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**PHARMACY EXAMINING BOARD**  
**N208, 4822 Madison Yards Way, 2<sup>nd</sup> Floor, Madison, WI**  
**Contact: Brad Wojciechowski (608) 266-2112**  
**April 28, 2022**

*The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the actions of the Board.*

**AGENDA**

**11:00 A.M.**

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

- A. Adoption of Agenda (1-4)**
- B. Approval of Minutes of March 3, 2022 (5-9)**
- C. Reminders: Conflicts of Interest, Scheduling Concerns**
- D. 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. Weiss, Shana – 7/1/2023
    - f. Weitekamp, John – 7/1/2022
    - g. Wilson, Christa – 7/1/2025
- E. Board Chair Meeting and Options to Address Department Resources – Discussion and Consideration**
- 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. Administrative Rule Matters – Discussion and Consideration (10)**
  - 1) Scope Statement
    - a. Phar 1, 5, 7, 10, and 19, Relating to Registration of Pharmacy Technicians **(11-12)**
    - b. Phar 1, 6, and 7, Relating to Remote Dispensing **(13-14)**
  - 2) Preliminary Rule Draft: Phar 7 and 10, Relating to Consumer Disclosures **(15-18)**
  - 3) Pending or Possible Rulemaking Projects **(19-20)**

**H. Legislative and Policy Matters – Discussion and Consideration**

- 1) 2021 Wisconsin Act 100 – Registration of Pharmacy Technicians, Extending the Time Limit for Emergency Rule Procedures, Providing an Exemption from Emergency Rule Procedures, and Granting Rule-Making Authority
- 2) 2021 Wisconsin Act 9 – Pharmacy Benefit Managers, Prescription Drug Benefits, and Granting Rule-Making Authority

**I. Education and Examination Matters- Discussion and Consideration**

- 1) Multistate Pharmacy Jurisprudence Examination (MPJE) Update

**J. Speaking Engagements, Travel, or Public Relation Requests, and Reports – Discussion and Consideration**

- 1) 2022 Annual Meeting Planning: NABP/American Association of Colleges of Pharmacy (AACCP) District IV – October 19-21, 2022 – Madison, WI

**K. COVID-19 – Discussion and Consideration**

**L. Pilot Program Matters – Discussion and Consideration**

**M. 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) Pilot Program Matters
- 13) Variances
- 14) Liaison Reports
- 15) Board Liaison Training and Appointment of Mentors
- 16) Informational Items
- 17) Division of Legal Services and Compliance (DLSC) Matters
- 18) Presentations of Petitions for Summary Suspension
- 19) Petitions for Designation of Hearing Examiner
- 20) Presentation of Stipulations, Final Decisions and Orders
- 21) Presentation of Proposed Final Decisions and Orders
- 22) Presentation of Interim Orders
- 23) Pilot Program Matters
- 24) Petitions for Re-Hearing
- 25) Petitions for Assessments
- 26) Petitions to Vacate Orders
- 27) Requests for Disciplinary Proceeding Presentations
- 28) Motions
- 29) Petitions
- 30) Appearances from Requests Received or Renewed
- 31) Speaking Engagements, Travel, or Public Relation Requests, and Reports

## **N. 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.).**

## **O. Review of Administrative Warning**

- 1) **11:30 AM APPEARANCE: Julie Zimmer, DLSC Attorney, B.A.P. and Mark Larson, Attorney for Respondent: 21 PHM 010 – B.A.P. (21-45)**

## **P. Deliberation on Division of Legal Services and Compliance Matters**

### **1) Administrative Warnings**

- a. 21 PHM 154 – R.A.H. **(46-47)**
- b. 21 PHM 159 – P.G. **(48-49)**
- c. 21 PHM 160 – C.M.P. **(50-51)**

### **2) Case Closings**

- a. 18 PHM 075, 19 PHM 058 – R.F.P.C. **(52-54)**
- b. 20 PHM 149 – P.N.S. **(55-64)**
- c. 21 PHM 141 – U.C. **(65-70)**
- d. 21 PHM 027 – W. **(71-75)**
- e. 21 PHM 084 – W. **(76-82)**
- f. 21 PHM 154 – W. **(83-87)**
- g. 21 PHM 156 – G.H. **(88-92)**
- h. 21 PHM 159 – M.I.A., M.R.S. **(93-99)**
- i. 22 PHM 014 – M.D. **(100-104)**

### **3) Proposed Stipulations, Final Decisions and Orders**

- a. 18 PHM 075, 19 PHM 058, 19 PHM 163, 21 PHM 049 – Paul F. Corcoran, Jr., R.Ph. **(105-112)**

## **Q. 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

R. Consulting with Legal Counsel

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

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

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

**ADJOURNMENT**

**NEXT MEETING: JUNE 16, 2022**

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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 at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. 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 deaf or hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer at 608-266-2112, or the Meeting Staff at 608-266-5439.

**VIRTUAL/TELECONFERENCE  
PHARMACY EXAMINING BOARD  
MEETING MINUTES  
MARCH 3, 2022**

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

**EXCUSED:** Shana Weiss

**STAFF:** Brad Wojciechowski, Executive Director; Joseph Ricker, 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 9:02 a.m. A quorum was confirmed with six (6) members present.

**ADOPTION OF AGENDA**

**MOTION:** Michael Walsh moved, seconded by Anthony Peterangelo, to adopt the Agenda as published. Motion carried unanimously.

**APPROVAL OF MINUTES OF JANUARY 27, 2022,  
FEBRUARY 14, 2022, FEBRUARY 18, 2022**

**MOTION:** Anthony Peterangelo moved, seconded by Michael Walsh, to approve the Minutes of January 27, 2022, February 14, 2022, and February 18, 2022 as published. Motion carried unanimously.

**ADMINISTRATIVE MATTERS**

**Delegation of Authorities**

***Delegation of Authority for Reciprocity/Endorsement Reviews***

**MOTION:** Michael Walsh moved, seconded by Susan Kleppin, to rescind the 1/27/2022 "Delegation of Authority for Reciprocity/Endorsement Reviews" motion, and to delegate authority to the Department Attorneys to review and approve reciprocity/endorsement applications in which the applicant met requirements comparable to those that existed in this state at the time the person became licensed in the other state. Motion carried unanimously.

**ADMINISTRATIVE RULE MATTERS**

**Adoption Order: Phar 2, Relating to Reciprocal Credentials for Service Members, Former Service Members, and Their Spouses**

**MOTION:** Susan Kleppin moved, seconded by Michael Walsh, to approve the Adoption Order for Clearinghouse Rule 21-028 (Phar 2), relating to Reciprocal Credentials for Service Members, Former Service Members, and their Spouses. Motion carried unanimously.

**Possible Scope Statement: 2021 Wisconsin Act 101**

**MOTION:** Christa Wilson moved, seconded by Michael Walsh, to request DSPS staff draft a Scope Statement, relating to Remote Dispensing. Motion carried unanimously.

**LEGISLATIVE AND POLICY MATTERS**

**2021 Wisconsin Act 100 – Registration of Pharmacy Technicians, Extending the Time Limit for Emergency Rule Procedures, Providing an Exemption from Emergency Rule Procedures, and Granting Rule-Making Authority**

**MOTION:** Michael Walsh moved, seconded by Anthony Peterangelo, to request DSPS staff draft a Scope Statement, relating to registration of Pharmacy Technicians. Motion carried unanimously.

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

**Consideration of Attendance: Multistate Pharmacy Jurisprudence Examination (MPJE) Item Writing Workshop – March 9-11, 2022 – Chicago, IL/Virtual**

**MOTION:** Anthony Peterangelo moved, seconded by Michael Walsh, to designate Tiffany O’Hagan, as the Board’s delegate, to attend the Multistate Pharmacy Jurisprudence Examination (MPJE) Item Writing Workshop on March 9-11, 2022 in Chicago, IL/Virtual. Motion carried unanimously.

**MOTION:** Anthony Peterangelo moved, seconded by Michael Walsh, to designate Tiffany O’Hagan, to work with DSPS staff regarding the MPJE Exam. Motion carried unanimously.

**Consideration of Attendance: 2022 NABP 118th Annual Meeting – May 19-21, 2022 – Phoenix, AZ**

**MOTION:** Michael Walsh moved, seconded by Anthony Peterangelo, to designate Tiffany O’Hagan, as the Board’s delegate, and John Weitekamp as the Board’s alternate delegate, to attend the 2022 NABP 118th Annual Meeting on May 19-21, 2022 in Phoenix, AZ. Motion carried unanimously.

## CLOSED SESSION

**MOTION:** Anthony Peterangelo moved, seconded by Michael Walsh, to convene to Closed Session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85(1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.). John Weitekamp, Chairperson, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Susan Kleppin-yes; Tiffany O’Hagan-yes; Anthony Peterangelo-yes; Michael Walsh-yes; John Weitekamp-yes; and Christa Wilson-yes. Motion carried unanimously.

The Board convened into Closed Session at 10:41 a.m.

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

#### Administrative Warnings

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

- a. 21 PHM 091 – L.A.W.
- b. 21 PHM 112 – R.L.A.

Motion carried unanimously.

#### Case Closings

**MOTION:** Christa Wilson moved, seconded by Anthony Peterangelo, to close the following DLSC Cases for the reasons outlined below:

1. 20 PHM 166 – S.S.M. – No Violation
2. 20 PHM 168 – C.V.S. – No Violation
3. 21 PHM 068 – J.R.M. – Prosecutorial Discretion (P2)
4. 21 PHM 074 – C.V.S. – No Violation
5. 21 PHM 091 – W. – No Violation
6. 21 PHM 100 – M.L.D. – No Violation
7. 21 PHM 112 – C.V.S. – No Violation

Motion carried unanimously.

#### Proposed Stipulations, Final Decisions and Orders

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

1. 19 PHM 307 – Kyle J. McGilligan, R.Ph.
2. 21 PHM 084 – Micah J. Thill, R.Ph.

Motion carried unanimously.

*18 PHM 075, 19 PHM 058, 19 PHM 163, 21 PHM 049 – Paul F. Corcoran, Jr., R.Ph.*

**MOTION:** Michael Walsh moved, seconded by Anthony Peterangelo, to table the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Paul F. Corcoran, Jr., R.Ph., DLSC Case Number 18 PHM 075, 19 PHM 058, 19 PHM 163, 21 PHM 049. Motion carried unanimously.

**Monitoring Matters**

**Kathryn Lindemann, Pharmacist  
Requesting Full Licensure and/or Requesting to Work Alone, Termination of Work Setting  
Pre-Approval, Quarterly Work Reports, and Controlled Substance Audits**

**MOTION:** Michael Walsh moved, seconded by Susan Kleppin, to grant the request of Kathryn Lindemann, R.Ph. for full licensure. Motion carried unanimously.

**McKesson Drug Company: Livonia, MI  
Requesting Full Licensure**

**MOTION:** Susan Kleppin moved, seconded by Michael Walsh, to grant the request of McKesson Drug Company: Livonia, MI for full licensure. Motion carried unanimously.

**McKesson Drug Company: Washington Court House, OH  
Requesting Full Licensure**

**MOTION:** Susan Kleppin moved, seconded by Michael Walsh, to grant the request of McKesson Drug Company: Washington Court House, OH for full licensure. Motion carried unanimously.

**Michael Ivey, R.Ph.  
Requesting Full Licensure**

**MOTION:** Michael Walsh moved, seconded by Susan Kleppin, to grant the request of Michael Ivey, R.Ph. for full licensure. Motion carried unanimously.

**RECONVENE TO OPEN SESSION**

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

The Board reconvened into Open Session at 11:32 a.m.



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

**MOTION:** Anthony Peterangelo moved, seconded by Christa Wilson, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

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

## **ADJOURNMENT**


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

The meeting adjourned at 11:35 a.m.

DRAFT

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

**AGENDA REQUEST FORM**

<b>1) Name and title of person submitting the request:</b>  Nilajah Hardin Administrative Rules Coordinator		<b>2) Date when request submitted:</b> 04/15/22 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
<b>3) Name of Board, Committee, Council, Sections:</b> Pharmacy Examining Board			
<b>4) Meeting Date:</b> 04/28/22	<b>5) Attachments:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<b>6) How should the item be titled on the agenda page?</b> Administrative Rule Matters – Discussion and Consideration 1. Scope Statement a. Phar 1, 5, 7, 10, and 19, Relating to Registration of Pharmacy Technicians b. Phar 1,6, and 7, Relating to Remote Dispensing 2. Preliminary Rule Draft: Phar 7 and 10, Relating to Consumer Disclosures 3. Pending or Possible Rulemaking Projects	
<b>7) Place Item in:</b> <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	<b>8) Is an appearance before the Board being scheduled?</b> <i>(If yes, please complete <a href="#">Appearance Request</a> for Non-DSPS Staff)</i> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>9) Name of Case Advisor(s), if required:</b> N/A	
<b>10) Describe the issue and action that should be addressed:</b>  Attachments: 1. Phar 1,5, 7, 10, and 19 Scope Statement 2. Phar 1, 6, and 7 Scope Statement 3. Phar 7 and 10 Preliminary Rule Draft 4. Rule Projects Chart  Copies of current Board Rule Projects Can be Viewed Here: <a href="https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx">https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx</a>			
<b>11) Authorization</b>			
Signature of person making this request 		Date 04/28/22	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)    Date			
<b>Directions for including supporting documents:</b> 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.			

# STATEMENT OF SCOPE

## PHARMACY EXAMINING BOARD

**Rule No.:** Phar 1, 5, 7, 10, and 19

**Relating to:** Registration of Pharmacy Technicians

**Rule Type:** Both Permanent and Emergency

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

2021 Wisconsin Act 100, Section 40 (1) provides:

“The pharmacy examining board may promulgate emergency rules under s. 227.24 necessary to implement this act. Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated under this subsection remain in effect until May 1, 2024, or the date on which permanent rules take effect, whichever is sooner. Notwithstanding s. 227.24 (1) (a) and (3), the examining board is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection.”

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

The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 100.

### **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:**

The Board intends to update the Pharmacy code to bring it into alignment with 2021 Wisconsin Act 100. An alternative would be to not revise the code to reflect these new requirements, which would create confusion and a lack of clarity for stakeholders as to what is required of pharmacists and the board as it relates to the new statutory requirements.

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

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) (a), Stats. allows the board to “promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.”

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.”

### **5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:**

Approximately 180 hours

**6. List with description of all entities that may be affected by the proposed rule:**

Pharmacies, Pharmacists, Pharmacy Technicians, Consumers of Prescription Pharmaceuticals

**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, (608) 267-7139, DSPSAdminRules@wisconsin.gov

Approved for publication:

Approved for implementation:

\_\_\_\_\_  
Authorized Signature

\_\_\_\_\_  
Authorized Signature

\_\_\_\_\_  
Date Submitted

\_\_\_\_\_  
Date Submitted

# STATEMENT OF SCOPE

## PHARMACY EXAMINING BOARD

**Rule No.:** Phar 1, 6, and 7

**Relating to:** Remote Dispensing

**Rule Type:** Permanent and Emergency

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

2021 Wisconsin Act 101, Section 14 (1) provides:

“The pharmacy examining board may promulgate emergency rules under s. 227.24 necessary to implement this act. Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated under this subsection remain in effect until May 1, 2024, or the date on which permanent rules take effect, whichever is sooner. Notwithstanding s. 227.24 (1) (a) and (3), the examining board is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection.”

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

The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 101.

### 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:

The Board intends to update the Pharmacy code to bring it into alignment with 2021 Wisconsin Act 101. An alternative would be to not revise the code to reflect these new requirements, which would create confusion and a lack of clarity for stakeholders as to what is required of pharmacists and the board as it relates to the new statutory requirements.

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

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) (a), Stats. allows the board to “promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.”

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.”

### 5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

Approximately 100 hours

**6. List with description of all entities that may be affected by the proposed rule:**

Pharmacies and pharmacists

**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, (608) 267-7139, DSPSAdminRules@wisconsin.gov

Approved for publication:

Approved for implementation:

\_\_\_\_\_  
Authorized Signature

\_\_\_\_\_  
Authorized Signature

\_\_\_\_\_  
Date Submitted

\_\_\_\_\_  
Date Submitted

STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD

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

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PROPOSED ORDER

An order of the Pharmacy Examining Board to **create** Phar 7.15, 10.03 (20), and 10.03 (21), relating to consumer disclosures.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:** ss. 15.08 (5) (b), 450.013 (5m), 450.013 (8m), Stats.

**Statutory authority:** ss. 15.08 (5) (b), 450.02 (3) (a), 450.02 (3) (d), and 450.02 (3) (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) (a), Stats. allows the board to “promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.”

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:** 2021 Wisconsin Act 9

**Plain language analysis:** The objective of the proposed rule is to revise the Pharmacy administrative code, including but not necessarily limited to chs. Phar 7 and 10, to bring the code into compliance with current statutory provisions as modified by 2021 Wisconsin Act 9.

The Pharmacy Examining Board is required under Act 9 to create and maintain a list of the 100 most commonly prescribed generic drug product equivalents, including the generic and brand name of the drug, which shall be made available to each pharmacy on an annual basis either directly or on the board's website.

Act 9 created several new requirements for pharmacies as well. A pharmacy must make available to the public information on how to access the list of 100 most commonly prescribed generic drug product equivalents maintained by the Pharmacy Examining Board. Pharmacies also must make available to the public information on how to access the FDA's list of all currently approved interchangeable biological products. Finally, a pharmacy must maintain disclosures to the public in a conspicuous place near where drugs are dispensed regarding the ability of a pharmacist to substitute a less expensive drug or interchangeable biological product.

**Summary of, and comparison with, existing or proposed federal regulation:** Federal Regulations part: 21 CFR Subchapter D covers regulations for the FDA on Drugs for Human Use.

**Comparison with rules in adjacent states:**

**Illinois:** The Illinois Department of Financial and Professional Regulation (IDFPR) under the State Board of Pharmacy, regulates pharmacists. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Illinois Board of Pharmacy is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

**Iowa:** Iowa pharmacists are regulated by the Board of Pharmacists. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Iowa Board of Pharmacists is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

**Michigan:** The Michigan Department of Licensing and Regulatory Affairs (MDLRA) regulates pharmacists under the authority of the Michigan Board of Pharmacy. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Michigan Board of Pharmacy is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

**Minnesota:** In Minnesota, pharmacists are regulated by the Minnesota Department of Health, with input from the Minnesota Board of Pharmacy. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Minnesota Board of Pharmacy is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.



**Summary of factual data and analytical methodologies:**

The proposed rules were developed by reviewing the current federal food and drug-approved interchangeable biological products; technical information provided by the American Pharmacists Association (APhA), and 2021 Wisconsin Act 9, relating to pharmacy benefit managers, prescription drug benefits, and granting rule-making authority.

**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, Dan Hereth, may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

**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.

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TEXT OF RULE

SECTION 1. Phar 7.15 is created to read:

**Phar 7.15 Consumer Disclosures.**

(1) Each pharmacy shall post in a prominent place and maintain the consumer disclosures required in ss. 450.013 (5m) and 450.013 (8m).

(2) The Board shall maintain a link to the Top 100 Most Commonly Prescribed Prescription Drugs on the Department website.

Note: Copies of the required consumer disclosures are located on the Department of Safety and Professional Service's website: <https://dsps.wi.gov/Documents/BoardCouncils/PHM/Top100MostPrescribedDrugs.pdf>

SECTION 2. Phar 10.03 (20) and (21) are created to read:

**Phar 10.03 (20)** Violating or attempting to violate any provision or term of ch. 450, Stats., or of any valid rule of the board.

**Phar 10.03 (21)** Failure to comply with ss 450.013 (5m) or 450.013 (8m), Stats.

SECTION 3. EFFECTIVE DATE. the rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

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(END OF TEXT OF RULE)

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**Pharmacy Examining Board  
Rule Projects (updated 04/15/22)**

<b>CH Rule Number</b>	<b>Scope Number</b>	<b>Scope Expiration Date</b>	<b>Code Chapter Affected</b>	<b>Relating Clause</b>	<b>Stage of Rule Process</b>	<b>Next Step</b>
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	Phar 1, 5, 7, 10, and 19	Registration of Pharmacy Technicians	Board Review of Scope Statement at 04/28/22 Meeting	Submission to the Governor's Office for Approval
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	Phar 1,6, and 7	Remote Dispensing	Board Review of Scope Statement at 04/28/22 Meeting	Submission to the Governor's Office for Approval
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	Drafting	Board Review and Approve for Posting for EIA Comments and Submission to Clearinghouse
21-028	080-20	12/22/2022	Phar 2	Reciprocal Credentials for Service Members, Former Service Members, and their Spouses	Rule Effective on 05/01/22	N/A
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	Incorporation of Standards Letter Pending Attorney General Approval	Submission of Final Rule Draft and Legislative Report to the Governor's Office for Approval
Not Assigned Yet	102-21	05/01/2024	Phar 7 and 10	Consumer Disclosures	Board Review of Preliminary Rules Draft at 04/28/22 Meeting	Board Approval for Posting for EIA Comments and Submission to Clearinghouse
21-071	074-19	2/12/2022	Phar 8	Controlled Substances Requirements	Legislative Review	Adoption Order Anticipated to be Presented at June 16, 2022 Meeting

**Pharmacy Examining Board  
Rule Projects (updated 04/15/22)**

<b>CH Rule Number</b>	<b>Scope Number</b>	<b>Scope Expiration Date</b>	<b>Code Chapter Affected</b>	<b>Relating Clause</b>	<b>Stage of Rule Process</b>	<b>Next Step</b>
Not Assigned Yet	096-19	03/09/2022	Phar 15	Compounding Pharmaceuticals	Legislative Review	Adoption Order Anticipated to be Presented at June 16, 2022 Meeting
Not Assigned Yet	097-21	04/18/2024	Phar 18	Third Party Logistics Providers	Drafting Both Emergency and Permanent Rules	Board Review and Approve for Posting for EIA Comments and Submission to Clearinghouse