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**Tony Evers, Governor**
**Dan Hereth, Secretary**

**HYBRID (IN-PERSON/VIRTUAL)**
**PHARMACY EXAMINING BOARD**
**Room N208, 4822 Madison Yards Way, 2nd Floor, Madison**
**Contact: Brad Wojciechowski (608) 266-2112**
**April 17, 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. A quorum of the Board may be present during any committee meetings.*

## AGENDA

**11:00 A.M.**

**OPEN SESSION – CALL TO ORDER – ROLL CALL**

**A. Adoption of Agenda (1-4)**

**B. Approval of Minutes of February 20, 2025 (5-14)**

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements and Recognition – Discussion and Consideration

**E. Administrative Matters – Discussion and Consideration**
1. Department, Staff and Board Updates
2. **Election of Officers, Appointments of Liaisons and Alternates, Delegation of Authorities**
3. 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

F. Legislative and Policy Matters – Discussion and Consideration

**G. Administrative Rule Matters – Discussion and Consideration (15-26)**
1. Final Rule Draft and Legislative Report: Phar 15, Relating to Compounding Pharmaceuticals **(16-25)**
2. Update on Phar 8, Relating to Controlled Substances Requirements
3. Pending or Possible Rulemaking Projects **(26)**

**H. Speaking Engagements, Travel, or Public Relation Requests, and Reports – Discussion and Consideration (27-43)**

1. Travel Report: MPJE Item Development Workshop, March 12-14, 2025, Mt. Prospect, IL – O'Hagan, Weitekamp
2. Speaking Engagement Report: PSW Legislative Day Presentation, March 19, 2025 – O'Hagan, Weitekamp **(28-43)**
3. Travel Request: APhA Institute on Substance Use Disorders, May 28-31, 2025, Salt Lake City, UT

**I. Interdisciplinary Advisory Committee – Discussion and Consideration (44)**

1. IV Hydration Guidance

J. **National Association of Boards of Pharmacy Matters – Discussion and Consideration (45)**

1. Interstate Privilege Working Group

K. NABP Pulse Regulator Monthly Champions Call – Discussion and Consideration

**L. Newsletter Matters – Discussion and Consideration**

M. Credentialing Matters – Discussion and Consideration

N. Liaison Reports – Discussion and Consideration

O. 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

**P. Public Comments**

**CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider 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.).**

**Q. Credentialing Matters**

**1. Application Review**

a. M.V.H.S. – Pharmacy Out-of-State (IA 519005) **(46-169)**

**R. Deliberation on Division of Legal Services and Compliance Matters**

**1. Administrative Warnings**

a. 24 PHM 0140 – N.J.O. **(170-171)**

**2. Case Closings**

a. 21 PHM 162 – W.P. **(172-186)**
b. 22 PHM 141 – P.P.S. **(187-190)**
c. 23 PHM 128 – O.S.S., C.P. **(191-194)**
d. 23 PHM 170 – W.P. **(195-199)**
e. 23 PHM 185 – E.P. **(200-203)**
f. 24 PHM 010 and 24 PHM 0090 – R.R. **(204-207)**
g. 24 PHM 0067 – W. **(208-212)**
h. 24 PHM 0140 – W.P. **(213-220)**
i. 24 PHM 0167 – T.T.C.S. **(221-226)**
j. 25 PHM 0005 – M.M.S. **(227-230)**

**3. Proposed Stipulations, Final Decisions and Orders**

a. 23 PHM 049 – Justin D. Smith **(231-236)**
b. 23 PHM 061 – Walgreens #03109 **(237-243)**

**S. Deliberation on Proposed Final Decision and Orders**

1. Taylor A. Roberts-Dever, Respondent (DHA Case Number SPS-24-0056/ DLSC Case Number 23 PHM 097) **(244-255)**

T. 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

U. Consulting with Legal Counsel

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

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

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

**ADJOURNMENT**

**NEXT MEETING: June 19, 2025**

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

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held 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**
**FEBRUARY 20, 2025**

**PRESENT:** Susan Kleppin; Tiffany O'Hagan; Anthony Peterangelo, Michael Walsh, John Weitekamp, Christa Wilson

**STAFF:** Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Brenda Taylor, Board Services Supervisor; and other Department staff

## CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 11:00 a.m. A quorum was confirmed with six (6) members present.

## ADOPTION OF AGENDA

***Amendments to the Agenda:***
S.3.a. page numbers s/b 344-351 *(scrivener's error)*

**MOTION:** Michael Walsh moved, seconded by Tiffany O'Hagan, to adopt the Agenda as amended. Motion carried unanimously.

## APPROVAL OF MINUTES OF DECEMBER 5, 2024

**MOTION:** Susan Kleppin moved, seconded by Anthony Peterangelo, to approve the Minutes of December 5, 2024, as published. Motion carried unanimously.

## INTRODUCTIONS, ANNOUNCEMENTS, AND RECOGNITION

**DSPS Secretary Hereth**

**MOTION:** John Weitekamp moved, seconded by Michael Walsh, to acknowledge and thank Secretary Hereth, for their appearance to the board. Motion carried unanimously.

## PRELIMINARY PUBLIC HEARING on STATEMENT OF SCOPE

**SS 002-25 on Phar 1, 6, 7, and 10, Relating to Pharmacy Workplace Conditions**

**Review Preliminary Hearing Comments**

**MOTION:** Susan Kleppin moved, seconded by Anthony Peterangelo, to affirm the Board has provided an opportunity to receive public comments concerning Scope Statement (SS) 002-25 on Phar 1, 6, 7, and 10, Relating to Pharmacy Workplace Conditions. Additionally, after consideration of all public comments and feedback the Board approves SS 002-25 for implementation. Motion carried unanimously.

## PUBLIC HEARING: CLEARINGHOUSE RULE 24-092 ON PHAR 15, RELATING TO COMPOUNDING PHARMACEUTICALS

**Review Public Hearing Comments and Respond to Clearinghouse Report**

**MOTION:** John Weitekamp moved, seconded by Anthony Peterangelo, to authorize Susan Kleppin to work with DSPS staff on responding to the Clearinghouse Report and drafting the Final Rule and Legislative Report for Clearinghouse Rule Clearinghouse Rule 24-092 (Phar 15), Relating to Compounding Pharmaceuticals. Motion carried unanimously.

## ADMINISTRATIVE MATTERS

**Election of Officers**

***Chairperson***

**NOMINATION:** Anthony Peterangelo nominated John Weitekamp for the Office of Chairperson. John Weitekamp accepted the nomination.

Brad Wojciechowski, Executive Director, called for nominations three (3) times.

John Weitekamp was elected as Chairperson by unanimous voice vote.

***Vice Chairperson***

**NOMINATION:** John Weitekamp nominated Tiffany O'Hagan for the Office of Vice Chairperson Tiffany O'Hagan accepted the nomination.

Brad Wojciechowski, Executive Director, called for nominations three (3) times.

Tiffany O'Hagan was elected as Vice Chairperson by unanimous voice vote.

***Secretary***

**NOMINATION:** John Weitekamp nominated Anthony Peterangelo for the Office of Secretary. Anthony Peterangelo accepted the nomination.

Brad Wojciechowski, Executive Director, called for nominations three (3) times.

Anthony Peterangelo was elected as Secretary by unanimous voice vote.

| 2025 OFFICERS | |
|---|---|
| **Chairperson** | John Weitekamp |
| **Vice Chairperson** | Tiffany O'Hagan |
| **Secretary** | Anthony Peterangelo |

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**Appointments of Liaisons and Alternates**

| LIAISON APPOINTMENTS | |
|---|---|
| **Credentialing Liaison(s)** | Anthony Peterangelo, Tiffany O'Hagan, Christa Wilson |
| **Education and Examinations Liaison(s)** | Susan Kleppin<br>*Alternate:* John Weitekamp |
| **Monitoring Liaison(s)** | Michael Walsh, Christa Wilson<br>*Alternate*: Anthony Peterangelo |
| **Professional Assistance Procedure (PAP) Liaison(s)** | Anthony Peterangelo<br>*Alternate*: Susan Kleppin |
| **Travel Authorization Liaison(s)** | John Weitekamp<br>*Alternate:* Tiffany O'Hagan |
| **Legislative Liaison(s)** | Anthony Peterangelo, Tiffany O'Hagan, John Weitekamp |
| **Pilot Program Liaison(s)** | Tiffany O'Hagan, Anthony Peterangelo |
| **Newsletter Liaison(s)** | Christa Wilson<br>*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<br>*Alternate:* John Weitekamp |
| **Variance Liaison(s)** | Tiffany O'Hagan<br>*Alternate:* Anthony Peterangelo |
| **Inspection Liaison(s)** | Susan Kleppin<br>*Alternate:* Tiffany O'Hagan |
| **SCREENING PANEL APPOINTMENTS** | |
| **Screening Panel** | John Weitekamp, Tiffany O'Hagan, Michael Walsh<br>*Alternate:* Anthony Peterangelo |
| **COMMITTEE MEMBER APPOINTMENTS** | |
| Pharmacy Rules Committee | Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo, John Weitekamp |
| **OTHER APPOINTMENTS** | |
| **Interdisciplinary Advisory Council** | John Weitekamp *Alternate:* Christa Wilson |

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## Delegation of Authorities

### Pre-Screening Delegation to Open Cases, Amended

**MOTION:** Michael Walsh moved, seconded by Christa Wilson, 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 unanimously.

### Liaison Update

**MOTION:** Susan Kleppin moved, seconded by Michael Walsh, to remove the designation of 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.

### Delegation to Department Monitor

**MOTION:** John Weitekamp moved, seconded by Michael Walsh, 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 90-day extension, 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 90-day extension 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 90-day extension, if warranted and requested in writing by a credential holder, to complete a Board ordered evaluation or exam.

Motion carried unanimously.

**Delegation to Department Attorneys to Approve Prior Discipline**

**MOTION**: Christa Wilson moved, seconded by Anthony Peterangelo, 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 unanimously.

**Delegation to Handle Administrative Rule Matters**

**MOTION**: Michael Walsh moved, seconded by Christa Wilson, 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.

**Review and Approval of 2024 Delegations including new modifications**

**MOTION:** Susan Kleppin moved, seconded by Tiffany O'Hagan, 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 unanimously.

## ADMINISTRATIVE RULE MATTERS

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

**MOTION**: John Weitekamp moved, seconded by Anthony Peterangelo, to request a second extension for EmR 2411 (Phar 8) relating to Controlled Substances Requirements. Motion carried unanimously. Motion carried unanimously.

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

**Travel Request: MPJE Item Development Workshop, March 12-14, 2025, NABP Headquarters**

**MOTION:** Michael Walsh moved, seconded by Anthony Peterangelo, to designate Tiffany O'Hagan and John Weitekamp, to attend the MPJE Item Development Workshop, March 12-14, 2025, NABP Headquarters, in Mount Prospect, IL. Motion carried unanimously.

**Speaking Engagement: Pharmacy Society of Wisconsin Legislative Day, March 19, 2025, Madison, WI**

**MOTION:** Anthony Peterangelo, seconded by Michael Walsh, to designate John Weitekamp and Tiffany O'Hagan, to speak on the Board's behalf at the Pharmacy Society of Wisconsin Legislative Day, on March 19, 2025, in Madison, WI. Motion carried unanimously.

**Pharmacy Technicians**

**MOTION:** Susan Kleppin moved, seconded by Anthony Peterangelo, to designate Christa Wilson and Michael Walsh to work with DSPS staff to publish guidance relating to Pharmacy Technicians. Motion carried unanimously.

## CLOSED SESSION

**MOTION:** Anthony Peterangelo moved, seconded by Michael Walsh, 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; Tiffany O'Hagan-yes; Anthony Peterangelo-yes; Michael Walsh-yes; John Weitekamp-yes; and Christa Wilson-yes. Motion carried unanimously.

The Board convened into Closed Session at 12:45 p.m.

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## MONITORING MATTERS

### *Omar H. Eliwa, Pharmacist – Requesting Full Licensure*

**MOTION:** John Weitekamp moved, seconded by Michael Walsh, to grant the request of Omar H. Eliwa, R.Ph., for Full Licensure. Motion carried unanimously.

*(Christa Wilson recused themself and left the meeting connection for deliberation and voting in the Monitoring Matter concerning Omar H. Eliwa, Pharmacist – Requesting Full Licensure.)*

### *Welltopia Pharmacy – Requesting Full Licensure*

**MOTION:** John Weitekamp moved, seconded by Anthony Peterangelo, to grant the request of Welltopia Pharmacy, for Full Licensure. Motion carried unanimously.

*(Christa Wilson recused themself and left the meeting connection for deliberation and voting in the Monitoring Matter concerning Welltopia Pharmacy– Requesting Full Licensure.)*

## CREDENTIALING MATTERS

**Application Reviews**

### *C.J.F. – Pharmacist (IA 367245)*

**MOTION:** Susan Kleppin moved, seconded by Michael Walsh, to authorize Board Counsel to request Applicant complete a comprehensive AODA assessment and to authorize the board liaison to make a final determination on the application (IA-367245). Motion carried unanimously.

### *C.L. – Pharmacist (IA 371498)*

**MOTION:** John Weitekamp moved, seconded by Christa Wilson, to find grounds exist to deny the renewal application of C.L., and the Board authorizes an offer of a limited license with the following conditions: requiring Applicant to enroll and participate in a drug and alcohol monitoring program approved by the Department which shall include random urine screens at a frequency of not less than 49 times per year and one annual hair screen, work setting approved by the Board or its designee, to participate in treatment with a Treater approved by the board or its designee, with quarterly treatment reports submitted to the Department Monitor, to submit quarterly work reports to the Department monitor, comply with conditions of probation and any additional limitations as appropriate. Applicant may petition the Board for full, unrestricted licensure upon demonstration of continuous, successful compliance with the terms of the order for at least two (2) year. Applicant may petition for modification on an annual basis but no petition for modification before one (1) year from the date of the order. Reason for Denial: Wis. Stat. s.

440.08(4), 450.10(1)(a)2. and 450.10(1)(b)1. & 3. Motion carried unanimously.

***C.S. – Pharmacy Technician (IA 456979)***

**MOTION:** Michael Walsh moved, seconded by Tiffany O'Hagan, to approve the Pharmacy Technician application of C.S., once all requirements are met. Motion carried unanimously.

***G.N. – Pharmacist (IA 480573)***

**MOTION:** John Weitekamp moved, seconded by Michael Walsh, to authorize Board Counsel to request additional information from G.N. and to authorize the Board liaison to make a final determination on the application (IA 480573). Motion carried unanimously.

***S.P. – Pharmacy (Out of State) (IA 509288)***

**MOTION:** Susan Kleppin moved, seconded by Christa Wilson, to authorize Board Counsel to request additional information from Applicant and to table further consideration and action on their application (IA 509288). Motion carried unanimously.

***Z.J. – Pharmacist (IA 520895)***

**MOTION:** Susan Kleppin moved, seconded by Michael Walsh, to find grounds exist to deny the renewal application of Z.J., and the Board authorizes an offer of a limited license with the following conditions: comply with terms of Ohio order, submit quarterly reports of compliance with Ohio order, and report any new violations. **Reason for Denial**: **Reason for Denial**: Wis. Stat. s. 440.08(4), 450.10(1)(a)2. & 3., 450.10(1)(b)1. & 3. and Wis. Admin. Code s. Phar 10.03(1), (2) and (20). Motion carried unanimously.

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

**Administrative Warnings**

**MOTION:** Susan Kleppin moved, seconded by Tiffany O'Hagan, to issue an Administrative Warning in the following DLSC Cases:
23 PHM 151 – W.P.
23 PHM 179 – S.M.D.
24 PHM 0088 – N.K.P.
24 PHM 0121 – K.G.V.
24 PHM 0151 – C.P.
Motion carried unanimously.

***24 PHM 0102 – G.J.R.***

**MOTION:** Christa Wilson moved, seconded by John Weitekamp, to issue an Administrative Warning in the matter of G.J.R.., DLSC Case Number 24 PHM 0102. Motion carried unanimously.

*(Tiffany O'Hagan recused themself and left the room for deliberation and voting in the matter concerning G.J.R., DLSC Case Number 24 PHM 0102.)*

***24 PHM 0102 – T.K.L.***

**MOTION:** Christa Wilson moved, seconded by Michael Walsh, to issue an Administrative Warning in the matter of T.K.L., DLSC Case Number 24 PHM 0102. Motion carried unanimously.

*(Tiffany O'Hagan recused themself and left the room for deliberation and voting in the matter concerning T.K.L., DLSC Case Number 24 PHM 0102.)*

**Case Closings**

**MOTION:** Christa Wilson moved, seconded by Michael Walsh, to close the following DLSC Cases for the reasons outlined below:
22 PHM 129 – P.S.P. – No Violation
21 PHM 094 – W. – No Violation
23 PHM 009 – H.P. – No Violation
24 PHM 014 – M.J.R. – No Violation
24 PHM 017 – W. – Insufficient Evidence
24 PHM 0047 – S.P. – No Violation
24 PHM 0051 – C.P. – Insufficient Evidence
24 PHM 0070 – H.P. – No Violation
24 PHM 0088 – W.P. – No Violation
24 PHM 0100 – H.P., N.A., T.J.A., A.B., and K.Z. – Insufficient Evidence
24 PHM 0102 – W.P. – Prosecutorial Discretion (P2)
24 PHM 0121 – W. – Prosecutorial Discretion (P2)
24 PHM 0121 – M.C. – Insufficient Evidence
24 PHM 0128 – K.E.B. and Y.O.P. – No Violation
24 PHM 0131 – C.P. and D.S. – No Violation
Motion carried unanimously.

**Proposed Stipulations, Final Decisions and Orders**

**MOTION:** Michael Walsh moved, seconded by Christa Wilson, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of the following cases:
23 PHM 054 – Chelsea L. Wilson
23 PHM 147 – Laquisha S. Clay
Motion carried unanimously.

## RECONVENE TO OPEN SESSION

**MOTION:** Anthony Peterangelo moved, seconded by Christa Wilson, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 3:37 p.m.

## VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

**MOTION:** Michael Walsh moved, seconded by Susan Kleppin, 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:** Christa Wilson moved, seconded by Susan Kleppin, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 3:38 p.m.

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# 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**<br>**Administrative Rules Coordinator** | **04/07/25**<br>**Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting** |

**3) Name of Board, Committee, Council, Sections:**

Pharmacy Examining Board

| 4) Meeting Date: | 5) Attachments: | 6) How should the item be titled on the agenda page? |
|---|---|---|
| **04/20/25** | ☒ Yes<br>☐ No | **Administrative Rule Matters – Discussion and Consideration**<br>**1. Final Rule Draft and Legislative Report: Phar 15, Relating to Compounding Pharmaceuticals**<br>**2. Update on Phar 8, Relating to Controlled Substances Requirements**<br>**3. Pending or Possible Rulemaking Projects** |

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

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

Attachments:

1. Phar 15 Legislative Report, Final Rule Draft, EIA
2. Rule Projects Chart

Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx

**11) Authorization**

Nilajah D. Hardin — 04/07/25

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

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

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

**Directions for including supporting documents:**

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

**STATE OF WISCONSIN**
**PHARMACY EXAMINING BOARD**

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| | | |
|---|---|---|
| **IN THE MATTER OF RULEMAKING** | **:** | |
| **PROCEEDINGS BEFORE THE** | **:** | **REPORT TO THE LEGISLATURE** |
| **PHARMACY EXAMINING BOARD** | **:** | **CR 24-092** |

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**I. THE PROPOSED RULE:**

The proposed rule, including the analysis and text, is attached.

**II. REFERENCE TO APPLICABLE FORMS:** N/A

**III. FISCAL ESTIMATE AND EIA:**

The Fiscal Estimate and EIA is attached.

**IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:**

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. The Board will request approval from the Attorney General, as required by s. 227.21 (2), Stats., prior to submission of this rule for final adoption and publication.

**V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:**

The Pharmacy Examining Board held a public hearing on February 20, 2025 on CR 24-092. The following people either testified at the hearing, or submitted written comments:

- Danielle Womack, Vice President of Public Policy and Advocacy for the Pharmacy Society of Wisconsin

The Pharmacy Examining Board summarizes the comments received either by hearing testimony or by written submission as follows:

- The Pharmacy Society of Wisconsin submitted the following comments:
  - Is it the Board's intent to require compliance with USP General Chapter 800, whether they compound or not?
  - Can a pharmacy document a different timeframe or do 14-day beyond-use dates for flavoring under Phar 15.02 (1)(b) required?
  - What patient protection is offered if flavoring is not considered compounding?
  - What grounds does the Board have for disciplinary action for failure to meet "should" standards under USP General Chapter 797?

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- Does USP General Chapter 797 being incorporated by reference into the Administrative Code mean that compliance is required with all other USP chapters cited in that chapter?
- Will copies of the incorporated chapters be available through the Legislative Reference Bureau?
- How should pharmacies label non-patient-specific or office use compounding products?

The Pharmacy Examining Board made the following modifications to its rule-making proposal based on public comments:

- Phar 15.02 (1) (b) is revised to read "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 a shorter beyond-use-date has been documented."
- The following has been added to section Phar 15.03: "**(2)** DIFFERING REQUIREMENTS. **(a)** Where any Board rule in this chapter differs from a requirement within a standard referenced in this chapter, the Board rule shall govern.

  **(b)** Except as provided in par. (a), where a provision of this chapter prescribes a general requirement and another provision of this chapter prescribes a specific or more detailed requirement regarding the same subject, the specific or more detailed requirement shall govern.

  **(c)** Except as provided in pars. (a) and (b), where different sections of this chapter specify conflicting requirements. The most restrictive requirement, as determined by the Board, shall govern."

## VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

**Comment 2b:** "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 provisions says it only "may" be considered a violation. Does that give adequate notice to practitioners about what is required?"

**Response**: The board accepts this comment and would like to note that the standards being incorporated are already required by the United States Food and Drug Administration, so there should be no need to give notice to licensees.

**Comment 2c:** "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. 1.06 (3), Manual.]"

**Response**: The board accepts this comment and would like to note that standards being incorporated are already required by the United States Food and Drug Administration, so there should be no need an initial applicability clause.

All of the remaining recommendations suggested in the Clearinghouse Report have been accepted in whole.

## VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS: N/A

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

| | | |
|---|---|---|
| IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD | : | PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 24-092) |

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), 227.21 (2) (a), and 450.02 (3) (d) and (e), Stats.

**Explanation of agency authority:**
Section 15.08 (5) (b), Stats. states that "~~The~~[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 227.21 (2)(a), Stats. states that "[e]xcept as provided in s. 601.41 (3) (b), to avoid unnecessary expense an agency may, with the consent of the attorney general, adopt standards established by technical societies and organizations of recognized national standing by incorporating the standards in its rules by reference to the specific issue or issues of the publication in which they appear, without reproducing the standards in full."

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

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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. The Board will request approval from the Attorney General, as required by s. 227.21 (2), Stats., prior to submission of this rule for final adoption and publication.

**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

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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) 266-2112.

**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 included in the record of rule-making proceedings.

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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 a shorter beyond-use date has been ~~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.

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**Phar 15.03 Compliance.** (1) UNPROFESSIONAL CONDUCT. Noncompliance with ch. Phar 15 shall~~may~~ be considered a violation of s. Phar 10.03 and may result in disciplinary action by the Board against a credential holder.

**(2)** DIFFERING REQUIREMENTS. **(a)** Where any Board rule in this chapter differs from a requirement within a standard referenced in this chapter, the Board rule shall govern.

**(b)** Except as provided in par. (a), where a provision of this chapter prescribes a general requirement and another provision of this chapter prescribes a specific or more detailed requirement regarding the same subject, the specific or more detailed requirement shall govern.

**(c)** Except as provided in pars. (a) and (b), where different sections of this chapter specify conflicting requirements. The most restrictive requirement, as determined by the Board, shall govern.

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

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(END OF TEXT OF RULE)

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This Proposed Order of the Pharmacy Examining Board is approved for submission to the Governor and Legislature.

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board

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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

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
12/09/24

3. Administrative Rule Chapter, Title and Number (and Clearinghouse 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 ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
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 Pharmaceopeia (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

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
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 units, and individuals. No comments were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
DSPS estimates a total of $5,955.00 in one-time costs for implementing this rule. The one-time staff costs support 0.1 limited term employee to undertake tasks such as rule drafting, regal review, training on new rules, and updating forms and website.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is that there will be clear and up to date standards fo pharmaceutical compounding, safe handling of hazardous drugs, and radiopharmaceuticals in Pharmacy practice.

16. Long Range Implications of Implementing the Rule
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
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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
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# ADMINISTRATIVE RULES
# Fiscal Estimate & Economic Impact Analysis

## ATTACHMENT A

1. 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

**Pharmacy Examining Board**
**Rule Projects (updated 04/07/25)**

| CH Rule Number | Scope Number | Scope Expiration Date | Code Chapter Affected | Relating Clause | Stage of Rule Process | Next Step |
|---|---|---|---|---|---|---|
| Not Assigned Yet | 002-25 | 07/13/2027 | Phar 1. 6, 7, and 10 | Pharmacy Workplace Conditions | Drafting | Board Approval of Preliminary Rule Draft for EIA Comment and Clearinghouse Review |
| 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; 2nd Extension Request Submitted to JCRAR on 03/14/25<br>Permanent Rule: Legislative Review | Emergency Rule: JCRAR Review of 2nd Extension Request<br>Permanent Rule: Approval of Adoption Order After JCRAR Review |
| 24-092 | 007-23 | 07/23/2025 | Phar 15 | Compounding Pharmaceuticals | Board Reviewed Final Rule and Legislative Report at 04/17/25 Meeting | Board Approval for Submission to Governor's Office and Legislature |

# State of Wisconsin
# Department of Safety & Professional Services

## AGENDA REQUEST FORM

| | | |
|---|---|---|
| **1) Name and title of person submitting the request:**<br>Brad Wojciechowski, Executive Director | | **2) Date when request submitted:**<br>4/7/2025<br>**Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting** |
| **3) Name of Board, Committee, Council, Sections:**<br>Pharmacy Examining Board | | |
| **4) Meeting Date:**<br>4/17/2025 | **5) Attachments:**<br>☒ Yes<br>☐ No | **6) How should the item be titled on the agenda page?**<br>Speaking Engagements, Travel, or Public Relation Requests, and Reports – Discussion and Consideration<br>1) Travel Report: MPJE Item Development Workshop, March 12-14, 2025, Mt. Prospect, IL – O'Hagan, Weitekamp<br>2) Speaking Engagement Report: PSW Legislative Day Presentation, March 19, 2025 – O'Hagan, Weitekamp<br>3) Travel Request: APhA Institute on Substance Use Disorders, May 28-31, 2025, Salt Lake City, UT |
| **7) Place Item in:**<br>☒ Open Session<br>☐ Closed Session | **8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)*<br>☐ Yes <Appearance Name(s)><br>☐ No | **9) Name of Case Advisor(s), if applicable:**<br><Click Here to Add Case Advisor Name or N/A> |
| **10) Describe the issue and action that should be addressed:**<br>PSW Legislative Day Presentation attached. | | |
| **11) Authorization**<br><NAME> | | <Date: M/D/YYYY> |
| **Signature of person making this request** | | **Date** |
| **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 Items folders.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

*Revised 03/2021*

# Wisconsin Pharmacy Examining Board Update

Pharmacy Society of Wisconsin Legislative Days

Wednesday, March 19, 2025

# Agenda

- Board Membership
- Rule Promulgation process overview
- Rule Projects Overview
  - Phar 15 – relating to compounding pharmaceuticals
- Pharmacy Technicians Guidance
- Multistate Jurisprudence Examination Pilot Program
- Interdisciplinary Advisory Committee
- Board Resources

# Board Membership

The Pharmacy Examining Board is created in appointed by the Governor and confirmed by the Legislature to serve 4-year terms. The Board consists of 5 licensed pharmacist members and 2 public members.

| Member | Officer | Member Type | Term Expiration |
|---|---|---|---|
| John Weitekamp | Chairperson | Pharmacist Member | 7/1/2026 |
| Tiffany O'Hagan | Vice Chairperson | Pharmacist Member | 7/1/2028 |
| Susan Kleppin | | Pharmacist Member | 7/1/2025 |
| Anthony Peterangelo | Secretary | Pharmacist Member | 7/1/2027 |
| Vacant** | | Public Member | |
| Michael Walsh | | Public Member | 7/1/2024 |
| Christa Wilson | | Pharmacist Member | 7/1/2025 |

# Overview of Administrative Rulemaking Process

- Preparation of scope by agency staff.
- DOA review.
- Gubernatorial approval.
- Publication in Administrative Register.
- Preliminary hearing, if held.
- Approval by agency head.

Time in Stage: 1 month
Total Time in Rulemaking Process: 1 month

→

- Initial drafting of rule by agency staff.
- Preparation of Economic Impact Analysis, including solicitation of public comment.

Time in Stage: 1 to 4 months
Total Time: 2 to 5 months

→

- Review by Legislative Council Staff.
- Agency public hearing and public comment period.

Time in Stage: 1 to 2 months
Total Time: 3 to 7 months

↓

- Agency responds to Legislative Council review and public comment.
- Rule revisions and final drafting.
- Gubernatorial approval.

Time in Stage: 2 weeks to 1 month
Total Time: 3.5 to 8 months

→

- Referral to standing committee by legislative leadership.
- 30-day standing committee passive review.
- 30-day JCRAR passive review.
- Opportunities for legislative objection.

Time in Stage: 3 months
Total Time: 6.5 to 11 months

→

- Agency submits rule to LRB.
- Formatting and publication by LRB in Administrative Register.
- Rule takes effect on the first day of the first month after publication.

Time in Stage: 1 to 2 months
Total Time: 7.5 to 13 months

Please note this overview describes the process for a "typical" rulemaking. Rules developed using extraordinary processes, such as citizen-initiated rulemaking or internal board approvals, may require additional time.

# Rule Projects Overview

| CH Rule Number | Scope Expiration | Code Chapter Affected | Relating Clause | Stage of Rule Process |
|---|---|---|---|---|
| Scope Number 002-25 | 7/13/2027 | Phar 1, 6, 7, and 10 | Pharmacy Workplace Conditions | Preliminary hearing on the scope statement was held on 2/20/2025 for both emergency and permanent rule. |
| Scope Number 089-24 | 2/5/2027 | Phar 7 | Remote Dispensing 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. | Rule Drafting |

# Rule Projects Overview Continued

| CH Rule Number | Scope Expiration Date | Code Chapter Affected | Relating Clause | Stage of Rule Process |
|---|---|---|---|---|
| CR 24-092 | 7/23/2025 | Phar 15 | Compounding Pharmaceuticals | **Permanent Rule:** Public hearing was held on 2/20/2025 |
| EmR 2411<br>CR 24-070 | 1/10/2026 | Phar 8 | Controlled Substances Requirements | **Emergency Rule:** Effective 10/1/2024-4/28/2025. First extension was granted on 2/27/2025. The Board authorized a second extension on 2/20/2025.<br>**Permanent Rule:** Legislative Review |

# Phar 15: Compounding Highlighted Updates

- The preliminary rule will update the Wisconsin Administrative Code to incorporate by reference the USP General Chapters 795 and 797 that were effective November 1, 2023.
- The rule clearly states exceptions to USP 795 – nonsterile compounding:
  - The exceptions include nonallergenic, therapeutically inert flavoring agents has been approved by the Board.
    - The pharmacist shall ensure that the flavoring agent is no more than 5% of the products total volume.
    - The pharmacist shall label the flavoring prescription with a BUD that shall be no longer than 14 days if stored in a refrigerator.
    - The pharmacist shall document the addition of flavoring as part of the prescription record. The document shall include; type of flavoring agent, manufacturer, lot number, and expiration date.
    - A prescription is **required** before a pharmacist may add flavoring to an OTC product.
- The rule also incorporates by reference USP 800 and 825

# Pharmacy Technicians
## *Who Should Register*

- Wis. Admin. Code Ch. Phar 19 outlines Registration, scope of practice, renewal and reinstatement, and change of address, employer, or name for those who register as pharmacy technicians.
- Definition: "Pharmacy technician means a person registered by the board under s. 450.068, Stats.
- Scope of practice: A pharmacy technician may administer vaccines as authorized under s. 450.035 (2h), Stats., and may perform technical dispensing functions, compounding, packaging, labeling and storage, pharmacy and inventory management, and other activities involved in the practice of pharmacy delegated by a pharmacist.
- The expectation is that the person has begun the registration process at the time of hiring and who is limited to performing duties under the direct supervision of a licensed pharmacist.
  - The Department has a ten-day turnaround policy for pharmacy technician registrants contingent if applicant satisfies application requirements.
- **Pharmacy staff who do not have to register**
  - A delivery driver engaged solely in the delivery of a prescription in compliance with this section does not need to be registered as a pharmacy technician.
  - "Interns" as defined in Wis. Admin. Code § Phar 17.02 (4).
  - "Pharmacy graduate" as defined in Wis. Admin. Code § Phar 1.02 (10m).

# Multistate Jurisprudence Examination (MPJE)Pilot Program

- Registering for the jurisprudence examination prior to graduating eliminates stressors of having to study and complete multiple examinations upon graduation
- The National Association of Boards of Pharmacy issued a pilot program with North Dakota and Wisconsin to allow students to take the MPJE prior to graduation.

NABP
National Association of Boards of Pharmacy

# Pilot Summary

*The 'Pilot Program' is a trial process for allowing pre-APPE pharmacy students to take the MPJE in their final year, prior to degree conferral.*

*Only North Dakota and Wisconsin schools currently.*

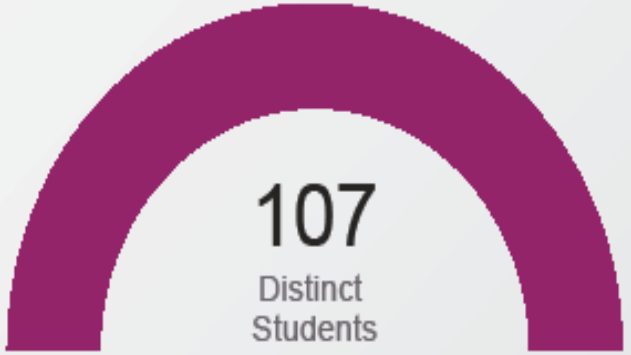
| | | | | | |
|---|---|---|---|---|---|
| **e-Profiles & Eligibility:** | Rostered Students | e-Profiles | | Elig Applied | Elig Granted |
| | 169 | 107 | 63% (% of Rostered) | 118 | 107 |
| **Timeframes:** | Pilot Purchase to Registration | | | Max Pilot Exams Taken | Max Historic Exams Taken |
| | 62 days | | | September | September |
| **Exams & Pass Rate:** | Scheduled | Delivered | Released | Pilot Passing Rate | 2023 Passing Rate |
| | 11 | 77 | 77 (57 PASS) | 74% | 82.9% |

# Eligibility Overview

MPJE

2025 Year | 118 Eligibility | 90 ATTs

## Pilot Students with Eligibility Applications




Roster Total
169

Eligibility Granted
107

Eligibility Requested
6

Application Withdrawn
5

| College | Eligibility Applied Students | e-Profiles |
|---|---|---|
| Concordia Univ Wisconsin | 32 | 32 |
| Medical Coll of Wisconsin | 31 | 31 |
| Univ of Wisconsin-Madison | 44 | 44 |
| **Total** | **107** | **107** |

| School | Roster |
|---|---|
| Concordia Univ of Wisc | 39 |
| Med Coll of Wisc | 35 |
| North Dakota State Univ | 49 |
| Univ of Wisc-Madison | 46 |
| **Total** | **169** |

| Year | Applications |
|---|---|
| **2024** | |
| May | 24 |
| June | 39 |
| July | 14 |
| August | 5 |
| September | 4 |
| October | 7 |
| November | 14 |
| December | 1 |
| **2025** | |
| January | 4 |
| February | 4 |
| March | 2 |
| **Total** | **118** |

NABP National Association of Boards of Pharmacy

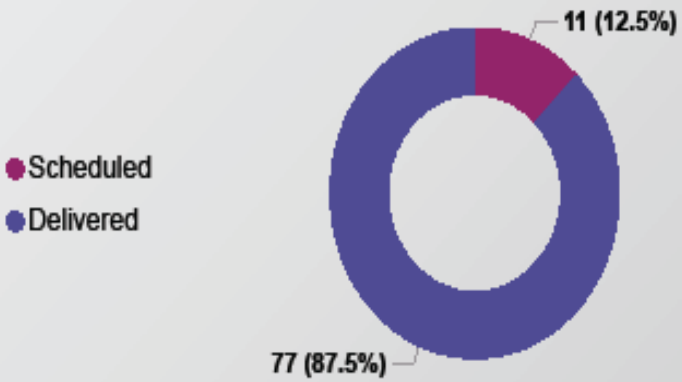
# Pearson VUE

| Scheduled | No Shows | Delivered |
|---|---|---|
| 11 | 0 | 77 |

3/9/2025
Latest Registration

7/29/2025
Latest Scheduled Exam

**MPJE Registered Students by Status**




| College | Eligibility | Scheduled | Delivered |
|---|---|---|---|
| Univ of Wisconsin-Madison | 44 | 3 | 31 |
| Concordia Univ Wisconsin | 32 | 6 | 24 |
| Medical Coll of Wisconsin | 31 | 2 | 22 |
| **Total** | **107** | **11** | **77** |

**Registration Date**

| Year | CUW | MCW | UWM |
|---|---|---|---|
| ⊟ 2024 | 20 | 22 | 31 |
| ⊞ May | 1 | | |
| ⊞ June | 2 | | 22 |
| ⊞ July | 2 | 8 | 2 |
| ⊞ August | 2 | 6 | 3 |
| ⊞ September | 2 | 4 | 1 |
| ⊞ October | 3 | 3 | 3 |
| ⊞ November | 7 | | |
| ⊞ December | 1 | 1 | |
| ⊞ 2025 | 4 | | |
| Total | 24 | 22 | 31 |

**Examination Date**

| Year | CUW | MCW | UWM |
|---|---|---|---|
| ⊟ 2024 | | | |
| June | 1 | | |
| July | | | 1 |
| August | 1 | | 10 |
| September | 3 | 7 | 9 |
| October | 1 | 1 | 2 |
| November | 1 | 6 | 5 |
| December | 6 | 5 | 2 |
| ⊞ 2025 | 11 | 3 | 2 |
| Total | 24 | 22 | 31 |

# Results

Exams Taken

77

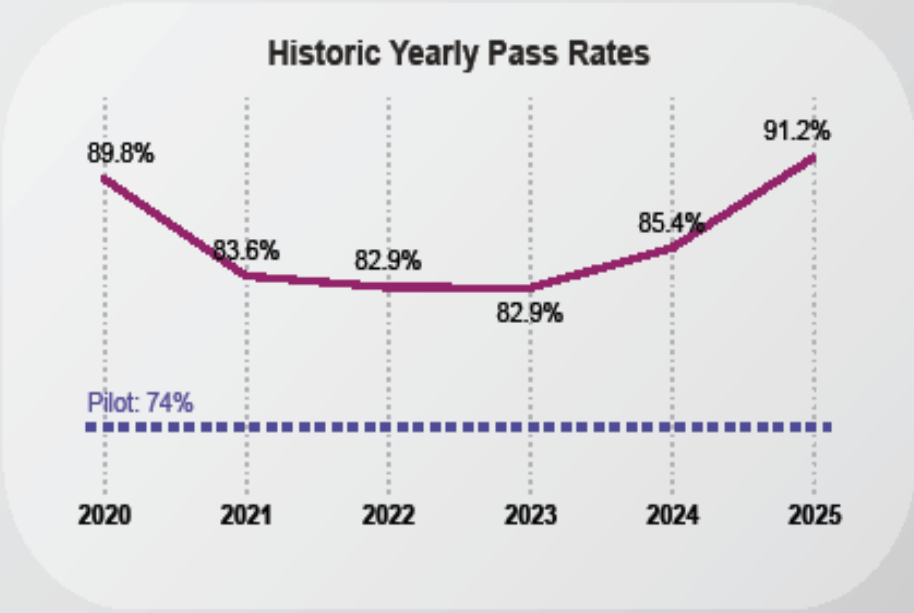
Pilot Passing Rate

74%

Unreleased

0

Released Results


Released Results

| College | FAIL | PASS | Total |
|---|---|---|---|
| Concordia Univ Wisconsin | 7 | 17 | **24** |
| Medical Coll of Wisconsin | 6 | 16 | **22** |
| Univ of Wisconsin-Madison | 7 | 24 | **31** |
| **Total** | **20** | **57** | **77** |

# Interdisciplinary Advisory Committee

- The Interdisciplinary Advisory Committee launched in August 2024.
  - Members are comprised from the Medical Examining Board, Physician Assistants Affiliated Credentialing Board, Board of Nursing, Cosmetology Examining Board, Controlled Substances Board, and the Pharmacy Examining Board.
- The committee's charge is to issue guidance or recommendations on emerging topics that effect public safety.
- The committee is currently working on guidance for IV Hydration Clinics that have become more prevalent in the past few years.
- Future topics:
  - Compounding semaglutides
  - Emerging Medi-spa Practices
  - Ketamine clinics

# Board Resources: Application/License

- DSPS Self Service Menu (Various links that may be of interest during presentation): https://dsps.wi.gov/Pages/SelfService/Default.aspx
  - LicensE FAQs https://dsps.wi.gov/Pages/LicensE.aspx
  - LicensE Lookup https://license.wi.gov/s/application-status-lookup
  - License Verification (OLVS) https://dsps.wi.gov/Pages/SelfService/BusinessHealth/OLVS.aspx
  - Inspections https://dsps.wi.gov/Pages/SelfService/Inspections.aspx
  - File a Complaint https://dsps.wi.gov/Pages/SelfService/FileAComplaint.aspx
  - Orders and Disciplinary Actions https://dsps.wi.gov/Pages/SelfService/OrdersDisciplinaryActions.aspx (Search by individual or by issuing Board within a set timeframe)
  - Professional Assistance Procedure (PAP) https://dsps.wi.gov/Pages/SelfService/ProfessionalAssistanceProcedure.aspx
  - Sign up for Email Communications https://public.govdelivery.com/accounts/WIDSPS/subscriber/new
  - Monthly License Counts https://dsps.wi.gov/Credentialing/General/LicenseCounts.pdf
  - Order List of Licensees https://dspslicenselist.wi.gov/

# Board Resources: Staying Informed

- Board Information
  - PEB Landing Page (Links to resources throughout DSPS site, most current vacancy information available to public: https://dsps.wi.gov/Pages/BoardsCouncils/Pharmacy/Default.aspx
  - PEB Meetings Page (access: Open Session Meeting Agendas, Meeting Dates): https://dsps.wi.gov/Pages/BoardsCouncils/Pharmacy/Meetings.aspx
  - Statute and Administrative Code https://dsps.wi.gov/Pages/RulesStatutes/Pharmacy.aspx
  - 2025 Top 100 Drug List https://dsps.wi.gov/Documents/BoardCouncils/PHM/20231207_TOP100DrugsAtoZBRANDNAME.pdf
  - 2022 Pharmacist's Manual for Controlled Substances https://www.deadiversion.usdoj.gov/GDP/%28DEA-DC-046R1%29%28EO-DEA154R1%29_Pharmacist%27s_Manual_DEA.pdf

# State of Wisconsin
# Department of Safety & Professional Services

## AGENDA REQUEST FORM

| | | | |
|---|---|---|---|
| 1) Name and title of person submitting the request:<br>Whitney DeVoe, Board Counsel | | 2) Date when request submitted:<br>04/01/25<br>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting | |
| 3) Name of Board, Committee, Council, Sections:<br>Pharmacy Examining Board | | | |
| 4) Meeting Date:<br>04/17/2025 | 5) Attachments:<br>☒ Yes<br>☐ No | 6) How should the item be titled on the agenda page?<br>Interdisciplinary Advisory Committee – Discussion and Consideration<br>1. IV Hydration Guidance | |
| 7) Place Item in:<br>☒ Open Session<br>☐ Closed Session | 8) Is an appearance before the Board being scheduled?<br>☐ Yes<br>☒ No | 9) Name of Case Advisor(s), if applicable: | |
| 10) Describe the issue and action that should be addressed:<br>Discussion and consideration of the rough draft of the IV hydration guidance document. | | | |
| 11) Authorization<br>Whitney DeVoe — 04/01/25<br>Signature of person making this request — Date<br>Supervisor (Only required for post agenda deadline items) — Date<br>Executive Director signature (Indicates approval for post agenda deadline items) — Date | | | |
| Directions for including supporting documents:<br>1. This form should be saved with any other documents submitted to the Agenda Items folders.<br>2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.<br>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 & Professional Services

## AGENDA REQUEST FORM

| | | |
|---|---|---|
| **1) Name and title of person submitting the request:**<br>Brad Wojciechowski, Executive Director | | **2) Date when request submitted:**<br>4/7/2025<br>**Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting** |
| **3) Name of Board, Committee, Council, Sections:**<br>Pharmacy Examining Board | | |
| **4) Meeting Date:**<br>4/17/2025 | **5) Attachments:**<br>☐ Yes<br>☒ No | **6) How should the item be titled on the agenda page?**<br>National Association of Boards of Pharmacy Matters – Discussion and Consideration<br>1) Interstate Privilege Working Group |
| **7) Place Item in:**<br>☒ Open Session<br>☐ Closed Session | **8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)*<br>☐ Yes <Appearance Name(s)><br>☐ No | **9) Name of Case Advisor(s), if applicable:**<br><Click Here to Add Case Advisor Name or N/A> |
| **10) Describe the issue and action that should be addressed:**<br><Click Here to Add Description> | | |
| **11) Authorization**<br>4/7/2025<br>Signature of person making this request — Date | | |
| 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:**<br>1. This form should be saved with any other documents submitted to the Agenda Items folders.<br>2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.<br>3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting. | | |