Wisconsin Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way, 2nd Floor
PO Box 8366
Madison WI 53708-8366

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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison
Contact: Brad Wojciechowski (608) 266-2112
August 29, 2024

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 June 28, 2024 (5-11)

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements, and Recognition

E. 11:00 A.M. Preliminary Hearing on Statement of Scope – SS 089-24 on Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substances Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check (12-16)

1) Review Preliminary Hearing Comments **(14-15)**

F. Administrative Matters – Discussion and Consideration

1) Department, Staff and Board Updates
2) Board Members – Term Expiration Dates
   a. Kleppin, Susan – 7/1/2025
   b. O'Hagan, Tiffany – 7/1/2028
   c. Peterangelo, Anthony – 7/1/2027
   d. Walsh, Michael – 7/1/2024
   e. Weitekamp, John – 7/1/2026
   f. Wilson, Christa – 7/1/2025

G. Administrative Rule Matters – Discussion and Consideration (16-27)

1) Preliminary Rule Draft:
   a. Phar 15, Relating to Compounding Pharmaceuticals **(17-21)**
   b. Phar 8, Relating to Controlled Substances Requirements **(22-26)**
2) Pending or Possible Rulemaking Projects **(27)**

H. Legislative and Policy Matters – Discussion and Consideration

I. Credentialing Matters – Discussion and Consideration

J. NABP Pulse Regulator Monthly Champions Call – Discussion and Consideration (28)

K. Interdisciplinary Advisory Council - Discussion and Consideration

L. Liaison Reports – Discussion and Consideration

M. Improving Pharmacist Workplace Satisfaction – Discussion and Consideration (29-33)

1) Virginia Emergency Rule

N. Pilot Program Matters – 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. Presentation and Deliberation of Petitions for Summary Suspension and Designation of Hearing Official

1) **12:30 P.M. APPEARANCE:** Nicolas Dalla Santa, DLSC Attorney; and L.S.C., Respondent: 23 PHM 147 – L.S.C. **(34-64)**

R. Credentialing Matters

1) **Application Review**
   a. T.D. – Pharmacy Technician (IA-987654) **(65-106)**

S. Deliberation on Division of Legal Services and Compliance Matters

1) **Administrative Warnings**
   a. 23 PHM 096 – E.S.P. & E.S. **(107-110)**
   b. 23 PHM 174 – W. **(111-112)**
   c. 24 PHM 009 – O.C. **(113-114)**
2) **Case Closings**
   a. 21 PHM 162 – W. **(115-128)**
   b. 22 PHM 125 – W. **(129-133)**
   c. 23 PHM 059 – A.P. **(134-139)**
   d. 23 PHM 066 – K.P.S.A.R.C. **(140-142)**
   e. 23 PHM 143 – C.P. **(143-146)**
   f. 23 PHM 158 – W. **(147-149)**
   g. 23 PHM 169 – C.P. **(150-154)**
   h. 23 PHM 177 – H.M.O. **(155-158)**
   i. 24 PHM 008 – A.V. **(159-161)**
   j. 24 PHM 020 – C.P. **(162-167)**
   k. 24 PHM 0064 – E.S.P.I. **(168-171)**
3) **Proposed Stipulations, Final Decisions and Orders**
   a. 22 PHM 067 – Christopher J. Stasiewski **(172-177)**
   b. 22 PHM 125 and 23 PHM 174 – Devin E. Jones **(178-184)**
   c. 22 PHM 129 – Richard D. Garrett **(185-190)**
   d. 23 PHM 131 and 24 PHM 002 – Kenneth J. Herrera **(191-198)**
   e. 23 PHM 178 – Brianna N. Heath **(199-204)**

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: OCTOBER 24, 2024

Board Member Training: November 15, 2024

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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 disciplinary hearings may be changed by the examiner for the convenience of the parties. 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
JUNE 28, 2024

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

EXCUSED: 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 Christa Wilson, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF APRIL 25, 2024

Amendments to the Minutes:
Update document footer to April 25, 2024

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to approve the Minutes of April 25, 2024, as amended. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Appointments of Liaisons and Alternates, Delegation of Authorities

Delegation to Monitoring Liaison

MOTION: Michael Walsh 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.

Delegation to Department Monitor

MOTION: Michael Walsh moved, seconded by Christa Wilson, to adopt the delegations to the Department Monitor listed in the "Roles and Authorities Delegated for Monitoring" document as presented in the January 18, 2024, agenda materials on pages 43-45. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Adoption Order: Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing

MOTION: John Weitekamp moved, seconded by Susan Kleppin, to approve the Adoption Order for Clearinghouse Rule 23-054 (Phar 1, 5, 6, 7, and 8), relating to Remote Dispensing. Motion carried unanimously.

Adoption Order: Phar 1, 5, 7, 10, and 19, Relating to Registration of Pharmacy Technicians

MOTION: John Weitekamp moved, seconded by Susan Kleppin, to approve the Adoption Order for Clearinghouse Rule 23-072 (Phar 1, 5, 7, 10, and 19), relating to Registration of Pharmacy Technicians. Motion carried unanimously.

Scope Statement: Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substances Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to approve the Scope Statement revising Phar 7, relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substances Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on the Scope Statement, the Chairperson is authorized to approve the required notice of hearing. Motion carried unanimously.

DSPS INTERDISCIPLINARY ADVISORY COUNCIL

Board Appointment of 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.

OTHER APPOINTMENTS	
Interdisciplinary Advisory Council	John Weitekamp *Alternate:* Christa Wilson

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

NABP District 4 Meeting, September 18-20 – Detroit, MI

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to designate John Weitekamp, Tiffany O'Hagan and Brad Wojciechowski to attend the NABP District 4 Meeting on September 18-20, 2024, in Detroit, MI. Motion carried unanimously.

NABP Executive Officer Forum, September 25-26 – Mount Prospect, IL

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to designate Brad Wojciechowski to attend the NABP Executive Officer Forum on September 25-26, 2024, in Mount Prospect, IL. 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 12:19 p.m.

DELIBERATION ON REVIEW OF ADMINISTRATIVE WARNING

12:30 P.M. APPEARANCE: Julie Zimmer, DLSC Attorney; Michael Ghobrial, Attorney; and A.H.G.I., Respondent: WARN00003717 – 24 PHM 011 – A.H.G.I.

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to affirm the issuance of the administrative warning in the matter of A.H.G.I., DLSC Case WARN00003717 – 24 PHM 011. Motion carried unanimously.

(Susan Kleppin recused herself and left the room for deliberation and voting in the matter concerning A.H.G.I. DLSC Case Number WARN00003717 – 24 PHM 011 – A.H.G.I.)

CREDENTIALING MATTERS

Application Reviews

A.F. – Pharmacy Technician

MOTION: Susan Kleppin moved, seconded by John Weitekamp, to approve the Pharmacy Technician application of A.F., once all requirements are met. Motion carried unanimously.

C.N.A.L. – Pharmacy (Out-of-State) and Wholesale Distributor

MOTION: John Weitekamp moved, seconded by Anthony Peterangelo, to approve the renewal of the following Pharmacy (Out-of-State) applications of C.N.A.L.
- IA-346062
- IA-348686
- IA-348717
- IA-348696
- IA-348708

once all requirements are met. Motion carried unanimously.

MOTION: John Weitekamp moved, seconded by Michael Walsh, to deny the request of C.N.A.L. for renewal of the following applications:
- IA-345483
- IA-358018
- IA-358041

but to offer a limited license with the following conditions: comply with all conditions of supervision in case number DVAW124MJ000009-001 and to report any new violations to the Board. **Reason for Denial**: 450.10(1)(a)2. And 450.10(1)(b)3. Motion carried unanimously.

M.V.S.I. – Wholesale Distributor

MOTION: Susan Kleppin moved, seconded by Christa Wilson, to request additional information from the Wholesale Distributor applicants of M.V.S.I., and to authorize the Board liaison to make a final determination on the applications. Motion carried unanimously.

J.D. – Pharmacy Technician

MOTION: John Weitekamp moved, seconded by Christa Wilson, to approve the Pharmacy Technician application of J.D. once all requirements are met. Motion carried unanimously.

L.H. – Pharmacy Technician

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to deny the request of L.H. for an unencumbered Pharmacy Technician credential but to offer a limited license with the following conditions: quarterly work reports, direct supervision by a pharmacist, to comply with bond conditions, to report any convictions or new violations to the Department monitor and to comply with the results of any pending criminal actions. Reason for Denial: 111.321, 111.322, and 111.335 and 450.10(1)(a)2. Motion carried unanimously.

L.S. – Pharmacy Technician

MOTION: Susan Kleppin moved, seconded by John Weitekamp, to approve the Pharmacy Technician application of L.S. once all requirements are met. Motion carried unanimously.

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

Administrative Warnings

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to issue an Administrative Warning in the following DLSC Cases:

1. 21 PHM 162 – C.N.M.
2. 21 PHM 162 – T.L.S.
3. 22 PHM 041 – A.H.G.I.
4. 22 PHM 116 – W.
5. 23 PHM 009 – F.H.
6. 23 PHM 096 – E.S.P.I.
7. 23 PHM 137 – O.I.
8. 23 PHM 159 – A.A.J.
9. 23 PHM 159 – V.R.A.
10. 23 PHM 189 – W.P.

Motion carried unanimously.

23 PHM 189 – E.G.

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to issue an Administrative Warning in the matter of E.G., DLSC Case Number 23 PHM 189 amended as follows: 1)d. December 15, 2023. Motion carried unanimously.

Case Closings

MOTION: John Weitekamp moved, seconded by Susan Kleppin, to close the following DLSC Cases for the reasons outlined below:

1. 20 PHM 064 – W.P. & O.E. – Insufficient Evidence
2. 21 PHM 110 – W.P. – Insufficient Evidence

3. 22 PHM 139 – D.C. – Insufficient Evidence
4. 22 PHM 178 – W. – No Violation
5. 22 PHM 184 – Q.P.I. – No Violation
6. 23 PHM 021 – C.P. – Insufficient Evidence
7. 23 PHM 036 – C.P. – Insufficient Evidence
8. 23 PHM 144 – M.D.I. – No Violation
9. 23 PHM 156 – W. – Prosecutorial Discretion (P2)
10. 23 PHM 159 – W. – Prosecutorial Discretion (P2)
11. 24 PHM 0042 – P.I. – 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:

1. 22 PHM 044 – Mohamed I. Alnahrawi
2. 23 PHM 085 – Omar H. Eliwa
3. 23 PHM 085 – Welltopia Pharmacy
4. 23 PHM 114 – Jessica Eicher
5. 23 PHM 144 – Mark C. Anderson

Motion carried unanimously.

DELIBERATION OF PROPOSED FINAL DECISIONS AND ORDERS

Complete Pharmacy and Medical Solutions, LLC – (DHA Case Number SPS-24-0013/DLSC Case Number 22 PHM 074)

MOTION: Christa Wilson moved, seconded by Anthony Peterangelo, to delegate to DSPS Chief Legal Counsel the Board's authority to preside over and resolve the matter concerning disciplinary proceedings against Complete Pharmacy and Medical Solutions, LLC – DHA Case Number SPS-24-0013/DLSC Case Number 22 PHM 074. Motion carried unanimously.

(Susan Kleppin recused herself and left the room for deliberation and voting in the matter concerning DLSC Case Number Complete Pharmacy and Medical Solutions, LLC – DHA Case Number SPS-24-0013/DLSC Case Number 22 PHM 074.)

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 3:05 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

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

The meeting adjourned at 3:06 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**	**08/19/24** 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?
08/29/24	☒ Yes ☐ No	**11:00 A.M. Preliminary Hearing on Statement of Scope – SS 089-24 on Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substances Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check** **1. Review Preliminary Hearing Comments**

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

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

The Board will hold a Preliminary Hearing on this scope statement as directed by the Joint Committee for Review of Administrative Rules.

11) Authorization

Nilajah D. Hardin 08/19/24

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.

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 089-24
Date:	Thursday, August 15, 2024 3:45:26 PM

August 15, 2024

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

RE: SS 089-24 – Electronic Prescriptions, Prescription Labeling, and other Changes

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 089-24, which was published in the Wisconsin Administrative Register on August 5, 2024.

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 7

Relating to: 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 Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule: The objective of the proposed rule is to update requirements in Wisconsin Administrative Code Phar 7 to align with current pharmacy practice in the areas of electronic prescriptions, prescription labelling, CPR for pharmacists, controlled substance prescription transfers, remote dispensing, the definition of a managing pharmacist, initial prescription consultation by a pharmacist, alteration of a prescription, and prescription final check. Additionally, the rule will implement the statutory changes from 2023 Wisconsin Act 27 by updating requirements for epinephrine delivery systems.

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 Phar 7 includes requirements for the practice of pharmacy. These requirements have the potential to become outdated on a regular basis. If the Board does not make regular updates via the permanent rules process, there will be inconsistencies between current pharmacy practice and what is required in the Wisconsin Administrative Code. This project will ensure that the Wisconsin Administrative Code continues to be current in the practice areas listed above.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):
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."

450.02 (2), Stats., states that "the 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) (a), Stats., states "[t]he Board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs."

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."

450.02 (5), Stats., states “[t]he Board may promulgate rules governing pharmacies that are operated as remote dispensing sites.”

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, Manufacturers, and Distributors; Registered Pharmacy Technicians

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:
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.

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. It 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:

John Waitekamp

Authorized Signature

7/10/2024

Date Submitted

Approved for implementation:

Authorized Signature

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**	**08/19/24** **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?
08/29/24	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Preliminary Rule Draft:** **a. Phar 15, Relating to Compounding Pharmaceuticals** **b. Phar 8, Relating to Controlled Substances Requirements** **2. Pending or Possible Rulemaking Projects**

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

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

Attachments:

1. Phar 15 Preliminary Rule Draft
2. Phar 8 Preliminary Rule Draft
3. 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 — 08/19/24

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

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE 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 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.

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 ot 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, Lousiana, 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 will be 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.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis will be attached upon completion.

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; 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, 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 on a date 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)

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)

PROPOSED ORDER

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 requirements for controlled substances.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

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

Statutory authority: ss. 15.08 (5) (b), 450.02 (2) (a), 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) (a), 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.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: The Pharmacy Examining Board held a Preliminary Hearing on Statement of Scope for this project on August 31, 2023. No comments were received.

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.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The rule will be 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.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis will be attached upon completion.

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

Agency contact person:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; 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, 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 on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

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 4. 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)

Pharmacy Examining Board
Rule Projects (updated 8/19/24)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
23-072 (EmR 2303)	052-22	12/27/2024	Phar 1, 5, 7, 10, and 19	Registration of Pharmacy Technicians	Permanent Rule Effective 09/01/24	N/A
23-054 (EmR 2213)	053-22	12/27/2024	Phar 1, 5, 6, 7 and 8	Remote Dispensing	Permanent Rule Effective 09/01/24	N/A
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	Preliminary Hearing on Statement of Scope at 08/29/24 Meeting	Scope Implementation
Not Assigned Yet	044-23	01/10/2026	Phar 8	Controlled Substances Requirements	Emergency Rule Pending 10/1/24 Publication in Wisconsin State Journal; Permanent Rule Reviewed at 08/29/24 Meeting	Board Approval of Preliminary Rule Draft for EIA Comment and Clearinghouse Review
Not Assigned Yet	007-23	07/23/2025	Phar 15	Compounding Pharmaceuticals	Preliminary Rule Draft Reviewed at 08/29/24 Meeting	Board Approval of Preliminary Rule Draft for Posting for EIA Comment and Submission to Clearinghouse for Review

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski, Executive Director		**2) Date when request submitted:** 8/19/2024 **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: 8/29/2024	**5) Attachments:** ☐ Yes ☒ No	**6) How should the item be titled on the agenda page?** NABP Pulse Regulator Monthly Champions Call – Discussion and Consideration	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes <Appearance Name(s)> ☐ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>	

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

Discussion topics from the August 19, 2024 Champions call. Meeting topics include:

1. Pulse/Industry Update
2. WEER Update
3. NABP Created Dispenser Guide
4. NABP Manufacturer-Regulator Zoom Workshop on DSCSA

11) Authorization

	8/19/2024
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.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski, Executive Director		**2) Date when request submitted:** 8/21/2024 **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: 8/29/2024	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Improving Pharmacist Workplace Satisfaction – Discussion and Consideration 1) Virginia Emergency Rule
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes <Appearance Name(s)> ☐ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>
10) Describe the issue and action that should be addressed: Please review Virginia Regulations Governing the Practice of Pharmacy 18VAC110-20		
11) Authorization  8/21/2024 **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

REGULATIONS VOL. 40 ISS. 5 - OCTOBER 23, 2023

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF PHARMACY

Chapter 20

Emergency

Title of Regulation: **18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-110; adding 18VAC110-20-113).**

Statutory Authority: §§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

Effective Dates: September 29, 2023, through March 28, 2025.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4456, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

Preamble:

Section 2.2-4011 of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of § 2.2-4006 A 4 of the Code of Virginia.

Pursuant to Chapter 628 of the 2022 Acts of Assembly, the amendments add a new section addressing pharmacy work environments, including to ensure (i) that the decisions of the pharmacist are not overridden by the pharmacy permit holder, including staffing decisions and the decision of whether pharmacy staff can safely provide vaccines at a given time; (ii) that pharmacy permit holders provide sufficient staffing levels to avoid interference with a pharmacist's ability to practice with reasonable competence and safety; (iii) that a pharmacist and pharmacy personnel are provided with proper and functioning equipment; (iv) pharmacists and pharmacy staff are not burdened with external factors that may inhibit the ability to provide services to the public; (v) staff are properly trained to provide the services with which they are tasked; (vi) pharmacists are provided appropriate breaks while maintaining drug stock integrity and providing required consultation services to the public; (vii) pharmacists are provided adequate time to perform professional duties; and (viii) the existence of a reporting mechanism for staffing concerns.

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist may, however, volunteer to work longer than 12 continuous hours. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break. Breaks, including uninterrupted rest periods and meal breaks, shall be provided consistent with 18VAC110-20-113 B 5.

C. The PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

D. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.

E. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, ~~he~~ the pharmacist shall immediately return the pharmacy permit to the board indicating the effective date on which ~~he~~ the pharmacist ceased to be the PIC.

F. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedules II through V controlled substances on hand on the date ~~he~~ the pharmacist ceases to be the PIC, unless the owner submits written notice

G. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

H. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

I. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

J. Before any permit is issued, the applicant shall attest to compliance with all federal, state, and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

18VAC110-20-113. Pharmacy working conditions.

A. A pharmacy permit holder shall protect the health, safety, and welfare of patients by consulting with the PIC or pharmacist on duty and other pharmacy staff to ensure patient care services are safely provided in compliance with applicable standards of patient care. A permit holder's decisions shall not override the control of the PIC or other pharmacist on duty regarding appropriate working environments for all pharmacy personnel necessary to protect the health, safety, and welfare of patients.

B. To provide a safe working environment in a pharmacy, a permit holder shall, at a minimum:

1. Ensure sufficient personnel are scheduled to work at all times in order to prevent fatigue, distraction, or other conditions that interfere with a pharmacist's ability to practice with reasonable competence and safety. Staffing levels shall not be solely based on prescription volume, but shall consider any other requirements of pharmacy staff during working hours;

2. Provide sufficient tools and equipment in good repair and minimize excessive distractions to support a safe workflow for a pharmacist to practice with reasonable competence and safety to address patient needs in a timely manner;

3. Avoid the introduction of external factors, such as productivity or production quotas or other programs, to the extent that they interfere with the pharmacist's ability to provide appropriate professional services to the public;

4. Ensure staff are sufficiently trained to safely and adequately perform their assigned duties, ensure staff demonstrate competency, and ensure that pharmacy technician trainees work closely with pharmacists and pharmacy technicians with sufficient experience as determined by the PIC;

5. Provide appropriate opportunities for uninterrupted rest periods and meal breaks consistent with 18VAC110-20-110 and the following:

a. A pharmacy may close when a pharmacist is on break based on the professional judgment of the pharmacist on duty provided that the pharmacy has complied with the 14-day notice to the public pursuant to § 54.1-3434 of the Code of Virginia and 18VAC110-20-135;

b. If a pharmacy does not close while the pharmacist is on break, the pharmacist must ensure adequate security of drugs by taking a break within the prescription department or on the premises. The pharmacist on duty must determine whether pharmacy technicians or pharmacy interns may continue to perform duties and whether the pharmacist is able to provide adequate supervision; and

c. If the pharmacy remains open, only prescriptions verified by a pharmacist pursuant to 18VAC110-20-270 may be dispensed when the pharmacist is on break. An offer to counsel any person filling a new prescription must be offered pursuant to § 54.1-3319 of the Code of Virginia. Persons who request to speak to the pharmacist shall be told that the pharmacist is on break and that they may wait to speak with the pharmacist or provide a telephone number for the pharmacist to contact them upon return from break. Pharmacists returning from break shall immediately attempt to contact persons who requested counseling and document when such counseling is provided;

6. Provide adequate time for a pharmacist to complete professional duties and responsibilities, including:

a. Drug utilization review;

b. Immunization;

c. Counseling;

e. Patient testing; and

f. All other duties required by Chapter 33 (§ 54.1-3300 et seq.) and Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and this chapter; and

7. Ensure that pharmacy technicians shall never perform duties otherwise restricted to a pharmacist.

C. A pharmacy permit holder shall not override the control of the pharmacist on duty regarding all aspects of the practice of pharmacy, including a pharmacist's decision not to administer vaccines when one pharmacist is on duty and, in the pharmacist's professional judgment, vaccines cannot be administered safely.

D. Staffing requests or concerns shall be communicated by the PIC or pharmacist on duty to the permit holder using a form developed by the board.

1. Executed staffing forms shall be provided to the immediate supervisor of the PIC or pharmacist on duty, with one copy maintained in the pharmacy for three years, and produced for inspection by the board.

2. The PIC or pharmacist on duty may report any staffing issues directly to the board if the PIC or pharmacist on duty believes the situation warrants immediate board review.

3. Under no circumstances shall a good faith report of staffing concerns by the PIC, pharmacist on duty, or notification of such issues by pharmacy personnel to the PIC or pharmacist on duty result in workplace discipline against the reporting staff member.

E. Permit holders shall review completed staffing reports and shall:

1. Respond to reporting staff member to acknowledge receipt of the staffing request or concern;

2. Resolve any issues listed in a timely manner to ensure a safe working environment for pharmacy staff and appropriate medication access for patients;

3. Document any corrective action taken, steps taken toward corrective action as of the time of inspection, or justification for inaction, which documentation shall be maintained on site or produced for inspection by the board within 48 hours of request; and

4. Communicate corrective action taken or justification for inaction to the PIC or reporting pharmacist on duty.

NOTICE: The following forms used in administering the regulation have been filed by the agency. Amended or added forms are reflected in the listing and are published following the listing. Online users of this issue of the Virginia Register of Regulations may also click on the name to access a form. The forms are also available from the agency contact or may be viewed at the Office of Registrar of Regulations, 201 North Ninth Street, 4th Floor, Richmond, Virginia 23219.

FORMS (18VAC110-20)

Application for a Pharmacy Permit (rev. 10/2020)

Application for a Non-resident Pharmacy Registration (rev. 10/2020)

Application for a Non-Resident Wholesale Distributor Registration (rev. 10/2020)

Application for Registration as Nonresident Manufacturer (rev. 10/2020)

Application for a Non-Resident Third Party Logistics Provider Registration (rev. 10/2020)

Application for Registration as a Nonresident Warehouser (rev. 10/2020)

Application for a Non-resident Outsourcing Facility Registration (rev. 10/2020)

Application for an Outsourcing Facility Permit (rev. 10/2020)

Application for a Medical Equipment Supplier Permit (rev. 10/2020)

Application for a Permit as a Restricted Manufacturer (rev. 10/2020)

Application for a Permit as a Non-Restricted Manufacturer (rev. 10/2020)

Application for a Permit as Warehouser (rev. 10/2020)

Application for a Permit as a Third-Party Logistics Provider (rev. 10/2020)

Application for Registration as a Non-resident Medical Equipment Supplier (rev. 10/2020)

Application for a Controlled Substances Registration Certificate (rev. 10/2020)

Closing of a Pharmacy (rev. 5/2018)

Application for Approval of an Innovative (Pilot) Program (rev. 8/2023)

Registration for a Pharmacy to be a Collection Site for Donated Drugs (rev. 5/2018)

Application for Approval of a Repackaging Training Program (rev. 10/2020)

Registration for a Facility to be an Authorized Collector for Drug Disposal (rev. 5.2018)

Application for Re-inspection of a Facility (rev. 3/2023)

Notification of Distribution Cessation due to Suspicious Orders (rev. 5/2018)

Staffing Requests or Concerns Form (eff. 9/2023)

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