



**HYBRID (IN-PERSON/VIRTUAL)
PHARMACY EXAMINING BOARD**
Room N208, 4822 Madison Yards Way, 2nd Floor, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
April 27, 2023

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. Be advised that board members may attend meetings designated as “Hybrid” in-person or virtually.

AGENDA

11:00 A.M.

(OR IMMEDIATELY FOLLOWING THE PHARMACY RULES COMMITTEE)

OPEN SESSION – CALL TO ORDER – ROLL CALL

- A. Adoption of Agenda (1-4)**
- B. Approval of Minutes of March 2, 2023 (5-9)**
- C. Reminders: Conflicts of Interest, Scheduling Concerns
- D. Introductions, Announcements, and Recognition**
 - 1) Recognition of Shana Weiss, Public Member (Resigned: 3/20/2023)
- E. 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 – 7/1/2024
 - c. Peterangelo, Anthony – 7/1/2023
 - d. Walsh, Michael – 7/1/2024
 - e. Weitekamp, John – 7/1/2026
 - f. Wilson, Christa – 7/1/2025
- F. Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State Boards of Pharmacy and the U.S. Food and Drug Administration – Discussion and Consideration**
- G. Legislative and Policy Matters – Discussion and Consideration
- H. Administrative Rule Matters – Discussion and Consideration (10)**
 - 1) Adoption Order: Phar 5, 6, 7, 11, and 12, Relating to Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References, and Technical Correction **(11-15)**

- 2) Scope Statement: Phar 8, Relating to Controlled Substances Requirements (**16-17**)
- 3) Pending or Possible Rulemaking Projects (**18**)

I. Variances – Discussion and Consideration

- 1) Pharmacy Technician Apprenticeship Program Variance Request

J. Speaking Engagements, Travel, or Public Relation Requests, and Reports

- 1) Travel Report: Multistate Pharmacy Jurisprudence Examination (MPJE) Item Writing Workshop – March 8-10, 2023 – Tiffany O’Hagan and Susan Kleppin
- 2) Travel Report: 2023 Pharmacy Society of Wisconsin (PSW) Legislative Day – Thursday, March 30, 2023 – Madison, WI – John Weitekamp and Tiffany O’Hagan
- 3) Upcoming Travel: NABP 119th Annual Meeting – Nashville, TN – May 10-12, 2023 (**19**)

K. Pilot Program Matters – Discussion and Consideration

L. 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

M. 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.).

N. Credentialing Matters

1) Application Reviews

- a. David Hauge – Predetermination Applicant **(20-51)**
- b. Jennifer Weiland – Pharmacy Technician Applicant **(52-58)**

O. Deliberation on Division of Legal Services and Compliance Matters

1) Administrative Warning

- a. 22 PHM 047 – C.R.B. **(59-60)**
- b. 22 PHM 118 – C.V.S. **(61-62)**
- c. 22 PHM 152 – S.K. **(63-64)**

2) Case Closings

- a. 21 PHM 075 – A.S.P. **(65-71)**
- b. 21 PHM 096 – W. **(72-77)**
- c. 21 PHM 066 – K.L.G. **(78-82)**
- d. 22 PHM 071 – E.S.P. **(83-86)**
- e. 22 PHM 072 – A.P. **(87-91)**
- f. 22 PHM 114 – S.R.X. **(92-102)**
- g. 22 PHM 124 – C.V.S., K.H.K. **(103-107)**
- h. 22 PHM 152 – C.V.S. **(108-111)**
- i. 22 PHM 161 – H.Z. **(112-115)**
- j. 22 PHM 171 – M.P. **(116-120)**
- k. 22 PHM 172 – M.P. **(121-125)**
- l. 22 PHM 173 – M.P. **(126-130)**
- m. 22 PHM 186 – J.C.W. **(131-134)**
- n. 23 PHM 028 – A.J.V. **(135-138)**
- o. 23 PHM 039 – A.H.G. **(139-141)**

3) Proposed Stipulation and Final Decision and Orders

- a. 22 PHM 147 – Mary M. Stieber, R.Ph. **(142-147)**

4) Monitoring Matters

- a. Jin Ryu, R.Ph. – Requesting Reduction in Drug Screens, Reduction of AA/NA Meetings to Once Per Week, and the Termination of the Treatment Requirement **(148-176)**

P. 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

Q. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: JUNE 15, 2023

 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
MARCH 2, 2023**

PRESENT: Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo, John Weitekamp, Michael Walsh (*arrived at 11:03 a.m.*), Christa Wilson

EXCUSED: Shana Weiss

STAFF: Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Katlin Schwartz, Bureau Assistant; and other Department staff

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 11:02 a.m. A quorum was confirmed with five (5) members present.

ADOPTION OF AGENDA

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to adopt the Agenda as published. Motion carried unanimously.

Michael Walsh arrived at 11:03 a.m.

APPROVAL OF MINUTES OF JANUARY 19, 2023

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to approve the Minutes of January 19, 2023 as published. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Review of Draft Biennial Report Under S. 227.296, Wis. Stats.

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to designate John Weitekamp to serve as liaison to DSPS staff for drafting a report pursuant to Wis. Stat. 227.29 for submission in 2023, relating to administrative rules, and to authorize the Chairperson to approve the report for submission to the Joint Committee for Review of Administrative Rules. Motion carried unanimously.

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

**Consideration of Attendance: 2023 Pharmacy Society of Wisconsin (PSW) Legislative Day
– Thursday, March 30, 2023 – Madison, WI**

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to designate John Weitekamp and Tiffany O’Hagan to attend and present at the 2023 Pharmacy Society of Wisconsin (PSW) Legislative Day on March 30, 2023 in Madison, WI. Motion carried unanimously.

CLOSED SESSION

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, 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 12:04 p.m.

CREDENTIALING MATTERS

Tara Fakrhi – Foreign Trained Applicant

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to approve the Foreign Trained application of Tara Fakrhi, once all requirements are met. Motion carried unanimously.

Crown Laboratories Inc – Wholesale Distributor Applicant

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to approve the Wholesale Distributor application of Crown Laboratories Inc, 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 Anthony Peterangelo, to issue an Administrative Warning in the following DLSC Cases:
- a. 22 PHM 057 – E.S.
 - b. 22 PHM 057 - E.S.S.D.S.
- Motion carried unanimously.

(John Weitekamp recused himself and left the room for deliberation and voting in the matter concerning E.S. DLSC Case Number 22 PHM 057 and E.S.S.D.S., DLSC Case Number 22 PHM 057.)

Case Closings

22 PHM 057 – E.S.

- MOTION:** Michael Walsh moved, seconded by Anthony Peterangelo, to close DLSC Case Number 22 PHM 057, against E.S., for No Violation. Motion carried unanimously.

(John Weitekamp recused himself and left the room for deliberation and voting in the matter concerning E.S., DLSC Case Number 22 PHM 057.)

Administrative Warnings

22 PHM 144 – E.C.H.

- MOTION:** Susan Kleppin moved, seconded by Michael Walsh, to issue an Administrative Warning in the matter of E.C.H., DLSC Case Number 22 PHM 144. Motion carried unanimously.

(Anthony Peterangelo recused himself and left the room for deliberation and voting in the matter concerning E.C.H., DLSC Case Number 22 PHM 144.)

Case Closings

22 PHM 144 – M.S.

- MOTION:** Michael Walsh moved, seconded by Susan Kleppin, to close DLSC Case Number 22 PHM 144, against M.S., for No Violation. Motion carried unanimously.

(Anthony Peterangelo recused himself and left the room for deliberation and voting in the matter concerning M.S., DLSC Case Number 22 PHM 144.)

Administrative Warnings

22 PHM 137 – A.S.

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to issue an Administrative Warning in the matter of A.S., DLSC Case Number 22 PHM 137. Motion carried unanimously.

Case Closings

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

1. 22 PHM 030, 22 PHM 039, 22 PHM 052 – O.P. – Prosecutorial Discretion (P2), No Violation, No Violation
 2. 22 PHM 036 – R.B.M. – Insufficient Evidence
 3. 22 PHM 054 – B.R.P. – Insufficient Evidence
 4. 22 PHM 095 – W. – Prosecutorial Discretion (P1)
 5. 22 PHM 108 – A.H.G. – Insufficient Evidence
 6. 22 PHM 112 – P. – No Violation
 7. 22 PHM 133 – J.A.Y. – No Violation
 8. 22 PHM 137 – W. – No Violation
 9. 22 PHM 142 – C.V.S. – No Violation
 10. 22 PHM 146 – A.R.P. – No Violation
- Motion carried unanimously.

Proposed Stipulations and Final Decisions and Orders

22 PHM 019 – Jason D. North, R.Ph.

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Jason D. North, R.Ph., DLSC Case Number 22 PHM 019. Motion carried unanimously.

RECONVENE TO OPEN SESSION

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

The Board reconvened into Open Session at 12:43 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: Susan Kleppin 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

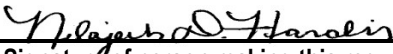
MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 12:45 p.m.

DRAFT

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Nilajah Hardin Administrative Rules Coordinator		2) Date when request submitted: 04/18/23 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: 04/27/23	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Administrative Rule Matters – Discussion and Consideration 1. Adoption Order: Phar 5, ,6, 7, 11, and 12, Relating to Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References, and Technical Correction 2. Scope Statement: Phar 8, Relating to Controlled Substances Requirements 3. Pending or Possible Rulemaking Projects	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <i>(If yes, please complete Appearance Request for Non-DSPS Staff)</i> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Attachments: 1. Phar 5, 6, 7, 11, and 12 Adoption Order 2. Phar 8 Scope Statement 3. Rule Projects Chart Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx			
11) Authorization			
Signature of person making this request 		Date 04/18/23	
Supervisor (if required) Brad Wojciechowski (approved via email)		Date 04/18/23	
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	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 21-074)

ORDER

An order of the Pharmacy Examining Board to repeal and recreate Phar 6.04 (3) (title); repeal Phar 6.04 (2) and (3) (a) 2. and 3., 6.04 (3) (a) 7., (b), (c), and (4), and ch. Phar 11; to renumber and amend Phar 6.04 (3) (a) (intro.), 1., 5., and 6.; and to amend s. Phar 5.02 (1) and (2), 6.04 (1), 7.04 (3) (intro.), and 12.04 relating to name and address change, floor design, procedures for disciplinary proceedings, superseded references, and technical correction.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.06 (1) and 450.09 (4), Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (3) (a), (b), (d), and 450.06 (1), Stats.

Explanation of agency authority:

Each examining 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. [s. 15.08 (5) (b), Stats.]

The board may promulgate rules relating to the distribution and dispensing of prescription drug and establishing security standards for pharmacies. [s. 450.02 (3) (a) and (b), Stats.]

The Board may promulgate rules necessary for the administration and enforcement of this chapters 450 and 961, Stats. [s. 450.02 (3) (d), Stats.]

No pharmacist may dispense at any location in this state that is not licensed as a pharmacy by the board. No person in this state may use or display the title "pharmacy," "drugstore," "apothecary," or any other title, symbol, or insignia having the same or similar meanings, except for a place of practice which is licensed under this section as a pharmacy by the board. [s. 450.06 (1), Stats.]

Related statute or rule: N/A

Plain language analysis:

The Pharmacy Examining Board identified the following rules in its 2019 report filed with the Joint Committee for Review of Administrative Rules pursuant to s. 227.29, Stats.

Phar 5.02 is revised to delete obsolete or unnecessary provisions to require the notification to the Board regarding name or address change to be submitted in writing.

Phar 6.04 is revised to delete economically burdensome requirements and requirements which do not correspond with the evolving types of pharmacies.

Phar 7.04 (3) is revised to correct a typographical error occurring in CR 19-145 related to which should refer to Schedule III – V drugs instead of Schedule III – IV drugs. The omission of Schedule V creates inconsistency with the federal law and confusion for pharmacists.

Ch. Phar 11 is repealed as it is duplicative and unnecessary.

Phar 12.04 is revised as the federal standards referenced have been superseded.

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: N/A**Comparison with rules in adjacent states:**

Illinois: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.610 outlines the standards for pharmacy structure/equipment standards. The section does require a locked area for drugs. However, Illinois does not identify professional service area square footage requirements or signage requirements.

Iowa: The complete Iowa Board of Pharmacy rules are contained in 657 Iowa Administrative Code. The Iowa Pharmacy Practice Act is codified under administrative code chapter 155A, specifically related to licensed pharmacies under s. 155A.13. Rules do require a locked area for drugs. However, there are no comparable requirements for professional service area square footage or signage.

Michigan: Michigan administrative code MCL 338.536 for housing of pharmacies specifically requires pharmacies to have a prescription department that is devoted primarily to the practice of pharmacy that occupies not less than 150 square feet of space, and that it includes a prescription counter that provides not less than 10 square feet of free working surface. For each additional pharmacist on duty, workspace must be increased by not less than 4 square feet and pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee must be permanently enclosed by partitions from the floor to the ceiling of substantial construction and must be securely lockable. There do not appear to be requirements for signage.

Minnesota: The Minnesota Administrative Code chapter 6800 related to pharmacies and pharmacists, provides the rules for the standards for pharmacies. Specifically, Minnesota Administrative Code section 6800.0700 provides minimum requirements for pharmacies. The pharmacy space requirements include the pharmacy must: contain more than 250 square feet in the dispensing and drug storage area; maintain a prescription dispensing counter at least 18 inches deep that provides 2 linear feet; maintain an aisle behind the prescription dispensing counter at least 36 inches wide, extending the full length of the counter; be surrounded by a continuous partition or wall extending from the floor to the permanent ceiling; and contain doors capable of being securely locked. There do not appear to be requirements for signage.

Summary of factual data and analytical methodologies:

The Board conducted a full review of its administrative codes in compliance with the Legislative Report to the Joint Committee of Review of Administrative Rules under s. 227.29, Stats. The items in this rule project are a result of that review.

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

This rule was posted for economic impact comments for 14 days. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The fiscal estimate and economic impact analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8306; phone (608) 267-7139; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. Phar 5.02 (1) and (2) are amended to read:

Phar 5.02 (1) A pharmacist shall notify the board ~~in writing~~ when ~~his or her~~ a pharmacist's name has been legally changed, within 30 days of the change.

(2) A pharmacist shall notify the board ~~in writing~~ when ~~his or her~~ a pharmacist's address has been changed, within 30 days of the change.

SECTION 2. Phar 6.04 (1) is amended to read:

Phar 6.04 (1) PROFESSIONAL SERVICE AREA. ~~The professional service area of a pharmacy shall not be less than 250 sq. ft. No more than 20% of the space may be used for storage of bulk pharmaceuticals. If the pharmacy building is open at any time solely as a non-prescription or sundry outlet, without a pharmacist present while the professional service area is closed, the professional service area shall be secured as specified in sub. (3). A variance to the 250 sq. ft. professional service area requirement may be authorized by the board upon submission of a specific plan describing the manner in which the proposed professional service plan varies from the requirement.~~

SECTION 3. Phar 6.04 (2) is repealed.

SECTION 4. Phar 6.04 (3) (title) is repealed and recreated to read:

Phar 6.04 (3) (title) REQUIREMENTS WHEN THE PROFESSIONAL SERVICE AREA IS CLOSED.

SECTION 5. Phar 6.04 (3) (a) (intro) and 1. are renumbered Phar 6.04 (3) (a) and (am) and amended to read:

Phar 6.04 (3) (a) ~~Except as provided in par. (c), if no pharmacist is present in the professional service area, a pharmacy may convert to a non-prescription or sundry outlet if~~ When the pharmacy professional service area is closed, the pharmacy shall meet all of the following requirements are met:

Phar 6.04 (3) (am). A ~~secured~~ locked, secure physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by ~~unlicensed~~ unauthorized personnel. A secured barrier may be constructed of other than a solid material with a continuous surface. If constructed of other than a solid material, the openings or interstices in the material shall not be large enough to permit removal of items from the professional service area by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. The plans and specifications of the barrier shall be submitted to the board for approval.

SECTION 6. Phar 6.04 (3) (a) 2. and 3. are repealed.

SECTION 7. Phar 6.04 (3) (a) 5. and 6. are renumbered Phar 6.04 (3) (bm) and (cm) and amended to read:

Phar 6.04 (3) (bm) Signs of reasonable size are posted at ~~the entrance of the building and~~ the professional service area which prominently displaying display the hours the ~~pharmacist will be on duty~~ professional services are available.

(cm) The manner in which the telephone is answered does not imply that the ~~location is, at that time, operating as a pharmacy~~ professional services are available.

SECTION 8. Phar 6.04 (3) (a) 7., (b), (c), and (4) are repealed.

SECTION 9. Phar 7.04 (3) (intro.) is amended to read:

7.04 (3) (intro.) The transfer of original prescription information for a controlled substance listed in Schedule III – ~~IVV~~ shall meet the following requirements:

SECTION 10. Chapter Phar 11 is repealed.

SECTION 11. Phar 12.04 is amended to read:

Phar 12.04 Inspections. Before a license is granted, an inspection of the establishment shall be conducted by the board or its representative to determine if the location meets the standards in 21 USC 351 and 352 (~~1984~~2022) and 21 CFR 210 and 211 (~~1985~~2022).

SECTION 12. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated _____

Agency _____

Chairperson
Pharmacy Examining Board

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 8

Relating to: Controlled Substances Requirements

Rule Type: Both Permanent and Emergency

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

Clearinghouse Rule 21-071 went into effect on October 1, 2022. This rule repealed and recreated all of Wisconsin Administrative Code Chapter Phar 8. Upon receiving feedback and completing an additional review, the Pharmacy Examining Board has determined that additional changes are needed to Phar 8 to address areas where requirements are no longer in effect or do not match federal regulations. Emergency rules are needed to ensure that these requirements can be updated to protect patient safety and allow effective regulation of the profession until permanent rules can be promulgated.

2. Detailed description of the objective of the proposed rule:

Wisconsin Administrative Code Chapter Phar 8 was recently repealed and recreated. As a result of this change, the Board has found additional areas of Phar 8 that may need to be revised to align with current Pharmacy practices and federal regulations.

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 8 includes requirements for controlled substance prescribing, record keeping, partial dispensing, and compliance with federal laws and regulations, among other requirements. The proposed rules would add to the existing requirements to address issues such as controlled substances prescribing, partial dispensing, and reporting and to create consistency between the code, current pharmacy practices and federal regulations.

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

15.08 (5) (b) 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) The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.

450.02 (3) (a) The Board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.

450.02 (3) (b) The Board may promulgate rules establishing security standards for pharmacies.

450.02 (3) (d) The Board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961.

450.02 (3) (e) The Board may promulgate rules establishing minimum standards for the practice of pharmacy.

961.31 The pharmacy examining board may promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state.

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

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:

Approved for implementation:

Authorized Signature

Authorized Signature

Date Submitted


Date Submitted

**Pharmacy Examining Board
Rule Projects (updated 04/18/23)**

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet	052-22	12/27/2024	Phar 1, 5, 7, 10, and 19	Registration of Pharmacy Technicians	Emergency Rule Public Hearing Held at 03/02/23 Meeting; Emergency Rule Effective 02/03/23-05/01/24	Drafting Permanent Rule
Not Assigned Yet (EmR 2213)	053-22	12/27/2024	Phar 1, 5, 6, 7 and 8	Remote Dispensing	Drafting Permanent Rule; Emergency Rule Effective 11/01/22-05/01/24	Board Approval of Preliminary Permanent Rule Draft
Not Assigned Yet	137-20	4/19/2023	Phar 1, 6, 7, 8, 12, 13	Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers, and Distributors	Project Will be Allowed to Expire	New Scope Statement if Needed after Updates to Drug Supply Chain Security Act in 2023
21-074	079-20	12/22/2022	Phar 5, 6, 7, 11, 12	Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References, and Technical Correction	Board Review of Adoption Order at 04/27/23 Meeting	Submission for Publication; Anticipated Effective Date of 07/01/23
Not Assigned Yet	102-21	05/01/2024	Phar 7 and 10	Consumer Disclosures	Ready for Submission to Clearinghouse for Review	Public Hearing Anticipated for either April or June Meeting
Not Assigned Yet	007-23	07/23/2025	Phar 15	Compounding Pharmaceuticals	Drafting	Board Review and Approval of Preliminary Rule Draft
Not Assigned Yet	097-21	04/18/2024	Phar 18	Third Party Logistics Providers	Ready for Submission to Clearinghouse for Review	Public Hearing Anticipated for either April or June Meeting

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski		2) Date when request submitted: 4/20/2023 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: 4/27/2023	5) Attachments: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	6) How should the item be titled on the agenda page? Speaking Engagements, Travel, or Public Relation Requests, and Reports	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <i>(If yes, please complete Appearance Request for Non-DSPS Staff)</i> <input type="checkbox"/> Yes <Appearance Name(s)> <input checked="" type="checkbox"/> 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: Upcoming Travel: NABP 119 th Annual Meeting - Nashville, TN – May 10 – 12, 2023			
11) Authorization			
		4/20/2023	
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.			