants, and Trauma Summit	Information Booth	5/6-5/8/2025	Wisconsin Dells
June	PMP InterConnect Steering Committee Meeting	Participant; Annual national meeting for PDMP administrators organized by National Association of Boards of Pharmacy (NABP)	6/23-6/24/2025	Mount Prospect, IL
July	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	7/10/2025	Virtual; Quarterly Meeting
August	·			
September	BadgerTraCS-PDMP Reporting Training	Collaborative project across DOJ, DOT, & DSPS on promoting entry of law enforcement alerts	On-going	
October	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	10/9/2025	Virtual; Quarterly Meeting
	NASCSA Conference (National Association of State Controlled Substances Authorities)	Participant; annual national meeting organized by NASCSA for government controlled substances authority, PDMP and healthcare professionals	10/20-10/23/2025	New Orleans, LA
November				
December	Bi-Annual RxCheck Governance Board Meeting	Board Member-Participant; Interstate PDMP data exchange discussion	TBD	TBD

State of Wisconsin Department of Safety & Professional Services

AGENDA REQUEST FORM

Name and title of person submitting the request:		2) Date when reques	st submitted:		
Whitney DeVoe on behalf of the Interdisciplinary Advisory Committee		_	6/26/2025		
		Items will be considered late if submitted after 12:00 p.m. on the			
Name of Board, Committee, Council, Sections and Meeting Dates:				is 8 business days before the meeting	
Name of Board, Committee, C	Journell, dections at	ia weetii	ig Dates.		
Physician Assistant Affiliated Credentialing Board, 6/26/2025 Board of Nursing, 7/10/2025 Controlled Substances Board, 7/11/2025 Medical Examining Board, 7/16/2025 Cosmetology Examining Board, 7/28/2025					
Pharmacy Examining Boa					
5) Attachments:		6) How s	should the item be titl	led on the agenda page?	
☑ Yes [Draft Doc]		Interdisc	ciplinary Advisory Co	mmittee – Discussion and Consideration	
□ No	1. Draft IV Hydration G 2. Future Topics			ildance Document	
7) Place Item in:	8) Is an appearance		the Board being	9) Name of Case Advisor(s), if applicable:	
□ Open Session	scheduled? (If yes,			n/a	
☐ Closed Session	Appearance Reque	st for Nor	n-DSPS Staff)		
10) Describe the issue and action	No	roos adı			
Seeking Board approval of the IV Hydration Guidance Document and referral back to IAC for finalization and discussion of potential future topics.					
11)	Aı	uthorizat	tion		
Whitney De Voe				6/26/2025	
Signature of person making this re	eguest			Date	
Directions for including supporting documents: 1. This form should be saved with any other documents submitted to the <u>Agenda Items</u> folders. 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.					

- 1 JOINT ADVISORY OPINION OF THE WISCONSIN EXAMINING BOARDS OF
- 2 MEDICAL, NURSING, PHARMACY, AND COSMETOLOGY, AND THE PHYSICIAN
- 3 ASSISTANT AFFLIATED CREDENTIALING BOARD, AND THE WISCONSIN
- 4 CONTROLLED SUBSTANCES BOARD
- 5 It is the overall duty of each Examining Board to improve the profession they supervise, both
- 6 within and outside its own profession, to bring about a better relationship between the profession
- 7 and the general welfare of this state. Each Examining Board is empowered to set standards of
- 8 professional competency and conduct for the profession it supervises. With these principles in
- 9 mind, the Interdisciplinary Advisory Committee (Committee) consisting of the Wisconsin Medical
- 10 Examining Board, Pharmacy Examining Board, Board of Nursing, Physician Assistant Affiliated
- 11 Credentialing Board, Cosmetology Examining Board and Controlled Substances Board was
- 12 established to discuss issues of mutual concern.
- In recent years, Wisconsin has seen an increase in the intravenous (IV) hydration therapy business
- and the Wisconsin Department of Safety and Professional Services (DSPS) has seen an increase
- in questions from healthcare professionals concerning the legal requirements for IV hydration
- therapy businesses.
- 17 IV hydration therapy businesses provide patients with IV fluids with or without prescription
- medications, vitamins, minerals and/or amino acids. Based on inquiries received by DSPS, there
- 19 appears to be confusion among healthcare professionals and the public as it relates to
- 20 understanding the responsibilities of healthcare professionals engaged in these businesses.
- 21 Because of the concern over the lack of any industry-specific guidelines or laws regarding the
- operation of these businesses and the potential harm to the residents of Wisconsin, the Committee
- 23 puts forth this guidance document. This guidance document is based upon the existing laws of
- 24 Wisconsin and sets forth the relevant laws and standards of care implicated by IV hydration
- 25 therapy businesses within the context of a retail or "on-demand" business setting.¹
- 26 For purposes of this guidance document, the Committee has divided the practice occurring at IV
- 27 hydration businesses into three main stages: assessment, compounding, and administration. The
- 28 guidance below is meant to assist licensees in understanding the laws and regulations implicated
- at each stage. Please note, this is not an exhaustive list, but rather a list addressing the most
- 30 commonly raised practice concerns.

BACKGROUND

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- 32 Prior to discussion of the specific stages, the Committee believes it is crucial to highlight that
- services offered by IV hydration therapy businesses constitute the practice of medicine and surgery.
- 34 The practice of medicine and surgery is defined as meaning:

¹ This guidance is meant to specifically address the emerging market for IV Hydration therapy or businesses offering IV Hydration therapy services. Underlying principles established in this guidance may be applicable to other services offered by healthcare professionals. Please contact private counsel to review your specific business model for compliance with relevant laws and regulations.

[t]o examine into the fact, condition or cause of human health or disease, or to treat, operate, prescribe or advise for the same, by any means or instrumentality ... [t]o apply principles or techniques of medical sciences in the diagnosis or prevention of any of the conditions described in par. (a) and in sub. (2) ... [t]o penetrate, pierce or sever the tissues of a human being ... [t]o offer, undertake, attempt or do or hold oneself out in any manner as able to do any of the acts described in this subsection.

See Wis. Stat. § 448.01(9). Further, pursuant to Wis. Stat. § 448.03, "[n]o person may practice medicine or surgery, or attempt to do so or make a representation as authorized to do so, without a license to practice medicine or surgery" except for "[a]ny person lawfully practicing within the scope of a license, permit, registration, certificate, or certification granted to practice... professional or practical nursing or nurse-midwifery under ch. 441... to practice as a physician assistant under subch. IX... or as otherwise provided by statute."

At its core, the IV hydration therapy business model involves offering patients, including on a walk-in basis, a menu of pre-selected mixtures ("cocktails") of additives to basic IV saline. The cocktails may include fluids with or without prescription medications, vitamins, minerals and/or amino acids. Some basic health screening generally occurs prior to the selection and administration of the IV. It is of concern to the Committee that the basic health screening and selection of IVs are being performed by unlicensed individuals or licensees whose scope of practice does not allow for the practice of medicine or surgery.

Although many IV hydration therapy businesses may have a physician, physician assistant (PA) or advanced practice nurse prescriber (APNP) associated with the business, in some instances a registered nurse (RN) may be the only licensed health care professional interacting with the patient. The Committee wants to make clear that a registered nurse (RN), or any individual not holding the proper credential, undertaking the diagnosing and prescribing of medications falls outside an RN's scope of practice² and can result in disciplinary action against not only the RN's license, but also the physician, PA, or APNP overseeing the practice.

Moreover, IV hydration therapy fluids and additives are prescription drugs requiring purchase and storage by a qualified practitioner which may include a physician, PA, or APNP. Fluids and additives must be purchased from FDA licensed manufacturers, distributors licensed in the state where they are being purchased, or from compounding pharmacies designated and licensed as 503B compounding facilities. Non-qualified individuals, including, but not limited to RNs or licensed practical nurses (LPNs), may not possess or store prescription drugs in any location not appropriately licensed by the Pharmacy Examining Board.

² It is not within the scope of practice for an RN or LPN to independently engage in acts that require independent medical diagnosis, or the ordering, compounding, or prescribing of IV fluids, IV medications, or IV therapeutic regimens. See Wis. Stat. § 441.001(4) and Wis. Admin. Code § N 6.03.

72 ASSESSMENT

- 73 The patient must be assessed prior to ordering any IV Hydration treatment. Practitioners who may
- order treatment appropriate to their area of competence as established by their education, training,
- 75 or experience include:

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- A physician licensed to practice medicine and surgery in this state as defined in Wis. Stat. § 448.01(5).
 - A PA licensed pursuant to Wis. Stat. § 448.974.
 - An APNP licensed pursuant to Wis. Stat. § 441.16.
- 80 Although telehealth may be utilized to perform the initial patient assessment, it is the
- 81 recommendation of this Committee that patient assessment should be done in person, as a
- 82 complete medical assessment is difficult to conduct via telehealth. Certain conditions may be
- hard to evaluate without an in-person assessment including an assessment of necessary organ
- 84 systems. An assessment consisting merely of a simple questionnaire without an appropriate
- 85 clinical assessment would not meet the standard of care and is considered unprofessional conduct
- pursuant to Wis. Admin. Code § Med 24.07(2). A patient assessment should include at minimum
- a history and physical exam. Although a nurse may complete certain delegated portions of the
- assessment, a patient assessment should not rely solely on findings from a nursing assessment.
- As part of the assessment, the practitioner may diagnose the patient's condition and shall make
- 90 recommendations consistent with the findings from the history and physical as to treatment.
- 91 Treatment recommendations may include a discussion with the patient surrounding which
- 92 therapies, including the addition of specific additives, may be appropriate to treat the patient's
- condition. These discussions should include a description of risks, benefits and alternative
- options. To be clear, this constitutes the practice of medicine and should only be undertaken by a
- 95 practitioner with statutory authority to diagnose and treat. The discussion with a patient and
- 96 recommendation shall be provided by the practitioner.
- 97 Following the assessment, the practitioner may prescribe the appropriate therapy or treatment. The
- 98 use of standing orders outside of an established practitioner-patient relationship for an
- 99 individualized assessment, diagnosis and treatment of patients may be considered prescribing in a
- manner inconsistent with the standard of minimal competence pursuant to Wis. Admin. Code §
- 101 Med 10.03(2)(c).
- To ensure the assessment complies with the standard of care, after evaluating the patient and
- making treatment recommendations, a comprehensive medical record must be created.
- Additionally, informed consent shall be obtained to be consistent with the standard of care.
- Informed consent should include, but not be limited to, the risks of additives to saline, the risks of
- 106 IV fluids, and the risks of an IV itself. Medical records must be stored in compliance with state
- and federal law, including those with the Wisconsin Department of Health Services.

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³ Telehealth is only acceptable if it meets established regulations. See Wis. Admin. Code chs. Med 24, PA 3 and N 8.

COMPOUNDING

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- After determining a course of treatment, a cocktail containing the additives ordered may need to
- be prepared. When an individual adds medications, vitamins, minerals and/or amino acids to IV
- bags, they are engaging in the practice of compounding, and federal and state law including section
- 503A of the Food, Drug, and Cosmetic Act apply. Application of these laws help ensure patients
- receive their treatment in sanitary conditions.
- Pursuant to Wis. Stat. § 450.01(16), the practice of pharmacy includes the compounding,
- packaging, and labeling of drugs and devices. Further, pursuant to Wis. Stat. § 450.01(3),
- compound "means to mix, combine or put together various ingredients or drugs for the purpose of
- dispensing." Federal law allows either a licensed pharmacist or a physician to perform
- 121 compounding.
- The United States Pharmacopeia (USP) is the recognized publication that contains standardized
- requirements for compounding, including sterile compounding found in USP <797> and has been
- adopted by the FDA and the Wisconsin Pharmacy Examining Board as the enforceable standard.
- USP <797> applies to all individuals who prepare compounded sterile preparations (CSPs) and all
- places where CSPs are prepared for human and animal patients.
- The utilization of the "immediate use" provision of USP <797> does not circumvent USP sterile
- 128 compounding requirements. Additionally, the "immediate use" provision requires certain
- conditions be met, including,
 - Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
 - Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.
 - The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies).
 - The preparation involves not more than 3 different sterile products. Please note, Saline Solution utilized in IV Hydration is a sterile product and must be included in this analysis.
 - Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.
 - Administration begins within 4 hours following the start of preparation. If administration has not begun within 4 hours following the start of preparation, it must be promptly, appropriately, and safely discarded.
- Unless it is directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all

- active ingredients, the name or initials of the person who prepared the preparation, and the 4-hour time period within which administration must begin.⁴
- 151 The provision of USP <797> allowing for immediate use should not be viewed as a workaround
- for the standards governing sterile product preparation. Failure to comply with these standards
- may result in unsanitary and unsafe conditions for patients.⁵

ADMINISTRATION

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- Upon receipt of an order for IV hydration therapy, an individual with appropriate training and
- experience⁶, including an RN or LPN (consistent with the requirements of Wis. Admin. Code ch.
- 157 N 6), may administer the treatment.
- 158 While the patient undergoes the IV administration, an RN should perform a nursing assessment of
- the patient including monitoring their vital signs. Please note that the performance of a nursing
- assessment is outside the scope of an LPN. An RN should monitor the patient for side effects,
- allergic reactions or any unusual or unexpected effects. An RN is expected to document all nursing
- acts performed by the RN as part of the administration and monitoring of the patient.

163 CONCLUSION

- The practices engaged in at IV hydration clinics involve the practice of multiple professions.
- Individuals engaged in these practices must hold the appropriate license and practice within the
- scope of practice allowed by their credentials. Licensees who fail to follow the laws governing
- their practice could be subject to disciplinary proceedings as appropriate.
- Licensees are charged with protecting the public by ensuring their practice complies with the laws
- and regulations of Wisconsin and any relevant federal regulations, including satisfying all
- applicable professional standards.

171 ACKNOWLEDGEMENT SECTION

- 172 These materials may have been consulted in the preparation of the above document.
- ARIZONA STATE BOARD OF NURSING, Advisory Opinion Intravenous Hydration and Other Therapies (Revised date
- May 2024), Available at https://azbn.gov/sites/default/files/AO-IV-Hydration-Other-Therapies.pdf

⁴ Handling of sterile hazardous drugs must comply with USP <800> as well.

⁵ See FDA highlights concerns with compounding of drug products by medical offices and clinics under insanitary conditions https://www.fda.gov/drugs/human-drug-compounding/fda-highlights-concerns-compounding-drug-products-medical-offices-and-clinics-under-insanitary

⁶ For example, if an electrolyte is being administered by IV, the IV should be administered using a volumetric infusion pump or rate-controller tubing to ensure the electrolytes are administered at an appropriate rate to avoid and prevent adverse reactions. The individual administering the IV in this case should have training and experience using these devices.

- 175 KENTUCKY.GOV, Joint Statement of the Kentucky Boards of Medical Licensure, Nursing, and Pharmacy Regarding
- 176 Retail IV Therapy (March 28, 2025), available at https://kbn.ky.gov/KBN%20Documents/Joint%20Statement%20-
- 177 %20IV%20Hydration%20Clinics.pdf

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- 178 MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE, Guidance Regarding IV Hydration Therapy from the Mississippi
- 179 State Board of Medical Licensure (Sept. 5, 2023), available at
- https://www.msbml.ms.gov/sites/default/files/news/IV%20Hydration%20Therapy%20Guidance%2009-05-23.pdf
- 181 NEBRASKA BOARD OF NURSING, Advisory Opinion: IV/Infusion Therapy (Nov. 2023), available at
- https://dhhs.ne.gov/licensure/Documents/IVInfusion.pdf
- 183 OHIO BOARD OF PHARMACY, Joint Regulatory Statement of the State Medical Board of Ohio, Ohio Board of Pharmacy,
- 184 and Ohio Board of Nursing Regarding Retail IV Therapy (May 15, 2025), available at
- https://www.pharmacy.ohio.gov/documents/pubs/special/ivtherapy/joint%20regulatory%20statement%20on%20the
- %20operation%20of%20retail%20iv%20therapy%20clinics%20in%20ohio.pdf
- 187 RHODE ISLAND DEPARTMENT OF HEALTH, Rhode Island Department of Health Guidance Document Regarding the
- 188 Operation of Medical Spas and Intravenous (IV) Therapy Businesses (July 2024), available at
- 189 https://health.ri.gov/sites/g/files/xkgbur1006/files/publications/guidance/Medical-Spa-and-IV-Therapy-Business.pdf
- 190 SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION, Joint Advisory Opinion of the South
- 191 Carolina State Boards of Medical Examiners, Pharmacy, and Nursing Regarding Retail IV Therapy Businesses (Aug.
- 192 15, 2023), available at https://llr.sc.gov/med/Policies/Joint-Position-Statement-Retail-IV-Therapy.pdf