Wisconsin Department of Safety and Professional Services Division of Policy Development 4822 Madison Yards Way, 2nd Floor 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 PHARMACY EXAMINING BOARD

Virtual, 4822 Madison Yards Way, Madison Contact: Brad Wojciechowski (608) 266-2112 February 20, 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 of the Board.

AGENDA

11:00 A.M.

OPEN SESSION - CALL TO ORDER - ROLL CALL

- A. Adoption of Agenda (1-5)
- B. Approval of Minutes of December 5, 2024 (6-10)
- C. Reminders: Conflicts of Interest, Scheduling Concerns
- D. Introductions, Announcements and Recognition Discussion and Consideration
 - 1. Introduction and Welcome DSPS Secretary Hereth
- E. 11:00 A.M. PRELIMINARY PUBLIC HEARING on STATEMENT OF SCOPE SS 002-25 on Phar 1, 6, 7, and 10, Relating to Pharmacy Workplace Conditions (11-14)
 - 1. Review Preliminary Hearing Comments
- F. 11:00 A.M. PUBLIC HEARING: Clearinghouse Rule 24-092 on Phar 15, Relating to Compounding Pharmaceuticals (15-26)
 - 1. Review Public Hearing Comments and Respond to Clearinghouse Report
- G. Administrative Matters Discussion and Consideration
 - 1. Department, Staff and Board Updates
 - 2. 2025 Meeting Dates (27)
 - 3. Annual Policy Review (28-30)
 - 4. Election of Officers, Appointments of Liaisons and Alternates, Delegation of Authorities (31-51)
 - 5. Board Members Term Expiration Dates
 - a. Kleppin, Susan -7/1/2025
 - b. O'Hagan, Tiffany M. -7/1/2028
 - c. Peterangelo, Anthony -7/1/2027
 - d. Walsh, Michael -7/1/2024
 - e. Weitekamp, John G. -7/1/2026
 - f. Wilson, Christa -7/1/2025

H. Legislative and Policy Matters – Discussion and Consideration

I. Administrative Rule Matters – Discussion and Consideration (52-61)

- 1. Second Extension Request: EmR 2411 on Phar 8, Relating to Controlled Substances Requirements (53-60)
- 2. Pending or Possible Rulemaking Projects (61)

J. Speaking Engagements, Travel, or Public Relation Requests, and Reports – Discussion and Consideration (62-63)

- 1. Travel Report: NABP Member Forum, December 4-5, 2024 Tiffany O'Hagan
- 2. Travel Request: MPJE Item Development Workshop, March 12-14, 2025, NABP Headquarters
- 3. Speaking Engagement: Pharmacy Society of Wisconsin Legislative Day, March 19, 2025, Madison, WI
- 4. Travel Request: NAPLEX Item Development Workshop, April 15-17, 2025, NABP Headquarters

K. Pharmacy Examining Board Guidance – Discussion and Consideration

- 1. Pharmacy Technicians (64)
- 2. Pending or Possible Guidance Projects
- L. NABP Pulse Regulator Monthly Champions Call Discussion and Consideration
- M. Interdisciplinary Advisory Council Discussion and Consideration
- N. Credentialing Matters Discussion and Consideration
- O. Liaison Reports Discussion and Consideration
- P. Discussion and Consideration on Items Added After Preparation of Agenda
 - 1. Introductions, Announcements and Recognition
 - 2. Nominations, Elections, and Appointments
 - 3. Administrative Matters
 - 4. Election of Officers
 - 5. Appointment of Liaisons and Alternates
 - 6. Delegation of Authorities
 - 7. Education and Examination Matters
 - 8. Credentialing Matters
 - 9. Practice Matters
 - 10. Legislative and Policy Matters
 - 11. Administrative Rule Matters
 - 12. Public Health Emergencies
 - 13. Pilot Program Matters
 - 14. Variances
 - 15. Liaison Reports
 - 16. Board Liaison Training and Appointment of Mentors
 - 17. Informational Items
 - 18. Division of Legal Services and Compliance (DLSC) Matters
 - 19. Presentations of Petitions for Summary Suspension
 - 20. Petitions for Designation of Hearing Examiner
 - 21. Presentation of Stipulations, Final Decisions and Orders
 - 22. Presentation of Proposed Final Decisions and Orders
 - 23. Presentation of Interim Orders

- 24. Pilot Program Matters
- 25. Petitions for Re-Hearing
- 26. Petitions for Assessments
- 27. Petitions to Vacate Orders
- 28. Requests for Disciplinary Proceeding Presentations
- 29. Motions
- 30. Petitions
- 31. Appearances from Requests Received or Renewed
- 32. Speaking Engagements, Travel, or Public Relation Requests, and Reports

Q. 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 closing disciplinary investigations with administrative warnings (ss. 19.85(1)(b), and 440.205, 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.).

R. Credentialing Matters

- 1. Application Reviews
 - a. C.J.F. Pharmacist (IA 367245) (65-92)
 - b. C.L. Pharmacist (IA 371498) (93-163)
 - c. C.S. Pharmacy Technician (IA 456979) (**164-187**)
 - d. G.N. Pharmacist (IA 480573) (188-191)
 - e. S.P. Pharmacy (Out of State) (IA 509288) (192-207)
 - f. Z.J. Pharmacist (IA 520895) (208-248)

S. Deliberation on Division of Legal Services and Compliance Matters

- 1. Administrative Warnings
 - a. 23 PHM 151 W.P. (249-250)
 - b. 23 PHM 179 S.M.D. (251-252)
 - c. 24 PHM 0088 N.K.P. (253-254)
 - d. 24 PHM 0102 G.J.R. (255-256)
 - e. 24 PHM 0102 T.K.L. (257-258)
 - f. 24 PHM 0121 K.G.V. (259-260)
 - g. 24 PHM 0151 C.P. (261-262)
- 2. Case Closings
 - a. 22 PHM 129 P.S.P. **(263-270)**
 - b. 21 PHM 094 W. (271-276)
 - c. 23 PHM 009 H.P. (277-280)
 - d. 24 PHM 014 M.J.R. (281-283)
 - e. 24 PHM 017 W. (284-286)
 - f. 24 PHM 0047 S.P. (287-290)
 - g. 24 PHM 0051 C.P. **(291-294)**
 - h. 24 PHM 0070 H.P. (295-298)
 - i. 24 PHM 0088 W.P. (299-303)
 - j. 24 PHM 0100 H.P., N.A., T.J.A., A.B., and K.Z. (304-316)
 - k. 24 PHM 0102 W.P. (317-323)
 - 1. 24 PHM 0121 W. and M.C. (324-330)
 - m. 24 PHM 0128 K.E.B. and Y.O.P. (331-335)
 - n. 24 PHM 0131 C.P. and D.S. (336-343)

3. Proposed Stipulations, Final Decisions and Orders

- a. 23 PHM 054 Chelsea L. Wilson (344-651)
- b. 23 PHM 147 Laquisha S. Clay (352-358)

T. Monitoring Matters (359-482)

- 1. Monitor Heller
 - a. Omar H. Eliwa, Pharmacist Requesting Full Licensure (361-385)
 - b. Welltopia Pharmacy, Pharmacy Entity Requesting Full Licensure (386-482)
- U. Deliberation of Items Added After Preparation of the Agenda
 - 1) Education and Examination Matters
 - 2) Credentialing Matters
 - 3) Application Reviews
 - 4) DLSC Matters
 - 5) Monitoring Matters
 - 6) Professional Assistance Procedure (PAP) Matters
 - 7) Petitions for Summary Suspensions
 - 8) Petitions for Designation of Hearing Examiner
 - 9) Proposed Stipulations, Final Decisions and Orders
 - 10) Proposed Interim Orders
 - 11) Administrative Warnings
 - 12) Review of Administrative Warnings
 - 13) Proposed Final Decisions and Orders
 - 14) Matters Relating to Costs/Orders Fixing Costs
 - 15) Case Closings
 - 16) Board Liaison Training
 - 17) Petitions for Assessments and Evaluations
 - 18) Petitions to Vacate Orders
 - 19) Remedial Education Cases
 - 20) Motions
 - 21) Petitions for Re-Hearing
 - 22) Appearances from Requests Received or Renewed
- V. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

ADJOURNMENT

NEXT MEETING: APRIL 17, 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 PHARMACY EXAMINING BOARD MEETING MINUTES DECEMBER 5, 2024

PRESENT: Susan Kleppin; Anthony Peterangelo, Michael Walsh, John Weitekamp, Christa

Wilson

ABSENT: Tiffany O'Hagan

STAFF: Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel;

Nilajah Hardin, Administrative Rules Coordinator; Tracy Drinkwater, Board

Administration Specialist; and other Department staff

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 11:03 a.m. A quorum was confirmed with five (5) members present.

ADOPTION OF AGENDA

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to adopt the

Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF OCTOBER 24, 2024

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to approve the

Minutes of October 24, 2024, as published. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Extension Request: EmR 2411 on Phar 8, Relating to Controlled Substances Requirements

MOTION: John Weitekamp moved, seconded by Michael Walsh, to request an

extension for EmR 2411 (Phar 8) relating to Controlled Substances

Requirements. Motion carried unanimously.

2025 Wis. Stat. s. 227.29 Biennial Report to the Legislature

MOTION: Christa Wilson moved, seconded by Anthony Peterangelo, to designate the

Chairperson to approve the report required under Wis. Stat. 227.29 for submission in March 2025 to the Joint Committee for Review of

Administrative Rules. Motion carried unanimously.

<u>IMPLEMENT 2021 WISCONSIN ACT 9 – TOP 100 MOST PRESCRIBED DRUGS</u>

MOTION: Michael Walsh moved, seconded by Christa Wilson, to designate

Chairperson John Weitekamp to approve the Top 100 Most Prescribed Drugs with DSPS Staff for publication on the DSPS website. Motion

carried unanimously.

Pharmacy Examining Board Meeting Minutes December 5, 2024 Page 1 of 5

SPEAKING ENGAGEMENTS, TRAVEL, OR PUBLIC RELATION REQUESTS, AND REPORTS

<u>Travel Request: 2025 Tri-Regulator Symposium and Opioid Regulatory Collaborative Summit</u>

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to designate

John Weitekamp, to attend the 2025 Tri-Regulator Symposium and Opioid Regulatory Collaborative Summit, March 6-7, 2025 – Tysons Corner, VA.

Motion carried unanimously.

Travel Request: 121st NABP Annual Meeting, May 13-16, 2025, Ft. Lauderdale, FL

MOTION: Christa Wilson moved, seconded by Michael Walsh, to designate John

Weitekamp, Tiffany O'Hagan and Brad Wojciechowski, to attend the 121st NABP Annual Meeting, May 13-16, 2025 – Fort Lauderdale, FL.

Motion carried unanimously.

CLOSED SESSION

MOTION: Susan Kleppin moved, seconded by Christa Wilson, to 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 closing disciplinary investigations with administrative warnings (ss. 19.85(1)(b), and 440.205, 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.). John Weitekamp, Chairperson, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Susan Kleppin-yes; Anthony Peterangelo-yes; Michael Walsh-yes; John Weitekamp-yes; and Christa Wilson-yes. Motion carried

unanimously.

The Board convened into Closed Session at 11:25 a.m.

CREDENTIALING MATTERS

Application Reviews

C.J.F. – Pharmacist (IA 367245)

MOTION: Susan Kleppin moved, seconded by Christa Wilson, to request additional

information from C.J.F. and to authorize the Board liaison to make a final

determination on the application (IA-367245). Motion carried

unanimously.

Z.A.L. – Pharmacy Technician (IA 375221)

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to approve the

Pharmacy Technician renewal application of Z.A.L. once all requirements

are met. Motion carried unanimously.

P.L.M. – Pharmacy Technician (IA 377278)

MOTION: Christa Wilson moved, seconded by Susan Kleppin, to request additional

information from P.L.M. and to authorize the Board liaison to make a final

determination on the application (IA-377278). Motion carried

unanimously.

T.O.E.S. – Pharmacy (Out of State) (IA 409292)

MOTION: John Weitekamp moved, seconded by Michael Walsh, to approve the

Pharmacy (Out of State) application of T.O.E.S., once all requirements are

met. Motion carried unanimously.

S.M.Y. – Pharmacy Technician (IA 432049)

MOTION: Christa Wilson moved, seconded by Michael Walsh, to approve the

Pharmacy Technician application of S.M.Y., once all requirements are

met. Motion carried unanimously.

DELIBERATION ON DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Administrative Warnings

23 PHM 134 - K.L.J.

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to issue an

Administrative Warning in the matter of K.L.J., DLSC Case Number 23

PHM 134 amended as follows: 1) c. "Ms.". Motion carried unanimously.

MOTION: Susan Kleppin moved, seconded by John Weitekamp, to issue an

Administrative Warning in the following DLSC Cases:

1. 23 PHM 149 – K.G.

2. 24 PHM 0032 – O.N.E.

3. 24 PHM 0032 – X.P.

Motion carried unanimously.

Case Closings

22 PHM 141 – P.P.S.

MOTION: Michael Walsh moved, seconded by John Weitekamp, to refer back DLSC

Case Number 22 PHM 141, against P.P.S., to DLSC for further

investigation. Motion carried unanimously.

Pharmacy Examining Board Meeting Minutes December 5, 2024 Page 3 of 5 **MOTION:** Anthony Peterangelo moved, seconded by Susan Kleppin, to close the following DLSC Cases for the reasons outlined below:

- 1. 22 PHM 077 W. No Violation
- 2. 23 PHM 005 F.P. No Violation
- 3. 23 PHM 017 W.I.P. No Violation
- 4. 23 PHM 058 H.V. No Violation
- 5. 23 PHM 086 P.N.S. No Violation
- 6. 23 PHM 092 W.P. No Violation
- 7. 23 PHM 095 W. No Violation
- 8. 23 PHM 124 W. Insufficient Evidence
- 9. 23 PHM 134 W. No Violation
- 10. 23 PHM 149 W. Prosecutorial Discretion (P2)
- 11. 23 PHM 168 B., B.I., M.I.D. Insufficient Evidence
- 12. 23 PHM 180 W. Prosecutorial Discretion (P1)
- 13. 24 PHM 013 M.S. No Violation
- 14. 24 PHM 021 M.I. No Violation
- 15. 24 PHM 0058 J.J.P. Prosecutorial Discretion (P1)
- 16. 24 PHM 0076 C.C.P. No Violation

Motion carried unanimously.

Proposed Stipulations, Final Decisions and Orders

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of the following cases:

- 1. 21 PHM 056, 21 PHM 152, 22 PHM 109, 23 PHM 022, 23 PHM 065, 23 PHM 102, 23 PHM 135, and 24 PHM 007 RGH Enterprises, LLC dba Edgepark Medical Supplies
- 2. 23 PHM 184 Mark G. Anderson

Motion carried unanimously.

RECONVENE TO OPEN SESSION

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 1:17 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

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

ADJOURNMENT

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 1:19 p.m.



State of Wisconsin Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:		2) Date when request submitted:				
Nilajah Hardin Administrative Rules Coordinator		02/07/25 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:
Pharmacy Examining I	Board					
4) Meeting Date:	5)	6) How should th	e item be title	ed on the agenda page?		
02/20/25	Attachments:	11.00 A M Dwo	liminam; Ua	paring on Statement of Seene SS 002 25 on Phon		
	⊠ Yes			inary Hearing on Statement of Scope – SS 002-25 on Phar ating to Pharmacy Workplace Conditions		
	☐ No			y Hearing Comments		
7) Place Item in:	8) Is an anneara	nce before the Boa	ard being	9) Name of Case Advisor(s), if required:		
<u> </u>		ves, please complete		N/A		
☑ Open Session☐ Closed Session	Appearance Re	<mark>guest</mark> for Non-DSPS	S Staff)	IVA		
Closed Session	☐ Yes					
	⊠ No					
10) Describe the issue a	and action that sho	uld be addressed:				
The Board will hold a	Preliminary He	aring on this scop	e statement	as directed by the Joint Committee for Review of		
Administrative Rules		3		·		
11)		Authoriza	ition			
Melajoura	Harolis			02/07/25		
Signature of person ma	king this request		Date			
Supervisor (if required)				Date		
Executive Director sign	ature (indicates an	proval to add post	agenda deag	Iline item to agenda) Date		
	ataro (maroatoo ap	provide to dad poor	agonaa acaa	amic nom to agonas, Dato		
Directions for including						
1. This form should be						
				he Policy Development Executive Director. signature to the Bureau Assistant prior to the start of a		
meeting			onan person s	signature to the Dureau Assistant prior to the start of a		

From: Sen.Nass

To: Hereth, Daniel - DSPS; DSPS Admin Rules; DSPS

Cc: Tierney, Michael - DSPS; Sen.Nass - LEGIS; Rep.Neylon - LEGIS; Grosz, Scott A - LEGIS; Kauffman, Jill - LEGIS;

Duchek, Mike - LEGIS

Subject: JCRAR Directive to Hold Preliminary Hearing on Scope Statement SS 002-25

Date: Tuesday, January 14, 2025 10:26:17 AM

CAUTION: This email originated from outside the organization.

Do not click links or open attachments unless you recognize the sender and know the content is safe.

January 14, 2025

John Weitekamp, Chairperson Pharmacy Examining Board Department of Safety & Professional Services P.O. Box 8366 Madison, WI 53708-8366

RE: SS 002-25 – Pharmacy Workplace Conditions

Dear Chairperson Weitekamp:

As co-chairperson of the Joint Committee for Review of Administrative Rules (JCRAR) and pursuant to s. 227.136 (1), Stats., I write to direct the Pharmacy Examining Board to hold a preliminary public hearing and comment period on Scope Statement SS 002-25, which was published in the Wisconsin Administrative Register on January 13, 2025.

Additionally, pursuant to s. 227.135 (2), Stats., please note that a scope statement may not be approved by the Secretary, the Department of Safety & Professional Services (DSPS), or any of the agencies under DSPS until after the preliminary public hearing and comment period is held by the agency, and accordingly, no activity may be conducted in connection with the drafting of a proposed rule until after such hearing and approval have occurred.

Please confirm receipt of this letter directing a preliminary hearing and comment period on the above scope statement.

Sincerely,

Steve Nass

Senator Steve Nass Co-Chair, JCRAR

Cc: Dan Hereth, Secretary-designee, DSPS

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.:	Phar 1, 6, 7, and 10
Relating to:	Pharmacy Workplace Conditions
Rule Type:	Both Permanent and Emergency

- 1. Finding/nature of emergency (Emergency Rule only): The Pharmacy Examining Board has identified a concern related to workplace safety including concerning behavior involving prescription accuracy, performing vaccinations, and patient care, among other areas of Pharmacy practice in the workplace. Due to these concerns, the Board deems an emergency rule to be appropriate to address the imminent public safety and welfare.
- **2. Detailed description of the objective of the proposed rule:** The objective of the proposed rule is to amend requirements in the Wisconsin Administrative Code to increase public safety by improving working conditions in pharmacies.
- 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:

Wisconsin Administrative Code Chapters Phar 1, 6, 7, and 10 currently outline requirements for authority and definitions, pharmacy licenses and equipment, pharmacy practice, and unprofessional conduct. These areas could be expanded upon to include requirements that improve working conditions for pharmacy staff, as well as patient safety. An alternative to amending these provisions is that the administrative code will continue to be silent on the issue of workplace conditions in the pharmacy profession.

- 4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):
- 15.08 (5) (b), Stats., states that the Board "[s]hall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."
- 450.02 (2), Stats., states that "[t]he board shall promulgate rules that do all of the following: (a) The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.
- (b) Define the activities that constitute the practice of a pharmacy technician for purposes if the registration requirement under s. 450.68."
- 450.02 (3) (b), Stats., states "[t]he board may promulgate rules establishing security standards for pharmacies."
- 450.02 (3) (d), Stats., states "[t]he board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961."
- 450.02 (3) (e), Stats., states "[t]he board may promulgate rules establishing minimum standards for the practice of pharmacy."
- 5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:
 120 hours

- 6. List with description of all entities that may be affected by the proposed rule:
- Licensed Pharmacies, Pharmacists; Registered Pharmacy Technicians, and their employers.
- 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: None.
- 8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. This rule is not likely to have a significant economic impact on small businesses.

Contact Person: Nilajah Hardin, Administrative Rules Coordinator, (608) 267-7139

Approved for publication:	Approved for implementation:		
John Weithoup			
Authorized Signature	Authorized Signature		
11/25/2024			
Date Submitted	Date Submitted		

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:			
Nilajah Hardin Administrative Rules Coordinator		02/07/25 Items will be considered late if submitted after 12:00 p.m. on the deadline			
			date which is	s 8 business days before the meeting	
3) Name of Board, Com		ctions:			
Pharmacy Examining I					
4) Meeting Date:	5) Attachments:	6) How should the	e item be title	d on the agenda page?	
02/20/25		Relating to Con	for Clearinghouse Rule 24-092 on Phar 15, Pharmaceuticals ring Comments and Respond to Clearinghouse		
7) Place Item in:	8) Is an appeara	nce before the Boa	ard being	9) Name of Case Advisor(s), if required:	
Open Session	scheduled? (If)	yes, please complete	Э	N/A	
Closed Session	Appearance Rec	quest for Non-DSPS	S Staff)		
	☐ Yes				
40) Decembe the icour	No	بالمحجم المالية			
10) Describe the issue a The Board will hold a					
11)	4.3	Authoriza	tion	00.07/07	
Signature of person ma	Harolis		02/07/25 Date		
Signature of person ma	king tills request			Date	
Supervisor (if required)				Date	
Executive Director signs	ature (indicates ap	proval to add post	agenda dead	line item to agenda) Date	
Directions for including			d to the sees	do.	
 This form should be Post Agenda Deadlin 				aa. ne Policy Development Executive Director.	
3. If necessary, provide				ignature to the Bureau Assistant prior to the start of a	
meeting.					

STATE OF WISCONSIN PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING :

PROPOSED ORDER OF THE

PROCEEDINGS BEFORE THE

PHARMACY EXAMINING BOARD

PHARMACY EXAMINING BOARD

ADOPTING RULES

(CLEARINGHOUSE RULE

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal and recreate chapter Phar 15, relating to Compounding Pharmaceuticals.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.01 (16), Stats.

Statutory authority: ss. 15.08 (5) (b), and 450.02 (3) (d) and (e), Stats.

Explanation of agency authority:

Section 15.08 (5) (b), Stats. states that "The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."

Section 450.02 (3) (d), Stats. says that the board "may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961."

Section 450.02 (3) (e), Stats. provides that the board "may promulgate rules establishing minimum standards for the practice of pharmacy."

Related statute or rule: N/A

Plain language analysis:

The Pharmacy Examining Board recently completed a revision to Wisconsin Administrative Code Chapter Phar 15 which became effective on August 1, 2022. The objective of this rule is to repeal and recreate the recent version of Phar 15 to incorporate by reference United States Pharmacopeia (USP) General Chapters 795 and 797, published on November 1, 2022. The Board will also be incorporating USP General Chapter 800, published on December 1, 2019, as well as USP General Chapter 825, published on December 1, 2020.

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

The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal. The states are primarily responsible for the oversight of compounding in pharmacies. Pursuant to the Drug Quality and Security Act, the federal government is responsible for outsourcing facilities, which by definition are not pharmacies, and are subject to current good manufacturing practice requirements, labeling requirements and may distribute compounded drugs in response to an order that is not patient specific. The Food, Drug and Cosmetic Act requires drugs to be prepared, packed or held under sanitary conditions.

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: For patient-specific prescriptions, sterile and unsterile pharmaceutical compounding is governed by the USP 42-NF 37 from the 2019 USP Compounding Compendium, except for USP Chapter 800. Additionally, all pharmacies that compound drugs must maintain a set of minimum standards and equipment. These requirements include a specific area for compounding materials, accurate scales or measuring equipment, a separate area for compounding, a record keeping system for tracking compounded drugs, drug distribution procedures, and labelling. Additional requirements for sterile compounding include current reference materials, pharmacist availability at all times to answer patient and health care professional questions, and emergency medications for adverse drug reactions to compounded sterile drugs. [Illinois Administrative Code s. 1330.640]. In Illinois, the definition of "compounding" excludes flavorings [225 Illinois Compiled Statutes 85 s. 3 (o)].

Iowa: Iowa requires compliance with the current revisions of USP Chapters 795 and 797. Additionally, Iowa includes requirements for the use of flavoring agents. These requirements include that pharmacist may add flavoring in the amount of not more than percent of the total volume of the drug. The beyond-use date of the flavored drug must be no greater than 14 days and the pharmacist must document that a flavoring agent was added to a drug. Compliance with USP Chapter 825 is not required, however Iowa does have its own rules for radiopharmaceuticals and nuclear pharmacy [Iowa Administrative Code ss.657.16 and 657.20].

Michigan: Michigan requires a pharmacy that provides compounding services to be licensed as a pharmacy and authorized to provide compounding services. The pharmacy must be accredited through a national accrediting organization and be in compliance with USP standards [Michigan Compiled Laws s. 333.17748a to c]. In Michigan, the definition of "compounding" does not include flavoring agents that are nonallergenic, inert, and not more than 5% of the drug's total volume [Michigan Administrative Rules R 338.501 (1) (e)].

Minnesota: Minnesota requires pharmacies compounding nonsterile drug preparations to follow USP chapter 795 standards. Pharmacies compounding sterile drug preparations are required to follow USP chapter 797 standards. [Minnesota Administrative Rules s.6800.3300]

Summary of factual data and analytical methodologies: In addition to the four adjacent states listed above, the Pharmacy Examining Board also reviewed statutes and regulations regarding compounding pharmaceuticals from other states including Arizona, California, Colorado, Connecticut, Idaho, Kentucky, Louisiana, Massachusetts, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, North Carolina, Ohio, Pennsylvania, South Carolina, South Dakota, Texas, Utah, West Virginia, and Wyoming.

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

The rule was posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These 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) 266-6795.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; 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, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to

DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held February 20, 2025 to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

Section 1. Chapter Phar 15 is repealed and recreated to read:

Chapter Phar 15 PHARMACEUTICAL COMPOUNDING, SAFE HANDLING OF HAZARDOUS DRUGS, AND RADIOPHARMACEUTICALS

Phar 15.01 Definitions. In this chapter:

(1) "USP-NF" means the United States Pharmacopeia-National Formulary published by the United States Pharmacopeial Convention.

Phar 15.02 Incorporation of Standards. (1) PHARMACEUTICAL COMPOUNDING - NONSTERILE PREPARATIONS. USP-NF general chapter 795, official as of November 1, 2023, is incorporated by reference into this chapter, subject to the exception that nonsterile compounding does not include the addition of nonallergenic, therapeutically inert flavoring agents to a conventionally manufactured drug product. The pharmacist shall also comply with the following requirements when adding flavoring agents to a drug product:

- (a) The pharmacist shall ensure that the flavoring agent is not more than 5 percent of the product's total volume.
- (b) The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise documented.
- (c) The pharmacist shall document the addition of flavoring as part of the prescription record. The documentation shall include the type of flavoring agent, manufacturer, lot number, and expiration date.
- (d) A prescription is required before a pharmacist may add flavoring to an over-the-counter product.
- (2) PHARMACEUTICAL COMPOUNDING STERILE PREPARATIONS. USP-NF general chapter 797, official as of November 1, 2023, is incorporated by reference into this chapter.
- (3) SAFE HANDLING OF HAZARDOUS DRUGS. USP-NF general chapter 800, official as of July 1, 2020, is incorporated by reference into this chapter.
- **(4)** RADIOPHARMACEUTICALS. USP-NF general chapter 825, official as of January 1, 2024, is incorporated by reference into this chapter.

Note: Copies of the above standards are on file in the office of the legislative reference bureau. A copy of the USP-NF can be purchased from the United States Pharmacopeial Convention at https://usp.org.

Phar 15.03 Compliance. Noncompliance with ch. Phar 15 may be considered a violation of s. Phar 10.03 and may result in disciplinary action by the Board against a credential holder.

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)

DIVISION OF EXECUTIVE BUDGET AND FINANCE 101 EAST WILSON STREET, 10TH FLOOR P.O. BOX 7864 MADISON, WI 53707-7864 FAX: (608) 267-0372

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis	2. Date					
☑ Original ☐ Updated ☐ Corrected3. Administrative Rule Chapter, Title and Number (and Clearinghous)	12/09/24 se Number if applicable)					
Phar 15						
4. Subject						
Compounding Pharmaceuticals						
5. Fund Sources Affected GPR FED PRO PRS SEG SEG-S	6. Chapter 20, Stats. Appropriations Affected s20.165 (1) (hg)					
7. Fiscal Effect of Implementing the Rule						
□ No Fiscal Effect □ Increase Existing Revenues	☐ Increase Costs ☐ Decrease Costs					
Indeterminate Decrease Existing Revenues 8. The Rule Will Impact the Following (Check All That Apply)	Could Absorb Within Agency's Budget					
	ific Businesses/Sectors					
·	c Utility Rate Payers					
	Businesses (if checked, complete Attachment A)					
9. Estimate of Implementation and Compliance to Businesses, Loca						
\$0						
10. Would Implementation and Compliance Costs Businesses, Loca Any 2-year Period, per s. 227.137(3)(b)(2)?	l Governmental Units and Individuals Be \$10 Million or more Over					
Yes No						
11. Policy Problem Addressed by the Rule The Pharmacy Examining Board recently completed a revision	an to Wisconsin Administrative Code Chanter Phor 15					
which became effective on August 1, 2022. The objective of	<u>*</u>					
15 to incorporate by reference United States Pharmaceopeia (
November 1, 2022. The Board will also be incorporating USI						
well as USP General Chapter 825, published on December 1,						
12. Summary of the Businesses, Business Sectors, Associations Rethat may be Affected by the Proposed Rule that were Contacted						
The rule was posted on the Department's website for 14 days	to solicit public comment on economic impact, including					
how the proposed rules may affect businesses, local government	ent units, and individuals. No comments were received.					
13. Identify the Local Governmental Units that Participated in the De None	evelopment of this EIA.					
 Summary of Rule's Economic and Fiscal Impact on Specific Bus Governmental Units and the State's Economy as a Whole (Included Incurred) 						
DSPS estimates a total of \$5,955.00 in one-time costs for imp	plementing this rule. The one-time staff costs support 0.1					
limited term employee to undertake tasks such as rule drafting	g, regal review, training on new rules, and updating forms					
and website.						
15. Benefits of Implementing the Rule and Alternative(s) to Impleme	nting the Rule					
The benefit is that there will be clear and up to date standards	· · · · · · · · · · · · · · · · · · ·					
hazardous drugs, and radiopharmaceuticals in Pharmacy prac	tice.					
16. Long Range Implications of Implementing the Rule	cofaty in phormony practice in Wisconsin					
The long range implications of implementing the rule are increased	safety in pharmacy practice in wisconsin.					
17. Compare With Approaches Being Used by Federal Government						

DIVISION OF EXECUTIVE BUDGET AND FINANCE 101 EAST WILSON STREET, 10TH FLOOR P.O. BOX 7864 MADISON, WI 53707-7864 FAX: (608) 267-0372

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal. The states are primarily responsible for the oversight of compounding in pharmacies. Pursuant to the Drug Quality and Security Act, the federal government is responsible for outsourcing facilities, which by definition are not pharmacies, and are subject to current good manufacturing practice requirements, labeling requirements and may distribute compounded drugs in response to an order that is not patient specific. The Food, Drug and Cosmetic Act requires drugs to be prepared, packed or held under sanitary conditions.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota) Illinois: For patient-specific prescriptions, sterile and unsterile pharmaceutical compounding is governed by the USP 42-NF 37 from the 2019 USP Compounding Compendium, except for USP Chapter 800. Additionally, all pharmacies that compound drugs must maintain a set of minimum standards and equipment. These requirements include a specific area for compounding materials, accurate scales or measuring equipment, a separate area for compounding, a record keeping system for tracking compounded drugs, drug distribution procedures, and labelling. Additional requirements for sterile compounding include current reference materials, pharmacist availability at all times to answer patient and health care professional questions, and emergency medications for adverse drug reactions to compounded sterile drugs. [Illinois Administrative Code s. 1330.640]. In Illinois, the definition of "compounding" excludes flavorings [225 Illinois Compiled Statutes 85 s. 3 (o)].

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Minnesota: Minnesota requires pharmacies compounding nonsterile drug preparations to follow USP chapter 795 standards. Pharmacies compounding sterile drug preparations are required to follow USP chapter 797 standards. [Minnesota Administrative Rules s.6800.3300]

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules Coordinator	608-267-7139

This document can be made available in alternate formats to individuals with disabilities upon request.

STATE OF WISCONSIN DEPARTMENT OF ADMINISTRATION DOA-2049 (R09/2016) DIVISION OF EXECUTIVE BUDGET AND FINANCE 101 EAST WILSON STREET, 10TH FLOOR P.O. BOX 7864 MADISON, WI 53707-7864 FAX: (608) 267-0372

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

 Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)
2. Summary of the data sources used to measure the Rule's impact on Small Businesses
3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses? Less Stringent Compliance or Reporting Requirements Less Stringent Schedules or Deadlines for Compliance or Reporting Consolidation or Simplification of Reporting Requirements Establishment of performance standards in lieu of Design or Operational Standards Exemption of Small Businesses from some or all requirements Other, describe:
4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses
5. Describe the Rule's Enforcement Provisions
6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form) Yes No



Wisconsin Legislative Council

RULES CLEARINGHOUSE

Scott Grosz Clearinghouse Director Margit Kelley Clearinghouse Assistant Director

Anne Sappenfield Legislative Council Director

CLEARINGHOUSE REPORT TO AGENCY

THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY: THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.

CLEARINGHOUSE RULE 24-092

AN ORDER to repeal and recreate ch. Phar 15, relating to compounding pharmaceuticals.

Submitted by **PHARMACY EXAMINING BOARD**

12-09-2024 RECEIVED BY LEGISLATIVE COUNCIL.

REPORT SENT TO AGENCY. 01-07-2025

MSK:SM

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1.	STATUTORY AUTHORITY [8	s. 227.15 (2) (a)]		
	Comment Attached	YES 🗸	NO	
2.	FORM, STYLE AND PLACEM	MENT IN ADMINISTR	ATIVE CODE [s. 227.15 (2) (c)]	
	Comment Attached	YES 🗸	NO	
3.	CONFLICT WITH OR DUPLIC	CATION OF EXISTING	G RULES [s. 227.15 (2) (d)]	
	Comment Attached	YES	NO 🗸	
4.	ADEQUACY OF REFERENCE [s. 227.15 (2) (e)]	ES TO RELATED STA	ΓUTES, RULES AND FORMS	
	Comment Attached	YES	NO 🗸	
5.	CLARITY, GRAMMAR, PUNG	CTUATION AND USE	OF PLAIN LANGUAGE [s. 227.15 (2) (f)]
	Comment Attached	YES	NO 🗸	
6.	POTENTIAL CONFLICTS WI' REGULATIONS [s. 227.15 (2)		BILITY TO, RELATED FEDERAL	
	Comment Attached	YES	NO 🗸	
7.	COMPLIANCE WITH PERMIT	T ACTION DEADLINE	E REQUIREMENTS [s. 227.15 (2) (h)]	
	Comment Attached	YES	NO 🗸	



Wisconsin Legislative Council

RULES CLEARINGHOUSE

Scott Grosz Clearinghouse Director Margit Kelley Clearinghouse Assistant Director

Anne Sappenfield Legislative Council Director

CLEARINGHOUSE RULE 24-092

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Council Staff and the Legislative Reference Bureau, dated November 2020.]

1. Statutory Authority

The rule proposes to incorporate by reference certain chapters of the U.S. Pharmacopeia. Section 227.21 (2), Stats., requires that an agency obtain the consent of the Attorney General in order to adopt standards established by technical societies and organizations of recognized national standing. Consistent with s. 1.14, Manual, the agency should provide additional information in the rule summary regarding its satisfaction of the statutory requirement.

2. Form, Style and Placement in Administrative Code

- a. In s. Phar 15.01, the designation for sub. (1) should be removed and all of the material should be merged without any subsections. The provision includes only one subunit. Subunits should only be used for a series of subunits. [s. 1.11 (4), Manual.]
- b. Should the material created in s. Phar 15.03 either be moved to, or at least referenced within, current s. Phar 10.03? Additionally, it is confusing that the provision says it only "may" be considered a violation. Does that give adequate notice to practitioners about what is required?
- c. The agency could consider whether an initial applicability clause should be added to the proposed rule, if there could be circumstances in which the new rule could apply to compounding that was initiated before the effective date of the rule. [s. 1.03 (3), Manual.]

PHARMACY EXAMINING BOARD 2025 MEETING DATES

Meeting Date	PHM Rules Committee	PHM Board	Location	Agenda Item Deadline
Thursday, February 20, 2025	9:00 AM	11:00 AM	Virtual	2/10/25
Thursday, April 17, 2025	9:00 AM	11:00 AM	Hybrid	4/7/25
Thursday, June 19, 2025	9:00 AM	11:00 AM	Virtual	6/9/25
Thursday, August 21, 2025	9:00 AM	11:00 AM	Virtual	8/11/25
Thursday, October 16, 2025	9:00 AM	11:00 AM	Hybrid	10/6/25
Thursday, December 18, 2025	9:00 AM	11:00 AM	Virtual	12/8/25

State of Wisconsin Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:				2) Date when reques	st submitted: 12/1/2024
Brenda Taylor, Board Services Supervisor					
3) Name of Board, Committee, Council, Sections: All Board			All Boards	3	
4) Meeting Date:	5) Attachments: 6) How she		should the item be titled on the agenda page?		
First Meeting of 2025		s	Adminis	trative Matters: Annu	al Policy Review
7) Place Item in:		8) Is an appearance before the Board being		the Board being	9) Name of Case Advisor(s), if applicable:
		scheduled? ⊠ No			N/A

10) Describe the issue and action that should be addressed: Board SharePoint Site: https://dsps.boards.wisconsin.gov/

Please be advised of the following Policy Items:

- In-Person and Virtual Meetings: Depending on the frequency of scheduled meetings, discussion topics, and member availability, DSPS may host one or more in-person meetings. Virtual connection options are available for all board meetings.
- 2. Attendance/Quorum: Thank you for your service and commitment to meeting attendance. If you cannot attend a meeting or have scheduling conflicts impacting your attendance, please let us know as soon as possible. A quorum is required for Boards, Sections, and Councils to meet pursuant to Open Meetings Law. Connect to / arrive at meetings 10 minutes before posted start time to allow for audio/connection testing, and timely Call to Order and Roll Call. Virtual meetings include viewable onscreen materials and A/V (speaker/microphone/video) connections.
- **3. Walking Quorum:** Board/Section/Council members must not collectively discuss the body's business outside a properly noticed meeting. If several members of a body do so, they could be violating the open meetings law.
- **4. Mandatory Training:** All Board Members must complete Public Records and Ethics Training, annually. Register to set up an account in the Cornerstone LearnCenter online portal or Log in to an existing account.
- **5. Agenda Deadlines:** Please communicate agenda topics to your Executive Director before the agenda submission deadline at 12:00 p.m., eight business days before a meeting. (Attachment: Timeline of a Meeting)
- **6. Travel Voucher and Per Diem Submissions:** Please submit all Per Diem and Reimbursement claims to DSPS within 30 days of the close of each month in which expenses are incurred. (Attachment: Per Diem Form) Travel Vouchers are distributed on travel approval.
- 7. Lodging Accommodations/Hotel Cancellation Policy: Lodging accommodations are available to eligible members for in-person meetings. Standard eligibility: the member must leave home before 6:00 a.m. to attend an inperson meeting by the scheduled start time.
 - a. If a member cannot attend a meeting, they must cancel their reservation with the hotel within the applicable cancellation timeframe.
 - b. If a meeting is changed to occur remotely, is canceled, or rescheduled, DSPS staff will cancel or modify reservations as appropriate.
- **8. Inclement Weather Policy:** In inclement weather, the DSPS may change a meeting from an in-person venue to a virtual/teleconference only.

11) Authorization	
AA	12/02/2024

Directions for including supporting documents:

- 1. This form should be saved with any other documents submitted to the Agenda Items folders.
- 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director

Timeline of a Meeting

8 business days prior to the meeting: All agenda materials are due to the Department by 12:00 pm, 8 business days prior to the meeting date.

7 business days prior to the meeting: The draft agenda page is due to the Executive Director. The Executive Director transmits to the Chair for review and approval.

5 business days prior to the meeting: The approved agenda is returned to the Board Administration Specialist for agenda packet production and compilation.

4 business days prior to the meeting: Agenda packets are posted on the DSPS Board SharePoint site and on the Department website.

Agenda Item Examples:

- o Approval of the Agenda and previous meeting Minutes
- Open Session Items
 - Public Hearings (relating to Administrative Rules)
 - Administrative Matters
 - Legislation and Policy Matters
 - Administrative Rules Matters
 - Credentialing Matters
 - Education and Exam Issues
 - Public Agenda Requests
 - Current Issues Affecting the Profession
 - Public Comments
- Closed Session items
 - Deliberations on Proposed Disciplinary Actions
 - Stipulations
 - Administrative Warnings
 - Case Closings
 - Monitoring Matters
 - Professional Assistance Procedure (PAP) Issues
 - Proposed Final Decisions and Orders
 - Orders Fixing Costs/Matters Relating to Costs
 - Credentialing Matters
 - Education and Exam Issues

Thursday of the Week Prior to the Meeting: Agendas are published for public notice on the Public Notices and Meeting Minutes website: publicmeetings.wi.gov.

1 business day after the Meeting: "Action" lists are distributed by staff detailing board actions on closed session business.

5 business days after the Meeting: "To Do" lists are distributed to staff to ensure that board decisions are acted on and/or implemented within the appropriate divisions in the Department. Minutes approved by the board are published on the the Public Notices and Meeting Minutes website: **publicmeetings.wi.gov**.

Department of Safety and Professional Services PER DIEM REPORT

INSTRUCTIONS: Record board-related activities by date, indicate relevant purpose code, the duration of time spent in B-code activities, location, and activity description. Only one \$25.00 per diem payment will be issued on any given calendar day. Submit one form per month and within 60 days of the last activity being reported. Send completed forms to your Board's Administrative Specialist.

Pu	rn	ose	C_0	d	PC	•
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A CODE	Official meetings including Board Meetings, Hearings and Examinations and Test Development Sessions
	(automatic day of per diem) Examples: board, committee, board training or screening panels; Senate Confirmation
	hearings, legislative and disciplinary hearings, or informal settlement conferences; test administration, test review or
	analysis events, national testing events, tour of test facilities, etc.

B CODE Other (One (1) per diem will be issued for every five (5) hours spent in category B, per calendar month): i.e., review of disciplinary cases, consultation on cases, review of meeting materials, board liaison work, e.g., contacts regarding Monitoring, Professional Assistance Procedure, Credentialing, Education and Examinations

	Monitorin	ng, Professional As	ssistance Procedure, Creden	tialing, Education and Examinations		
Name of Examining Board or Council				Board or Council Member's Name		
Month		Year		Employee ID Number		
Date	Purpose Code	Duration of B activity	Where Performed	Activity		
	A or B	Hours: Minutes	(Home, DSPS, or City, State)	Describe Activity Performed (see purpose codes)		
TOTALS						
CLAIMAN for per dier by law.	NT'S CERTI m, is just and o	FICATION The Bo correct; and that this	oard/Council member named ab claim is for service necessarily i	bove, certifies, in accordance with § 16.53, Wis. Stats., that this account incurred in the performance of duties required by the State, as authorized (Rev.04/24)		
Board Men	nher Annrova	1 & Date:				

Supervisor Approval & Date: __

30

TOTAL DAYS CLAIMED: _____ @ \$25.00 =

PHARMACY EXAMINING BOARD 2024 Elections, Liaisons and Delegations

OFFICERS			
Chairperson	John Weitekamp		
Vice Chairperson	Tiffany O'Hagan		
Secretary	Susan Kleppin		

LIAISON APPOINTMENTS			
Credentialing Liaison(s)	Anthony Peterangelo, Tiffany O'Hagan, Christa Wilson		
Education and Examinations Liaison(s)	Susan Kleppin Alternate: John Weitekamp		
Monitoring Liaison(s)	Michael Walsh, Christa Wilson Alternate: Anthony Peterangelo		
Professional Assistance Procedure (PAP) Liaison(s)	Anthony Peterangelo Alternate: Susan Kleppin		
Travel Authorization Liaison(s)	John Weitekamp Alternate: Tiffany O'Hagan		
Legislative Liaison(s)	Anthony Peterangelo, Tiffany O'Hagan, John Weitekamp Tiffany O'Hagan, Anthony Peterangelo		
Pilot Program Liaison(s)			
Newsletter Liaison(s)	Christa Wilson Alternate: John Weitekamp		
Website Liaison(s)	Michael Walsh		
Appointed to Controlled Substances Board as per Wis. Stats. §15.405(5g)	John Weitekamp		
PHARM Rep to SCAODA	Susan Kleppin Alternate: John Weitekamp		

Variance Liaison(s)	Tiffany O'Hagan Alternate: Anthony Peterangelo		
Inspection Liaison(s)	Susan Kleppin Alternate:		
Phar 7.08(8) Approval Requests Liaison(s)	Susan Kleppin Alternate:		
SCREENING PANEL APPOINTMENTS			
Screening Panel	John Weitekamp, Tiffany O'Hagan, Michael Walsh Alternate: Anthony Peterangel		
COMMITTEE MEMBER APPOINTMENTS			
Pharmacy Rules Committee	Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo, John Weitekamp		
OTHER APPOINTMENTS			
Interdisciplinary Advisory C	ouncil	John Weitekamp <i>Alternate:</i> Christa Wilson	

State of Wisconsin Department of Safety & Professional Services

AGENDA REQUEST FORM

Name and title of person submitting the request: Paralegal Richanda Turner, on behalf of Attorney Whitney DeVoe				2) Date when request submitted:		
				01/30/25		
					dered late if submitted after 12:00 p.m. on the	
				deadline date whic	h is 8 business days before the meeting	
3) Name of Board, Comr	nittee, Co	ouncil, Sections:				
Pharmacy Examining Bo	oard					
4) Meeting Date: 5) Attachments: 6) How			6) How	should the item be ti	tled on the agenda page?	
02/20/2025	⊠ Yes		Reaffirming 2024 delegations and new 2025 delegations			
					•	
7) Place Item in:		8) Is an appearanc			9) Name of Case Advisor(s), if applicable:	
☑ Open Session		scheduled? (If yes,			N/A	
☐ Closed Session		Appearance Reque	st for No	n-DSPS Staff)		
Olosed oession		☐ Yes				
		⊠ No				
10) Describe the issue a	nd action	that should be add	ressed:			
The Board members nee	ed to revi	ew and consider rea	ffirming	2024 delegations ar	nd new delegations for 2025.	
			J	•		
11)		Aı	uthoriza	tion		
Ríchanda Turi	ner				01/30/25	
Signature of person mal	king this	request			Date	
Supervisor (Only require	ed for no	st agenda deadline it	tame)		Date	
Supervisor (Only required for post agenda deadline items) Date						
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.						
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						
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.						



State of Wisconsin

DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES

CORRESPONDENCE / MEMORANDUM

DATE: January 1, 2025

TO: Board, Council, and Committee Members

FROM: Legal Counsel

SUBJECT: Liaison Definitions and Delegations Explanations

Overall Purpose of Liaison Appointments

Each Board/Section (Board) has inherent authority that is established in our Wisconsin Statutes. This authority may change from Board to Board. Further information on your Board's authority can be found in Wis. Stat. ch. 15. Generally, each Board has authority to grant credentials, discipline credential holders, and set standards for education and examinations. In order to efficiently accomplish these tasks, Boards may appoint Liaisons. Liaisons assist with the operations of the Boards' purpose by weighing in on legislative matters, traveling to national conferences, or communicating with stakeholders.

The Department asks that each year the Boards make Liaison appointments to assist the Board and Department to accomplish these tasks in an efficient manner. Your practical knowledge and experience, as an appointed member of a professional board, are essential in making determinations regularly. The Liaison positions listed below assist the Department to complete operations between Board meetings. In most cases, Liaisons can make decisions for the full Board in their designated area. However, these areas are determined through the delegation process. Please note, a Liaison may also decide to send the delegated matter to the full Board for consideration as appropriate. Delegations assist the Board in defining the roles and authorities of each Liaison and other Board functions.

Liaison Definitions

Credentialing Liaison: The Credentialing Liaison is empowered by the Board to review and make determinations regarding certain credential applications. The Credentialing Liaison may be called on by Department staff to answer questions that pertain to qualifications for licensure, which may include whether a particular degree is suitable for the application requirements, whether an applicant's specific work experience satisfies the requirements in statute or rule for licensure, or

whether an applicant's criminal or disciplinary history is substantially related to the practice of the profession in such a way that granting the applicant a credential would create a risk of harm to the public. Questions will likely be sent by Department staff to the Credentialing Liaison via email and may include application materials. The Credentialing Liaison serves a very important role in the credentialing process.

Monitoring Liaison: The Monitoring Liaison is empowered by the Board to make decisions on any credential that is limited either through a disciplinary order or initial licensure. The Department Monitors will send requests from credential holders to the Monitoring Liaison. These requests vary wildly. A common request could be to remove a limitation that has been placed on a credential or to petition for full licensure. The Monitoring Liaison can review these requests and make decisions on behalf of the Board. The Board has the authority to grant decision making latitude to their liaison to any degree. If the Monitoring Liaison has a question on a request, it is advisable for the Liaison to consult further with Department staff or bring the matter to the full Board for consideration.

Professional Assistance Procedure (PAP) Liaison: PAP is a voluntary program open to credential holders with substance abuse issues who wish to seek help by being held accountable through treatment and monitoring by the Department and Board. As part of PAP, the credential holder enters into an agreement with the Department to undergo testing, counseling, or other rehabilitation. The PAP Liaison's role includes responding to credential holders' requests for modifications and terminations of provisions of the agreement. Similar to the Monitoring Liaison, the Department Monitors will send requests from credential holders to the PAP Liaison for further review.

Education and Examination Liaison: Some Boards are required by statute or rule to approve qualifying education and examinations. The Education and Examination Liaison provides guidance to Department staff to exercise authority of the Board to approve or decline examinations and educational programs. This determination requires a level of professional expertise and should be performed by a professional member of the Board. For some Boards, the Education and Examination Liaison will also be tasked with approving continuing education programs and courses.

Legislative Liaison: The Legislative Liaison is permitted to act and speak on the Board's behalf regarding pending and enacted legislation or actions being considered by the legislature outside of Board meetings. The Legislative Liaison is not the Board's designated lobbyist and should exercise their delegated authority carefully.

Travel Authorization Liaison: The Travel Authorization Liaison is authorized to approve a Board member to travel to events and speak or act on the Board's behalf between Board meetings. The Travel Authorization Liaison is called upon to make decisions when sufficient notice was not received, and the full Board could not determine a representative to travel. The Travel Authorization Liaison is tasked with making determinations if the Board appointed representative is not able to attend or if the Board becomes authorized to send additional members as scholarship and funding streams can be unpredictable.

Communication Liaison: The Communication Liaison responds to questions that arise on behalf of the Board. The Communication Liaison works with the Department to cultivate an appropriate response which will be sent by the Executive Director or Board Counsel. The Communication Liaison can be responsible for all types of communication on behalf of the Board. However, the Board can appoint a separate **Website Liaison** to work with DSPS staff to make changes and ensure the Board webpage contains updated and accurate information. Additionally, for the Boards that are required by statute to produce a newsletter or digest, the Board can appoint a separate **Newsletter/Digest Liaison** to assemble and approve content for those communications.

Screening Panel Members: Screening Panel Members review incoming complaints against credential holders and determine which complaints should be opened for investigation and which complaints should be closed without further action. The complexity and amount of work in this role depends substantially on your Board. As a member of the Screening Panel, you are asked to apply your professional expertise to determine if a complaint alleges unprofessional conduct.

Delegations Explanations

CREDENTIALING DELEGATIONS

The overall purpose of credentialing delegations is to allow the credentialing process to proceed as efficiently and effectively as possible.

Delegation of Authority to Credentialing Liaison (Generic)

MOTION EXAMPLE: to delegate authority to the Credentialing Liaison(s) to serve as a liaison between the Department and the Board and to act on behalf of the Board in regard to credentialing applications or questions presented to them, including the signing of documents related to applications.

PURPOSE: To allow a representative of the Board to assist Department staff with credentialing applications and eliminate the need for the entire Board to convene to consider credential application content or questions. Additionally, it is most efficient to have the designated liaison who has assisted with the credentialing process be able to effectuate decisions which require a signature.

Delegation of Authority to DSPS When Credentialing Criteria is Met

MOTION EXAMPLE: to delegate credentialing authority to the Department to act upon applications that meet all credentialing statutory and regulatory requirements without Board or Board liaison review.

PURPOSE: To permit Department staff to efficiently issue credentials and eliminate the need for Board/Section/Liaison review when all credentialing legal requirements are met in an application. This delegation greatly decreases workload on Board members and cuts down processing time on applications.

Delegation of Authority for Predetermination Reviews

MOTION EXAMPLE: to delegate authority to the Department Attorneys to make decisions regarding predetermination applications pursuant to Wis. Stat. § 111.335(4)(f).

PURPOSE: In general, the Wisconsin Fair Employment Act (codified in Wis. Stat. Ch. 111) prohibits licensing agencies from discriminating against applicants because of their arrest and/or conviction record. However, there are exceptions which permit denial of a license in certain circumstances. Individuals who do not possess a license have a legal right to apply for a determination of whether they are disqualified from obtaining a license due to their conviction record. This process is called "Predetermination." Predetermination reviews must be completed within 30 days. This delegation allows Department Attorneys to conduct predetermination reviews and efficiently make these legal determinations without need for Board/Section/Liaison review.

Delegation of Authority for Conviction Reviews

MOTION EXAMPLE: to delegate authority to the Department Attorneys to review and approve applications with convictions which are not substantially related to the relevant professional practice.

PURPOSE: As used here, "substantially related" is a legal standard that is used in the Wisconsin Fair Employment Act. The concept of what is "substantially related" is informed by case law. This delegation permits Department Attorneys to independently conduct conviction reviews and efficiently approve applications if convictions are not substantially related to the practice of the profession. Applications that contain conviction records that may be substantially related to the practice of a profession will still be submitted to the Credentialing Liaison for input.

Delegation to DSPS When Applicant's Disciplinary History Has Been Previously Reviewed

MOTION EXAMPLE: to delegate authority to Department staff to approve applications where Applicant's prior discipline has been approved for a previous credential and there is no new discipline.

PURPOSE: Some Boards offer progressive levels of credentials. This delegation eliminates the need for a re-review of discipline that has already been considered and approved by the Board/Section/Liaison for a lower-level credential.

Delegation to DSPS When Applicant's Conviction History Has Been Previously Reviewed

MOTION EXAMPLE: to delegate authority to Department staff to approve applications where criminal background checks have been approved for a previous credential and there is no new conviction record.

PURPOSE: Some Boards offer progressive levels of credentials. This delegation eliminates the need for a re-review of conviction history that has already been reviewed and approved for a lower-level credential.

Delegation of Authority for Reciprocity Reviews

MOTION EXAMPLE: to delegate authority to the Department Attorneys to review and approve reciprocity applications in which the out of state license requirements meet Wisconsin license requirements. (specific legal standards are referenced in the motion depending on credential/profession type).

PURPOSE: Applications via reciprocity or endorsement require comparison of Wisconsin licensing requirements to the licensing requirements of another jurisdiction. These reviews consider the legal standard for reciprocity, which varies by profession, as well as the specified legal requirements to obtain licensure in the profession. This delegation permits Department Attorneys to independently conduct reciprocity reviews and efficiently approve applications if legal standards and requirements are met for licensure. Applications for which reciprocity may not be available will still be submitted to the Credentialing Liaison for input.

Delegation of Authority for Military Reciprocity Reviews

MOTION EXAMPLE: to delegate authority to the Department Attorneys to review and approve military reciprocity applications in which the individual meets the requirements of Wis. Stat. § 440.09.

PURPOSE: The law permits service members, former service members, and their spouses to be licensed if they hold licensure in other jurisdictions that qualify them to perform acts authorized by the credential they are seeking in Wisconsin. This is a shortened path to licensure that does not require meeting the specific requirements/standards for licensure/reciprocity in a profession. By law, the Department/Board must expedite the issuance of a reciprocal license via military reciprocity. This delegation permits Department Attorneys to independently conduct military reciprocity reviews and efficiently approve applications if legal standards and requirements are met for licensure. Applications for which reciprocity may not be available will still be submitted to the Credentialing Liaison for input.

Delegation of Authority for Application Denial Reviews

MOTION EXAMPLE: to delegate authority to the Department's Attorney Supervisors to serve as the Board designee for purposes of reviewing and acting on requests for hearing as a result of a denial of a credential.

PURPOSE: When an application is denied, the applicant has a legal right to appeal the denial determination. Applicants must meet a specified legal standard in order to have an appeal granted. Additionally, Wisconsin law sets specific time frames for appeal decisions. This delegation permits Department Attorney Supervisors to independently review and efficiently act on requests for hearing as a result of a denial of a credential.

Delegation to Department Attorneys to Approve Duplicate Legal Issue

MOTION EXAMPLE: to delegate authority to Department Attorneys to approve a legal matter in connection with a renewal application when that same/similar matter was already addressed by the Board and there are no new legal issues for that credential holder.

PURPOSE: The intent of this delegation is to be able to approve prior discipline by the Board for the renewal applicant. This delegation eliminates the need for a re-review of discipline that has already been considered and approved by the Board/Section/Liaison.

Delegation to Department Attorneys to Approve Prior Discipline

MOTION EXAMPLE: to delegate authority to Department Attorneys to approve an applicant's prior professional discipline which resulted in a forfeiture/fine/other monetary penalty, remedial education, and/or reprimand, that is 10 years old or older, and the previously disciplined credential is currently in good standing.

PURPOSE: In order to continue improving processing application legal reviews in a timely matter, this delegation gives Department Attorneys authority to approve prior professional discipline which meets all of the following criteria: (1) it is at least ten years old; (2) it resulted in a monetary penalty, remedial education, and/or reprimand; and (3) the previously disciplined credential is currently in good standing.

MONITORING DELEGATIONS

The overall purpose of monitoring delegations is to be able to enforce the Boards orders and limited licenses as efficiently and effectively as possible. Monitoring delegations have two categories: delegations to the Monitoring Liaison and delegations to the Department Monitor.

Delegation of Authority to Department Monitor

MOTION EXAMPLE: to delegate authority to the Department Monitor:

- a. to grant full reinstatement of licensure if education is the only limitation and credential holder has submitted the required proof of course completion.
- b. to suspend the credential if the credential holder has not completed Board ordered education, paid costs, paid forfeitures, within the time specified by the Board Order.
- c. to lift a suspension when compliance with education and costs provisions have been met.

PURPOSE: These delegations allow for the Department Monitor to automatically act on requests when certain criteria are met or not met without needing to burden the Monitoring Liaison. The Board can set their own criteria for what actions they would like to be handled by the Department, the Monitoring Liaison, and the full Board.

Delegation of Authority to Monitoring Liaison

MOTION EXAMPLE: to delegate authority to the Monitoring Liaison to approve or deny all requests received by the credential holder.

PURPOSE: These delegations allow the Board to set criteria for what decisions can be made by the Board member(s) serving as the Monitoring Liaison and what matters should be decided by the full Board.

Education and Examination Delegations

MOTION EXAMPLE: to delegate authority to the Education and Examination Liaison(s) to address all issues related to qualifying education, continuing education and examinations. Motion carried unanimously. (Differs by Board)

PURPOSE: Some Boards are responsible for approving qualifying educational programs or continuing education courses. A delegation is executed in order for an Education and Examination Liaison to make these determinations on behalf of the Board and with assistance of the Department. Additionally, some Boards review examinations and individual scores to qualify for a credential.

MISCELLANEOUS DELEGATIONS

Document Signature

MOTION EXAMPLE: to delegate authority to the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to sign documents on behalf of the Board in order to carry out its duties. Motion carried unanimously.

MOTION EXAMPLE: in order to carry out duties of the Board, the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) has the ability to delegate signature authority for purposes of facilitating the completion of assignments during or between meetings. The members of the Board hereby delegate to the Executive Director, Board Counsel, or DPD Division Administrator the authority to sign on behalf of a Board member as necessary. Motion carried unanimously.

PURPOSE: To take the action approved at Board meetings, the Department may need to draft correspondence and/or Orders after the meetings have adjourned. These actions then need to be signed by a Board Member. This interaction usually takes place over email and a Board member can authorize the use of his/her signature that is kept on file.

Urgent Matters

MOTION EXAMPLE: in order to facilitate the completion of urgent matters between meetings, the Board delegates its authority to the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving Board member in that succession), to appoint liaisons to the Department to act in urgent matters. Motion carried unanimously.

PURPOSE: Allows for quick responses to urgent matters that may need Board approval or for which the Department requires guidance from the Board.

Delegation to Chief Legal Counsel-Due to Loss of Quorum

MOTION EXAMPLE: to delegate the review and authority to act on disciplinary cases to the Department's Chief Legal Counsel due to lack of/loss of quorum after two consecutive meetings. Motion carried unanimously.

PURPOSE: Sometimes Boards can struggle to meet quorum necessary to conduct business. This happens for a multitude of reasons, but this delegation allows for the Boards to have disciplinary cases decided by Chief Legal Counsel if the Board fails to meet quorum for two consecutive meetings.

Delegation to Chief Legal Counsel-Stipulated Resolutions

MOTION EXAMPLE: to delegate to the Department's Chief Legal Counsel (CLC) the authority to act on behalf of the Board concerning stipulated resolutions providing for a surrender, suspension, or revocation of a credential, where the underlying merits involve serious and dangerous behavior, and where the signed stipulation is received between Board meetings. The Board further requests that CLC only act on such matters when the best interests of the Board, Department, and the Public are best served by acting upon the stipulated resolution at the time the signed stipulation is received versus waiting for the next Board meeting. Motion carried unanimously.

PURPOSE: For matters of public safety, it may be necessary to take immediate action on a stipulated agreement rather than allowing a credential holder to continue practicing unencumbered until the next scheduled meeting. This delegation allows CLC to act on behalf of the Board when there is a stipulated agreement. A stipulated agreement is an agreement to which all relevant parties have consented to the terms.

Voluntary Surrenders

MOTION: to delegate authority to the assigned case advisor to accept or refuse a request for voluntary surrender pursuant to Wis. Stat. § 440.19 for a credential holder who has a pending complaint or disciplinary matter.

MOTION: to delegate authority to the Department to accept the voluntary surrender of a credential when there is no pending complaint or disciplinary matter with the Department pursuant to Wis. Stat. § 440.19.

PURPOSE: Credential holders can ask the Boards to accept surrender of their credentials at any time. These delegations are in place for the different situations that arise from those requests. If a credential holder is seeking to surrender their credential because they wish to leave the profession, that can be processed with this delegation by the Department if they have no pending disciplinary complaints. If the credential holder wishes to surrender while they have a pending disciplinary complaint, that request is reviewed by the individual Board member assigned to the case.

DLSC Pre-screening

MOTION EXAMPLE: to delegate pre-screening decision making authority to the DSPS screening attorney for opening cases where the credential holder has failed to respond to allegations contained in the complaint when requested by intake (case will be opened on failure to respond and the merits of the complaint).

PURPOSE: Pre-screening delegations exist so the Board can define specific parameters where the Department can review disciplinary complaints and open those cases if they meet certain criteria. Boards also have the authority to set certain criteria that would allow the Department to review and close a case if the criteria is met.

Delegation to Handle Administrative Rule Matters

MOTION EXAMPLE: to delegate authority to the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving Board member in that succession), to act on behalf of the Board regarding administrative rule matters between meetings. Motion carried unanimously.

PURPOSE: In order to advance the administrative rules process, action may need to occur between meetings. This allows for quick responses to urgent matters that may need Board approval or for which the Department requires guidance from the Board.

PHARMACY EXAMINING BOARD JANUARY 18, 2024 2024 DELEGATIONS

All Combined Delegations for 2024

Review and Approval of 2023 Delegations

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to reaffirm all

delegation motions from 2023 as reflected in the agenda materials. Motion

carried unanimously.

Document Signature Delegations

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, to delegate

authority to the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to sign documents on behalf of the Board in order to carry out its duties.

Motion carried unanimously.

MOTION: Michael Walsh moved, seconded by Susan Kleppin, in order to carry out

duties of the Board, the Chairperson (or in absence of the Chairperson, the

highest-ranking officer or longest serving board member in that

succession) has the ability to delegate signature authority for purposes of facilitating the completion of assignments during or between meetings. The members of the Board hereby delegate to the Executive Director, Board Counsel or DPD Division Administrator, the authority to sign on behalf of a board member as necessary. Motion carried unanimously.

Delegated Authority for Urgent Matters

MOTION: Anthony Peterangelo moved, seconded by Tiffany O'Hagan, that in order

to facilitate the completion of urgent matters between meetings, the Board

delegates its authority to the Chairperson (or, in the absence of the

Chairperson, the highest-ranking officer or longest serving board member in that succession), to appoint liaisons to the Department to act in urgent

matters. Motion carried unanimously.

Delegation to Chief Legal Counsel Due to Loss of Quorum

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to delegate the

review and authority to act on disciplinary cases to the Department's Chief

Legal Counsel due to lack of/loss of quorum after two consecutive

meetings. Motion carried unanimously.

Delegation to Chief Legal Counsel for Stipulated Resolutions

MOTION:

Michael Walsh moved, seconded by Anthony Peterangelo, to delegate to DSPS Chief Legal Counsel the authority to act on behalf of the Board concerning stipulated resolutions providing for a surrender, suspension, or revocation of a credential, where the underlying merits involve serious and dangerous behavior, and where the signed stipulation is received between Board meetings. The Board further requests that CLC only act on such matters when the best interests of the Board, Department and the Public are best served by acting upon the stipulated resolution at the time the signed stipulation is received versus waiting for the next Board meeting. Motion carried unanimously.

Monitoring Delegations

Delegation of Authorities for Monitoring

MOTION:

Susan Kleppin moved, seconded by Tony Peterangelo, to adopt the "Roles and Authorities Delegated for Monitoring" document as presented in the January 18, 2024, agenda materials on pages 43-45. Motion carried unanimously.

Delegation of Authorities for Legal Counsel to Sign Monitoring Orders

MOTION:

Susan Kleppin moved, seconded by Anthony Peterangelo, to delegate to Legal Counsel the authority to sign Monitoring orders that result from Board meetings on behalf of the Board Chairperson. Motion carried unanimously.

Delegation to Monitoring Liaison

MOTION:

Michael Walsch moved, seconded by Christa Wilson, to delegate authority to the Monitoring Liaison(s) to make any determination on Orders under monitoring and to refer to the Full Board any matter the monitoring Liaison deems appropriate. Motion carried unanimously.

Credentialing Authority Delegations

Delegation of Authority to Credentialing Liaison

MOTION:

Michael Walsh moved, seconded by Tiffany O'Hagan, to delegate authority to the Credentialing Liaison(s) to serve as a liaison between the Department and the Board and to act on behalf of the Board in regard to credentialing applications or questions presented to them, including the signing of documents related to applications. Motion carried unanimously.

Delegation of Authority to DSPS When Credentialing Criteria is Met

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to delegate

credentialing authority to the Department to act upon applications that meet all credentialing statutory and regulatory requirements without Board

or Board liaison review. Motion carried unanimously.

Delegation of Authority for Predetermination Reviews

MOTION: Michael Walsh moved, seconded by Christa Wilson, to delegate authority

to the Department Attorneys to make decisions regarding predetermination

applications pursuant to Wis. Stat. § 111.335(4)(f). Motion carried

unanimously.

Delegation of Authority for Conviction Reviews

MOTION: Christa Wilson moved, seconded by Anthony Peterangelo, to delegate

authority to Department Attorneys to review and approve applications with municipal/ordinance violations and misdemeanors which are not substantially related to the practice of pharmacy. Motion carried

unanimously.

Delegation to DSPS When Applicant's Discipline History Has Been Previously Reviewed

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to delegate authority

to Department staff to approve applications where Applicant's prior

discipline has been approved for a previous pharmacy credential and there

is no new discipline. Motion carried unanimously.

Delegation to DSPS When Applicant's Conviction History Has Been Previously Reviewed

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to delegate

authority to Department staff to approve applications where criminal background checks have been approved for a previous pharmacy credential and there is no new conviction record. Motion carried

unanimously.

Delegation of Authority for Reciprocity/Endorsement Reviews

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to delegate

authority to the Department Attorneys to review and approve reciprocity/endorsement applications in which the applicant met

requirements comparable to those that existed in this state at the time the person became licensed in the other state. Motion carried unanimously.

Delegation of Authority for Military Reciprocity Reviews

MOTION:

Susan Kleppin moved, seconded by Michael Walsh, to delegate authority to the Department Attorneys to review and approve military reciprocity applications in which the individual meets the requirements of Wis. Stat. § 440.09. Motion carried unanimously.

Delegated Authority for Application Denial Reviews

MOTION:

Michael Walsh moved, seconded by Anthony Peterangelo, to delegate authority to the Department's Attorney Supervisors to serve as the Board's designee for purposes of reviewing and acting on requests for hearing as a result of a denial of a credential. Motion carried unanimously.

Pre-Screening Delegation to Open Cases

MOTION:

Susan Kleppin moved, seconded by Michael Walsh, to delegate prescreening decision making authority to the Department screening attorney for opening cases as outlined below:

- 1. OWIs of 3 or more that occurred in the last 5 years.
- 2. Reciprocal discipline cases.
- 3. Impairment and/or diversion at work that includes a positive drug/alcohol test or admission by respondent.
- 4. Conviction of a misdemeanor or felony that the attorney believes is substantially related and is not otherwise excluded from consideration via Wis. Stat. ch. 111.
- 5. No response from the respondent after intake requested a response (case would be opened for the failure to respond issue as well as the merits).

Motion carried unanimously.

Pre-Screening Delegation to Close Cases

MOTION:

Anthony Peterangelo moved, seconded by Michael Walsh, to delegate prescreening decision making authority to the Department screening attorney for closing cases as outlined below:

- 1. One OWI that is non-work related and if AODA assessment completed, assessment does not indicate dependency.
- 2. Complaints that even if allegations are true, do not amount to a violation of law or rules.
- 3. To close at prescreening complaints that the Board has already reviewed and acted upon that are the result of multiple-state discipline based on original violations.

Motion carried unanimously.

Delegation to Department Attorneys to Approve Duplicate Legal Issue

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to delegate authority

to Department Attorneys to approve a legal matter in connection with a renewal application when that same/similar matter was already addressed

by the Board and there are no new legal issues. Motion carried

unanimously.

Voluntary Surrenders

MOTION: Michael Walsh moved, seconded by Christa Wilson, to delegate authority

to the assigned case advisor to accept or refuse a request for voluntary surrender pursuant to Wis. Stat. § 440.19 for a credential holder who has a pending complaint or disciplinary matter. Motion carried unanimously.

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to delegate

authority to the Department to accept the voluntary surrender of a credential when there is no pending complaint or disciplinary matter with

the Department pursuant to Wis. Stat. § 440.19. Motion carried

unanimously.

Education and Examination Liaison(s) Delegation

MOTION: Christa Wilson moved, seconded by Michael Walsh, to delegate authority

to the Education and Examination Liaison(s) to address all issues related to continuing education, and examinations. Motion carried unanimously.

Pilot Program Liaison(s) Delegation

MOTION: Christa Wilson moved, seconded by Anthony Peterangelo, to delegate

authority to the Pilot Program Liaison(s) to address all issues related to

pilot program matters. Motion carried unanimously.

Authorization for DSPS to Provide Board Member Contact Information to National Regulatory Related Bodies

MOTION: Michael Walsh moved, seconded by Christa Wilson, to authorize the

Department staff to provide national regulatory related bodies with all board member contact information that the Department retains on file.

Motion carried unanimously.

Optional Renewal Notice Insert Delegation

MOTION: Christa Wilson moved, seconded by Michael Walsh, to designate the

Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to provide a brief statement or link relating to board-related business within the license

renewal notice at the Board's or Board designee's request. Motion carried unanimously.

Rules Committee Delegation

MOTION: Susan Kleppin moved, seconded by Christa Wilson, to grant the Rules

Committee the ability to address all rulemaking as related to drafting and making recommendations to the full Board. Motion carried unanimously.

Committee Membership Delegation

MOTION: Tiffany O'Hagan moved, seconded by Christa Wilson, that in order to

facilitate the completion of its duties between meetings, the Board delegates authority to the Chairperson (or, in the absence of the

Chairperson, the highest-ranking officer or longest serving board member

in that succession) to appoint members to its committees between

meetings as necessary. Motion carried unanimously.

Legislative Liaison Delegation

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to delegate authority

to the Legislative Liaisons to speak on behalf of the Board regarding

legislative matters. Motion carried unanimously.

Travel Authorization Liaison Delegation

MOTION: Christa Wilson moved, seconded by Tiffany O'Hagan, to delegate

authority to the Travel Authorization Liaison to approve any board member travel to and/or participation in events germane to the board, and to designate representatives from the Board to speak and/or act on the

Board's behalf at such events. Motion carried unanimously.

Newsletter Liaison(s) Delegation

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to delegate

authority to the newsletter liaison(s) to handle all matters relating to

newsletters. Motion carried unanimously.

Website Liaison(s) Delegation

MOTION: Susan Kleppin moved, seconded by Christa Wilson, to authorize to the

Website Liaison(s) to act on behalf of the Board in working with

Department staff to identify and execute website updates. Motion carried

unanimously.

SCAODA Representative Delegation

MOTION: Anthony Peterangelo moved, seconded by Christa Wilson, to authorize the

SCAODA representative to vote on behalf of the Board at the State Council on Alcohol and Other Drug Abuse meetings. Motion carried

unanimously.

Variance Liaison(s) Delegation

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to delegate to

the Variance Liaison(s) the Board's authority to approve, rescind, and modify variances under §450.02(3m). Motion carried unanimously.

Improving Pharmacist Workplace Satisfaction Delegation

MOTION: John Weitekamp moved, seconded by Tiffany O'Hagan, to designate

Anthony Peterangelo to work with DSPS to identify topics of

consideration and discussion related to improving pharmacist workplace

satisfaction by the Pharmacy Examining Board. Motion carried

unanimously.

Phar 7.08(8) Approval Request Liaison(s) Delegation

MOTION: John Weitekamp moved, seconded by Tiffany O'Hagan, to designate the

Phar 7.08(8) Approval Request Liaison to serve as the liaison for review

of Phar 7.08(8) approval requests. Motion carried unanimously.

Inspection Liaison(s) Delegation

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, to designate the

Inspection Liaison(s) to address all issues related to the inspection of

credentialed facilities. Motion carried unanimously.

Interdisciplinary Advisory Committee Liaison

MOTION: Michael Walsh moved, seconded by Christa Wilson, to delegate authority

to the Interdisciplinary Advisory Council liaison to speak and take action on behalf of the Pharmacy Examining Board in matters considered by the Council, and to report back to the Pharmacy Examining Board on any

actions taken by the Council. Motion carried unanimously.

Pre-Screening Delegation to Open Cases, Amended

MOTION:

[Board Member Name]moved, seconded by [Board Member Name], to delegate pre-screening decision making authority to the Department screening attorney for opening cases as outlined below:

- 1. OWIs of 3 or more that occurred in the last 5 years.
- 2. Reciprocal discipline cases.
- 3. Impairment and/or diversion at work that includes a positive drug/alcohol test or admission by respondent.
- 4. Conviction of a misdemeanor or felony that the attorney believes is substantially related and is not otherwise excluded from consideration via Wis. Stat. ch. 111.
- 5. No response from the respondent after intake requested a response (case would be opened for the failure to respond issue as well as the merits).
- 6. Out of state discipline cases that have not been previously reported and/or investigated.

Motion	carried	١.

Delegation to Monitoring Liaison

MOTION:

[Board Member Name] moved, seconded by [Board Member Name], to delegate authority to the Monitoring Liaison(s) to make any determination on Orders under monitoring and to refer to the Full Board any matter the Monitoring Liaison deems appropriate. Motion carried [____].

Delegation to Department Monitor

MOTION:

[Board Member Name] moved, seconded by [Board Member Name], to delegate authority to the Department Monitor as outlined below:

- 1. to grant reinstatement of licensure if education and/or costs are the sole condition of the order and the credential holder has submitted the required proof of completion for approved courses and paid the costs.
- 2. to suspend the license if the credential holder has not completed Board ordered education and/or paid costs and forfeitures within the time specified by the Board order. The Department Monitor may remove the suspension and issue an order when proof of completion and/or payment has been received.

- 3. to suspend the license (or remove stay of suspension) if a credential holder fails to enroll and participate in an Approved Program for drug and alcohol testing within 30 days of the order, or if credential holder ceases participation in the Approved Program without Board approval. This delegated authority only pertains to respondents who must comply with drug and/or alcohol testing requirements.
- 4. to grant or deny approval when a credential holder proposes treatment providers, mentors, and supervisors unless the Order specifically requires full-Board or Board designee approval.
- 5. to grant a maximum of one <u>90-day extension</u>, if warranted and requested in writing by a credential holder, to complete Board ordered continuing, disciplinary, or remedial education.
- 6. to grant a maximum of one <u>90-day extension</u> or payment plan for proceeding costs and/or forfeitures if warranted and requested in writing by a credential holder.
- 7. to grant a maximum of one <u>90-day extension</u>, if warranted and requested in writing by a credential holder, to complete a Board ordered evaluation or exam.

Motion carried [].

Delegation to Department Attorneys to Approve Prior Discipline

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[Board member name] moved, seconded by [Board member name], to delegate authority to Department Attorneys to approve an applicant's prior professional discipline which resulted in a forfeiture/fine/other monetary penalty, remedial education, and/or reprimand, that is 10 years old or older, and the previously disciplined credential is currently in good standing. Motion carried [_____].

Delegation to Handle Administrative Rule Matters

MOTION:

[Board member name] moved, seconded by [Board member name], to delegate authority to the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving Board member in that succession), to act on behalf of the Board regarding administrative rule matters between meetings. Motion carried [_____].

Review and Approval of 2024 Delegations including new modifications

MOTION:

[Board member name] moved, seconded by [Board member name], to reaffirm all delegation motions made in 2024, as reflected in the February 20, 2025 agenda materials, which were not otherwise modified or amended during the February 20, 2025 meeting. Motion carried [_____].

AGENDA REQUEST FORM

1) Name and title of person submitting the request:			2) Date when request submitted:				
Nilajah Hardin		02/07/25					
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:							
Pharmacy Examining I	Pharmacy Examining Board						
4) Meeting Date:	5) 6) How should the item be titled on the agenda page?						
02/20/25	Attachments:	Administrativa	Dula Mattar	s – Discussion and Consideration			
	⊠ Yes			Request: EmR 2411 on Phar 8, Relating to			
	□ No			ces Requirements			
		2. Pending	g or Possible	Rulemaking Projects			
7) Place Item in:		ance before the Boa		9) Name of Case Advisor(s), if required:			
		yes, please complete guest for Non-DSPS		N/A			
Closed Session		<u>quest</u> for Non-DSF3	o Stall)				
	☐ Yes						
10) Describe the issue a	10) Describe the issue and action that should be addressed:						
Attachments:	ina action that she	aid be addressed.					
	n on Phar 8 1st Ex						
 Phar 8 2nd Exten EmR 2411 	sion Request Lett	er					
4. Rule Projects Ch	nart						
	10.10	C 1 W 1H	1 //1	'			
Copies of current Boa	ard Rule Projects	Can be Viewed He	ere: https://ds	ps.wi.gov/Pages/RulesStatutes/PendingRules.aspx			
11)	W 2003	Authoriza	tion				
Melajars al	Harolis			02/07/25			
Signature of person ma	king this request			Date			
Supervisor (if required) Date							
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date							
Executive Director signs	ature (indicates ap	proval to add post	agenda dead	ine item to agenda) Date			
Directions for including 1. This form should be			d to the agend	la.			
2. Post Agenda Deadlin	ie items must be a	uthorized by a Supe	ervisor and th	e Policy Development Executive Director.			
3. If necessary, provide	original documen	its needing Board C	Chairperson s	ignature to the Bureau Assistant prior to the start of a			

Record of Committee Proceedings

Joint Committee for Review of Administrative Rules

EmR 2411

Relating to Controlled substances requirements (Pharmacy Examining Board).

January 29, 2025 **Public Hearing Held**

Present: (10) Senator Nass; Representative Neylon; Senators

Bradley, Tomczyk, Roys and Ratcliff;

Representatives Petersen, Spiros, Snodgrass

and Arney.

Absent: (0) None. Excused: (0) None.

Appearances For

• John Weitekamp - Pharmacy Examining Board

Appearances Against

None.

Appearances for Information Only

• None.

Registrations For

- Brad Wojciechowski DSPS
- Mike Tierney DSPS

Registrations Against

• None.

Registrations for Information Only

• None.

January 29, 2025 **Executive Session Held**

Present: (10) Senator Nass; Representative Neylon; Senators

Bradley, Tomczyk, Roys and Ratcliff;

Representatives Petersen, Spiros, Snodgrass

and Arney.

Absent: (0) None. Excused: (0) None.

Moved by Senator Tomczyk, seconded by Senator Bradley that the Joint Committee for Review of Administrative Rules, pursuant to s. 227.24 (2), Stats., extend the effective period of an emergency

rule of the Pharmacy Examining Board, relating to controlled substances requirements (EmR 2411-1st Ext.), for a period of 60 days through April 28, 2025.

Ayes: (10) Senator Nass; Representative Neylon; Senators Bradley, Tomczyk, Roys and Ratcliff; Representatives Petersen, Spiros, Snodgrass and Arney.

Noes: (0) None.

MOTION PASSED, Ayes 10, Noes 0

Nathan Cobb Committee Clerk

Pharmacy Examining Board

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



March , 2025

Senator Stephen Nass, Senate Co-Chairperson Joint Committee for Review of Administrative Rules Room 10 South, State Capitol Madison, WI 53702

Representative Adam Neylon, Assembly Co-Chairperson Joint Committee for Review of Administrative Rules Room 204 North, State Capitol Madison, WI 53702

RE: Request for Second Extension of Emergency Rule, Pharmacy Examining Board

Dear Senator Nass and Representative Neylon:

Pursuant to Wis. Stat. s. 227.24 (2), I am writing to request a second extension of EmR2411, an emergency rule amending Phar 8, relating to Controlled Substances Requirements. A copy of the emergency rule is attached.

This rule revises ch. Phar 8 of the Wisconsin Administrative Code to reduce conflicts between state and federal law, while maintaining public safety. The Board has been working diligently on drafting the permanent rule associated with this project. However, the emergency rule is set to expire on April 28, 2025. The permanent rule is with the Governor's Office for approval and then will need to be submitted for review by the Legislature. Given these remaining steps, a publication and effective date have not been determined yet.

Therefore, the Pharmacy Examining Board is requesting an extension of the emergency rule to cover the anticipated gap between April 28, 2025 and when the permanent rule will be effective in order to avoid confusion for stakeholders and licensees.

Sincerely,

John Weitekamp Chairperson Pharmacy Examining Board

STATE OF WISCONSIN PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING : ORDER OF THE

PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD PHARMACY EXAMINING BOARD : ADOPTING EMERGENCY RULES

The statement of scope for this rule, SS 044-23, was approved by the Governor on June 22, 2023, published in Register 811A2 on July 10, 2023, and approved by the Pharmacy Examining Board on September 5, 2023. This emergency rule was approved by the Governor on July 11, 2024.

<u>ORDER</u>

An order of the Pharmacy Examining Board to create Phar 8.03 (3), amend Phar 8.04, and repeal and recreate Phar 8.07, relating to controlled substances requirements.

Analysis prepared by the Department of Safety and Professional Services.

FINDING OF EMERGENCY

The Pharmacy Examining Board finds that an emergency exists and that this rule is necessary for the immediate preservation of the public peace, health, safety, or welfare. A statement of facts constituting the emergency is: Clearinghouse Rule 21-071 went into effect on October 1, 2022. This rule repealed and recreated all of Wisconsin Administrative Code Chapter Phar 8. Upon receiving feedback and completing an additional review, the Pharmacy Examining Board has determined that additional changes are needed to Phar 8 to address areas where requirements are no longer in effect or do not match federal regulations. Emergency rules are needed to ensure that these requirements can be updated to protect patient safety and allow effective regulation of the profession until permanent rules can be promulgated.

ANALYSIS

Statutes interpreted: ss. 450.09, 450.11, and 961.31, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (2), 450.02 (3) (a), (d), and (e)., 961.31, Stats.

Explanation of agency authority:

Section 15.08 (5) (b), Stats. states that "[t]he Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."

Section 450.02 (2), Stats. provides that the board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.

Section 450.02 (3) (a), Stats. provides that the board "may promulgate rules [r]elating to the manufacture of drugs and the distribution and dispensing of prescription drugs."

Section 450.02 (3) (d), Stats. provides that the board "may promulgate rules [n]ecessary for the administration and enforcement of this chapter and ch. 961."

Section 450.02 (3) (e), Stats. provides that the board "may promulgate rules [e]stablishing minimum standards for the practice of pharmacy."

Section 961.31, Stats. providers that "[t]he pharmacy examining board may promulgate rules relating to the manufacture, distribution, and dispensing of controlled substances within this state."

Related statute or rule: Wisconsin Administrative Code ch. Phar 7

Plain language analysis: This rule project revises ch. Phar 8 to reduce regulatory burdens on pharmacies, while maintaining public safety. These revisions include the addition of language regarding changes to controlled substances prescriptions, amendments to remove language regarding suspicious controlled substances orders, and amendments to clarify that partial dispensing of controlled substances is allowed.

Summary of, and comparison with, existing or proposed federal regulation: The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

Comparison with rules in adjacent states:

Illinois: 225 Illinois Compiled Statutes 85 outlines Illinois' Pharmacy Practice Act. These statutes are further described in the Illinois Administrative Code Title 68 Part 1330. Included in both are requirements for pharmacy standards and pharmacy operation [225 Illinois Compiled Statutes 85, Illinois Administrative Code Title 68 Chapter VII Subchapter b Part 1330 Sections 1330.600 to 1330.800]. Illinois law also requires a pharmacist to report theft or loss of controlled substances to the board at the same time it is reported to the DEA [Illinois Administrative Code Title 68 Chapter VII Subchapter b Part 1330 Sections 1330.710].

In the Illinois Controlled Substances Act, partial filling of schedule III to V controlled substances is allowed within 6 months after the date the prescription was issued, as long as the total quantity dispensed does not exceed the total quantity prescribed and each partial fill is recorded in the same manner as a refill. Schedule II partial refills are allowed under certain circumstances. Those circumstances include if the pharmacist is unable to provide the full quantity of a prescription, then the remaining quantity may be filled within 72 hours. If the remaining quantity is not filled within 72 hours, the pharmacist shall notify the prescribing practitioner and a new prescription is required to dispense any further quantity of that medication. Other circumstances include requirements for partial filling of schedule II controlled substance prescriptions for patients in long term care facilities with a terminal illness [Illinois Administrative Code Title 77 Chapter XV Part 3100 Section 3100.420]. Illinois also allows certain changes to schedule II controlled substance prescriptions. Outside of the changing or adding the date, name of the patient, name of the prescriber or adding a signature, and the name of the drug, any other components of a schedule II controlled substance prescription may be changed after consultation with the prescriber [Illinois Administrative Code Title 77 Chapter XV Part 3100 Section 3100.400].

Iowa: The Iowa Pharmacy Board requires pharmacist to report theft or loss of controlled substances to the Iowa Board if there is reason to believe that the theft was committed by a pharmacy board licensee, otherwise it is sufficient to report the theft to the DEA [657 Iowa Administrative Code Chapter 10 Section 10.21]. Iowa allows the partial filling of schedule II controlled substance prescriptions if there is an insufficient supply on hand for the pharmacist, for a long-term care or terminally patient, or a patient or prescriber request [657 Iowa Administrative Code Chapter 10 Section 10.27]. Changes to schedule II controlled substances are allowed after consultation with the prescriber or prescriber's agent in the areas of drug strength, dosage form, drug quantity, directions for use, date the prescription was issued, or the prescriber's address or DEA registration number. The pharmacist is not allowed to change the patient's name, the controlled substance prescribed except for generic substitution, or the name or signature of the prescriber [657 Iowa Administrative Code Chapter Section 10.30].

Michigan: Michigan requires theft or diversion of a controlled substance to be reported to the Michigan Department of Licensing and Regulatory Affairs within 15 days of completion of an investigation regarding a suspected theft or significant loss of a controlled substance, whether or not it is also reported to the DEA [Michigan Administrative Rules R 338.3141]. Michigan allows partial dispensing of schedule II controlled substances when the pharmacist is unable to supply the full quantity, at the request of the patient or prescriber, or for a patient in a long-term care facility or one who has a terminal illness. When the pharmacist is unable to supply the full quantity of a schedule II controlled substance prescription, the remaining quantity must be dispensed within 72 hours. If the remaining quantity is not dispensed within 72 hours, the pharmacist is required to notify the prescriber and a new prescription is required to dispense any further quantity. When a patient or prescriber requests a partial refill of a schedule II controlled substance prescription, the remaining portion may be dispensed within 30 days after the date of the on which the prescription was written. When the

schedule II controlled substance prescription is for a patient in a long-term care facility or for one with a terminal illness, individual dosage units may be dispensed and the prescription is valid for 60 days from the issue date. Partial filling of schedule III to V controlled substances prescriptions is also allowed as long as each partial fill is recorded as the same manner as a refill, the total quantity dispensed is not more than the total prescribed, and no dispensing can occur after 6 months for the date the prescription was issued [Michigan Administrative Rules R 338.3166]. Michigan Administrative Rules do not appear to mention requirements for changes to controlled substance prescriptions.

Minnesota: Minnesota allows the partial filling of schedule II controlled substances for patients in long term care facilities or those that are terminally ill [Minnesota Administrative Code Section 6800.4300]. Pharmacists, drug wholesalers, drug manufacturers, and controlled substance researchers must report loss or theft of controlled substances to the DEA immediately [Minnesota Administrative Code Section 6800.4800]. Minnesota Administrative Rules do not appear to mention requirements for changes to controlled substance prescriptions.

Summary of factual data and analytical methodologies: The Pharmacy Examining Board completed a comprehensive review of ch. Phar 8, Requirements for Controlled Substances, in order to identify and make revisions to ensure the chapters are statutorily compliant with state and federal law and are current with professional standards and practices. The board also evaluated ch. Phar 8 for ways to reduce the regulatory impact on pharmacies without negatively impacting public safety.

Fiscal Estimate: The Fiscal Estimate 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; 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, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

SECTION 1. Phar 8.03 (3) is created to read:

Phar 8.03 (3) Pharmacists are to use professional judgement to contact prescribers for changes to controlled substances prescriptions as needed and in accordance with federal law and s. Phar 7.02 (5).

SECTION 2. Phar 8.04 is amended to read:

Phar 8.04 Notification of suspicious orders for and theft or loss of controlled substances. A pharmacy or pharmacist shall notify the board of a suspicious order or series of orders for controlled substances or the theft or loss of controlled substances on the same day notification is required to be provided to the drug enforcement administration. Notification to the board shall include all of the information required to be provided in the notification to the drug enforcement administration.

SECTION 3. Phar 8.07 is repealed and recreated to read:

Phar 8.07 Partial Dispensing. Partial dispensing of controlled substances is allowed in accordance with federal law.

SECTION newspap	· ·	y rule shall take effect	upon publication in the official state
		(END OF TEXT (OF RULE)
Dated	5/10/2024	Agency	John Weitekamp
		_	Chairperson Pharmacy Examining Board

Pharmacy Examining Board Rule Projects (updated 02/07/25)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet	Not Assigned Yet	TBD	Phar 1. 6, 7, and 10	Pharmacy Workplace Conditions	Preliminary Scope Hearing Held at 02/20/25 Meeting	Scope Implementation
Not Assigned Yet	089-24	05/05/2027	Phar 7	Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check	Drafting	Board Approval of Preliminary Rule Draft for EIA Comment and Clearinghouse Review
24-070 (EmR 2411)	044-23	01/10/2026	Phar 8	Controlled Substances Requirements	Emergency Rule: Effective 10/01/24-04/28/25; 2 nd Extension Request Reviewed at 02/20/25 Meeting Permanent Rule: Submitted to the Governor for Approval on 11/21/24	Emergency Rule: JCRAR Review of 2 nd Extension Request Permanent Rule: Legislative Review
Not Assigned Yet	007-23	07/23/2025	Phar 15	Compounding Pharmaceuticals	Public Hearing Held at 02/20/25 Meeting	Drafting Final Rule and Legislative Report

AGENDA REQUEST FORM

1) Name and title of person submitting the request:		2) Date when request submitted:			
Brad Wojciechowski, Executive Director				2/4/2025	
					dered late if submitted after 12:00 p.m. on the h is 8 business days before the meeting
3) Name of Board, Comr	nittee, Co	uncil, Sections:			and a successful succe
Pharmacy Examining Bo	oard				
4) Meeting Date:	5) Attac	hments:	6) How	should the item be tit	tled on the agenda page?
2/20/2025	□ Yes ⊠ No		Speaking Engagements, Travel, or Public Relations Requests, and Reports – Discussion and Consideration		
			1)	Travel Report: NAB Tiffany O'Hagan	P Member Forum, December 4-5, 2024 –
			2)	Travel Request: MF 2025, NABP Headqu	PJE Item Development Workshop, March 12-14, uarters
			3)		ent: Pharmacy Society of Wisconsin ednesday, March 19, 2025, Madison, WI
			4)	Travel Request: NA 17, 2025, NABP Hea	PLEX Item Development Workshop, April 15- adquarters
7) Place Item in:		,		the Board being	9) Name of Case Advisor(s), if applicable:
☑ Open Session☐ Closed Session		scheduled? (If yes, please complete Appearance Request for Non-DSPS Staff)			<click a="" add="" advisor="" case="" here="" n="" name="" or="" to=""></click>
			Yes <appearance name(s)=""></appearance>		
		□ No			

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

MPJE Item Development Workshop

At the upcoming Item Development Workshop, MPJE item writers will prepare content for the MPJE.

Dedicated volunteers from all areas of pharmacy practice and faculty from schools and colleges of pharmacy will devote their time at the upcoming MPJE Item Development Workshop to uphold the integrity and validity of the exam. During the workshop, item writers will develop content for the exam.

Examination Item Writers - NABP welcomes pharmacists in all areas of practice as well as school and college of pharmacy faculty to apply as item writers for the Association's examinations and assessments. Item writers must have at least two years' experience in practice, teaching in a US pharmacy program, or in residency.

Speaking Engagement: Pharmacy Society of Wisconsin Legislative Day

The Pharmacy Society of Wisconsin (PSW) is hosting its annual Legislative Day on Wednesday, March 19, 2025, in Madison, Wisconsin. We anticipate an attendance of over three hundred pharmacists, pharmacy technicians, and pharmacy students. The agenda will include a discussion of several pharmacy-related legislative and regulatory priorities.

On behalf of the Board of Directors and staff of the Pharmacy Society of Wisconsin, I would like to invite you and other members of the Pharmacy Examining Board to attend our Legislative Day and address our members. They would appreciate hearing a regulatory update from Pharmacy Examining Board members.

NAPLEX Item Development Workshop

At the upcoming Item Development Workshop, NAPLEX item writers will prepare content for the NAPLEX.

Dedicated volunteers from all areas of pharmacy practice and faculty from schools and colleges of pharmacy will devote their time at the NAPLEX Item Development Workshop to uphold the integrity and validity of the exam. During the workshop, item writers will develop content for the exam.

Examination Item Writers - NABP welcomes pharmacists in all areas of practice as well as school and college of pharmacy faculty to apply as item writers for the Association's examinations and assessments. Item writers must have at least two years' experience in practice, teaching in a US pharmacy program, or in residency.

		
11) Authorization		
BLAHN		
CS (A)	2/4/2025	
Signature of person making this request	Date	—
olynature of person making this request	Dute	
Supervisor (Only required for post agenda deadline items)	Date	
Executive Director signature (Indicates approval for post agenda deadline items)	Date	
Directions for including supporting documents:		
1. This form should be saved with any other documents submitted to the Agenda Item		
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy De 3. If necessary, provide original documents needing Board Chairperson signature to	•	fa
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If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

AGENDA REQUEST FORM

1) Name and title of person submitting the request:				2) Date when request submitted:		
Brad Wojciechowski, Executive Director				2/10/2025		
					dered late if submitted after 12:00 p.m. on the	
				deadline date which	n is 8 business days before the meeting	
3) Name of Board, Comi	mittee, Co	ouncil, Sections:				
Pharmacy Examining Bo	oard					
4) Meeting Date:	5) Attac	chments:	6) How	should the item be tit	tled on the agenda page?	
2/20/2025	□ Y	es	Pharma	cy Examining Board	Guidance – Discussion and Consideration	
	⊠ N	0	1)	Pharmacy Technicia	ans	
			2)		e Guidance Projects	
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		□ No				
10) Describe the issue a	nd action	n that should be ad	dressed:			
					ing to Pharmacy Technician licensing	
	l like guid	dance from the Pha	rmacy Ex	amining Board to wh	at duties require an employee of a pharmacy	
to apply for a license.						
11)		,	Authoriza	tion		
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501.10					2/10/2025	
Signature of person making this request				Date		
Supervisor (Only required for post agenda deadline items)				Date		
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Executive Director signs			post age	nda deadline items)	Date	
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					e to the Bureau Assistant prior to the start of a	
meeting.	J			,		