Wisconsin Department of Safety and Professional Services
Division of Policy Development
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**Tony Evers, Governor**
**Dan Hereth, Secretary**

**HYBRID (IN-PERSON/VIRTUAL)**
**PHARMACY EXAMINING BOARD**
**Room N208, 4822 Madison Yards Way, 2nd floor, Madison**
**Contact: Brad Wojciechowski (608) 266-2112**
**October 24, 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. Be advised that board members may attend meetings designated as "Hybrid" in-person or virtually.*

## AGENDA

**11:00 A.M.**

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

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

**B. Approval of Minutes of August 29, 2024 (5-9)**

C. Reminders: Conflicts of Interest, Scheduling Concerns

**D. Introductions, Announcements, and Recognition**
1) Introduction: Brady M. Coulthard, Public Member

**E. 11:00 A.M. Public Hearing Emergency Rule 2411 and Clearinghouse Rule 24-070 on Phar 8, Relating to Controlled Substances Requirements (10-27)**
1) Review Public Hearing Comments and Respond to Clearinghouse Report

**F. Administrative Matters – Discussion and Consideration**
1) Department, Staff and Board Updates
2) Board Members – Term Expiration Dates
   a. Coulthard, Brady M. – 7/1/2027
   b. Kleppin, Susan – 7/1/2025
   c. O'Hagan, Tiffany M. – 7/1/2028
   d. Peterangelo, Anthony – 7/1/2027
   e. Walsh, Michael – 7/1/2024
   f. Weitekamp, John G. – 7/1/2026
   g. Wilson, Christa – 7/1/2025

**G. Education and Examination Matters – Discussion and Consideration (28-43)**
1) Appearance: Al Carter, Executive Director, NABP – MPJE Pilot Program and UPJE Update Pilot Program Matters

**H. Administrative Rule Matters – Discussion and Consideration (44-56)**

1) Scope Statement: Phar 1, 6, 7, and 10, Relating to Pharmacy Workplace Conditions **(45-46)**
2) Administrative Code Note: Phar 7. 085 – Delivery Drivers **(47)**
3) Preliminary Rule Draft: Phar 15, Relating to Compounding Pharmaceuticals **(48-55)**
4) Pending or Possible Rulemaking Projects **(56)**

I. Legislative and Policy Matters – Discussion and Consideration

**J. NABP Pulse Regulator Monthly Champions Call – Discussion and Consideration**

**K. Interdisciplinary Advisory Council – Discussion and Consideration**

**L. Speaking Engagements, Travel, or Public Relation Requests, and Reports – Discussion and Consideration (57)**

1) Travel Request: NABP Member Forum, December 4-5, 2024 – Mount Prospect, IL
2) Travel Report: NABP District 4 Meeting on September 18-20, 2024, in Detroit, MI – (Weitekamp, O'Hagan, Wojciechowski)
3) Travel Report: NABP Executive Officer Forum on September 25-26, 2024, in Mount Prospect, IL (Wojciechowski)

M. Credentialing Matters – Discussion and Consideration

N. Liaison Reports – Discussion and Consideration

O. Discussion and Consideration on Items Added After Preparation of Agenda

1) Introductions, Announcements and Recognition
2) Nominations, Elections, and Appointments
3) Administrative Matters
4) Election of Officers
5) Appointment of Liaisons and Alternates
6) Delegation of Authorities
7) Education and Examination Matters
8) Credentialing Matters
9) Practice Matters
10) Legislative and Policy Matters
11) Administrative Rule Matters
12) Public Health Emergencies
13) Pilot Program Matters
14) Variances
15) Liaison Reports
16) Board Liaison Training and Appointment of Mentors
17) Informational Items
18) Division of Legal Services and Compliance (DLSC) Matters
19) Presentations of Petitions for Summary Suspension
20) Petitions for Designation of Hearing Examiner
21) Presentation of Stipulations, Final Decisions and Orders
22) Presentation of Proposed Final Decisions and Orders
23) Presentation of Interim Orders
24) Pilot Program Matters
25) Petitions for Re-Hearing
26) Petitions for Assessments

27) Petitions to Vacate Orders
28) Requests for Disciplinary Proceeding Presentations
29) Motions
30) Petitions
31) Appearances from Requests Received or Renewed
32) Speaking Engagements, Travel, or Public Relation Requests, and Reports

**P. Public Comments**

**CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85(1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).**

**Q. Deliberation on Review of Administrative Warning**

1) **12:30 P.M. APPEARANCE:** Nicolas Dalla Santa, DLSC Attorney; and W.P. Respondent: WARN00003752 – 23 PHM 189 – W. P. **(58-73)**

**R. Credentialing Matters**

1) **Application Review**
   a. E.P. – Pharmacy (Out of State) (IA 115774) **(74-331)**
   b. S.K.J.H. – Pharmacy Technician (IA 368461) **(332-364)**
   c. P.L.M. – Pharmacy Technician (IA 222729) **(365-415)**
   d. W.P. – Pharmacy (Out of State) (IA 374618) **(416-570)**

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

1) **Administrative Warnings**
   a. 22 PHM 077 – Z.A.B. **(571-572)**
   b. 23 PHM 176 – J.J.M. **(573-574)**
   c. 23 PHM 176 – N.M.A. **(575-576)**
2) **Case Closings**
   a. 21 PHM 164 – T.H.C.P. **(577-580)**
   b. 22 PHM 032 – W. & C.M.P. **(581-593)**
   c. 22 PHM 091 – M.D.G. & J.D.Z. **(594-599)**
   d. 23 PHM 050 – W. **(600-604)**
   e. 23 PHM 062 – C.P. & K.H.K. **(605-619)**
   f. 23 PHM 083 – B.H.C.I. **(620-623)**
   g. 23 PHM 136 – H.E.R. **(624-628)**
   h. 23 PHM 157 – J.H.P. **(629-632)**
   i. 23 PHM 176 – O.W.P. **(633-638)**
   j. 23 PHM 180 – N.N.L. **(639-643)**
   k. 24 PHM 0035 – W.P. **(644-648)**
   l. 24 PHM 0060 – P.S.L. **(649-652)**

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: DECEMBER 5, 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 any agenda item may be changed by the board for the convenience of the parties. The person credentialed by the board has the right to demand that the meeting at which final action may be taken against the credential be held in open session. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer or reach the Meeting Staff by calling 608-267-7213.

**VIRTUAL/TELECONFERENCE**
**PHARMACY EXAMINING BOARD**
**MEETING MINUTES**
**AUGUST 29, 2024**

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

**STAFF:** Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Tracy Drinkwater, Board Administration Specialist; and other Department staff

## CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 11:01 a.m. A quorum was confirmed with six (6) 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 JUNE 28, 2024

**MOTION:** Susan Kleppin moved, seconded by Christa Wilson, to approve the Minutes of June 28, 2024, as published. Motion carried unanimously.

## 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

**Review Preliminary Hearing Comments**

**MOTION:** Susan Kleppin moved, seconded by Anthony Peterangelo, to affirm the Board has provided an opportunity to receive public comments concerning Scope Statement (SS) 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. Additionally, after consideration of all public comments and feedback, the Board approves SS 089-24 for implementation. Motion carried unanimously.

## ADMINISTRATIVE RULE MATTERS

**Phar 8, Relating to Controlled Substances Requirements**

**MOTION:** Christa Wilson moved, seconded by Michael Walsh, to approve the preliminary rule draft of Phar 8, relating to Controlled Substances Requirements for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

## CLOSED SESSION

**MOTION:** Michael Walsh 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; 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 12:21 p.m.

## CREDENTIALING MATTERS

**Application Reviews**

***T.D. – Pharmacy Technician (IA-987654)***

**MOTION:** Michael Walsh moved, seconded by Christa Wilson, to approve the Pharmacy Technician application of T.D., once all requirements are met. Motion carried unanimously.

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

**Administrative Warnings**

***23 PHM 096 – E.S.P. & E.S.***

**MOTION:** Susan Kleppin moved, seconded by Christa Wilson, to rescind the administrative warning issued at the June 28, 2024, meeting for E.S.P., DLSC case number 23 PHM 096. Motion carried unanimously.

**MOTION:** Tiffany O'Hagan moved, seconded by Michael Walsh, to issue an Administrative Warning in the matter of E.S., DLSC Case Number 23 PHM 096 as presented at the August 29, 2024, meeting. Motion carried unanimously.

**MOTION:** John Weitekamp moved, seconded by Tiffany O'Hagan, to issue an Administrative Warning in the following DLSC Cases:

1. 23 PHM 174 – W.
2. 24 PHM 009 – O.C.

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 125 – W. – No Violation
2. 23 PHM 059 – A.P. – No Violation
3. 23 PHM 066 – K.P.S.A.R.C. – No Violation
4. 23 PHM 143 – C.P. – No Violation
5. 23 PHM 158 – W. – No Violation
6. 23 PHM 169 – C.P. – No Violation
7. 23 PHM 177 – H.M.O. – No Violation
8. 24 PHM 008 – A.V. – No Violation
9. 24 PHM 020 – C.P. – No Violation
10. 24 PHM 0064 – E.S.P.I. – No Violation

Motion carried unanimously.

**Proposed Stipulations, Final Decisions and Orders**

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

1. 22 PHM 067 – Christopher J. Stasiewski
2. 22 PHM 125 and 23 PHM 174 – Devin E. Jones
3. 22 PHM 129 – Richard D. Garrett
4. 23 PHM 131 and 24 PHM 002 – Kenneth J. Herrera
5. 23 PHM 178 – Brianna N. Heath

Motion carried unanimously.

**Case Closing**

***21 PHM 162 – W.***

**MOTION:** Susan Kleppin moved, seconded by Christa Wilson, to refer back DLSC Case Number 21 PHM 162, against W., for further investigation by DLSC. Motion carried unanimously.

## PRESENTATION AND DELIBERATION OF PETITIONS FOR SUMMARY SUSPENSION

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

**MOTION:** Michael Walsh moved, seconded by Christa Wilson, to acknowledge that oral arguments in the Summary Suspension proceedings for DLSC Case Number 23 PHM 147 were presented to the Board by Nicholas Dalla Santa, DLSC Attorney. Motion carried unanimously.

**MOTION:** John Weitekamp moved, seconded by Christa Wilson, to find that notice was given to L.S.C., DLSC Case Number 23 PHM 147, of the Summary Suspension proceedings pursuant to Wis. Admin. Code SPS § 6.05. Motion carried unanimously.

**MOTION:** Christa Wilson moved, seconded by Tiffany O'Hagan, to confirm a finding of probable cause to believe that L.S.C., Respondent, has engaged in or is likely to engage in conduct such that the public health, safety or welfare imperatively requires emergency suspension of the Respondent's license and to issue the Order for Summary Suspension in the matter of disciplinary proceedings against Respondent, DLSC Case Number 23 PHM 147, pursuant to Wis. Admin. Code § SPS 6.06. Motion carried unanimously.

**MOTION:** Michael Walsh moved, seconded by Christa Wilson, to authorize the Board Chair as having the authority to act on behalf of the Board to review, approve, and sign the Summary Suspension Order in the matter of the Summary Suspension of L.S.C., Respondent, DLSC Case Number 23 PHM 147. Motion carried unanimously.

*(Susan Kleppin recused herself and left the room for deliberation and voting in the matter concerning L.S.C., DLSC Case Number 23 PHM 147)*

## RECONVENE TO OPEN SESSION

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

The Board reconvened into Open Session at 2:48 p.m.

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

**MOTION:** Christa Wilson 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 Tiffany O'Hagan, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 2:51 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**<br>**Administrative Rules Coordinator** | **10/11/24**<br>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting |

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

Pharmacy Examining Board

| 4) Meeting Date: | 5) Attachments: | 6) How should the item be titled on the agenda page? |
|---|---|---|
| **10/24/24** | ☒ Yes<br>☐ No | **11:00 A.M. Public Hearing for Emergency Rule 2411 and Clearinghouse Rule 24-070 on Phar 8, Relating to Controlled Substances Requirements**<br>**1. Review Public Hearing Comments and Respond to Clearinghouse Report** |

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

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

**The Board will hold a public hearing on this rule as required by the rulemaking process.**

**11) Authorization**

Nilajah D. Hardin — 10/11/24

**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

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|---|---|---|
| IN THE MATTER OF RULEMAKING | : | ORDER OF THE |
| PROCEEDINGS BEFORE THE | : | PHARMACY EXAMINING BOARD |
| PHARMACY EXAMINING BOARD | : | ADOPTING EMERGENCY RULES |

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

## 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 controlled substances requirements.

Analysis prepared by the Department of Safety and Professional Services.

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## FINDING OF EMERGENCY

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

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## ANALYSIS

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

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

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

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

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

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

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

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

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

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

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

**Comparison with rules in adjacent states:**

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

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

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

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

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

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

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

**Fiscal Estimate:** The Fiscal Estimate will be attached upon completion.

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

**Agency contact person**:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

**Place where comments are to be submitted and deadline for submission**:
Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

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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. This emergency rule shall take effect upon publication in the official state newspaper.

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(END OF TEXT OF RULE)

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Dated 5/10/2024 Agency John Waitekamp

Chairperson
Pharmacy Examining Board

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

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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.

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

**Fiscal Estimate and Economic Impact Analysis:**
The Fiscal Estimate and Economic Impact Analysis is attached.

**Effect on small business**:
These 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; 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 October 24, 2024, to be included in the record of rule-making proceedings.

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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.

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(END OF TEXT OF RULE)

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STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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

# ADMINISTRATIVE RULES
## Fiscal Estimate & Economic Impact Analysis

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

2. Date
09/23/24

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 8 (Permanent Rule)

4. Subject
Controlled Substances Requirements

5. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
20.165 (1) (g)

7. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☐ Increase Existing Revenues ☒ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

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

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

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

11. Policy Problem Addressed by the Rule
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.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
The rule was posted on the Department's website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

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

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
DSPS estimates a total of $5,025 in one-time costs for implemetning this rule. The estimated funds support the equivalent of a 0.1 limited term employee and their associated overhead for rulemaking activites and form and website updates. The one-time costs cannot be absorbed in the currently appropriated agency budget.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefits of implementing this rule are alignment of Wisconsin requirements for controlled substances with DEA requirements and standards.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing this rule is clear requirements for practcing Pharmacy in the area of controlled substances..

17. Compare With Approaches Being Used by Federal Government

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# ADMINISTRATIVE RULES
## Fiscal Estimate & Economic Impact Analysis

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

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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].
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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.

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

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

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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# ADMINISTRATIVE RULES
# Fiscal Estimate & Economic Impact Analysis

## ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

LCRC
FORM 2

# Wisconsin Legislative Council

## RULES CLEARINGHOUSE

**Scott Grosz**
Clearinghouse Director

**Anne Sappenfield**
Legislative Council Director

**Margit Kelley**
Clearinghouse Assistant Director

## CLEARINGHOUSE REPORT TO AGENCY

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

CLEARINGHOUSE RULE **24-070**

AN ORDER to create Phar 8.03 (3); to amend Phar 8.04 and to repeal and recreate Phar 8.07, relating to requirements for controlled substances.

Submitted by **PHARMACY EXAMINING BOARD**

09-23-2024 RECEIVED BY LEGISLATIVE COUNCIL.
10-02-2024 REPORT SENT TO AGENCY.

MSK:SM

**LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT**

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

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☐ NO ☑

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☑ NO ☐

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☑ NO ☐

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☑ NO ☐

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☐ NO ☑

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

Wisconsin Legislative Council
RULES CLEARINGHOUSE

**Scott Grosz**
Clearinghouse Director

**Anne Sappenfield**
Legislative Council Director

**Margit Kelley**
Clearinghouse Assistant Director

# CLEARINGHOUSE RULE 24-070

## Comments

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

### 2. Form, Style and Placement in Administrative Code

In the caption for the proposed rule, the enumeration of affected provisions should be shown in the following order: to amend; to repeal and recreate; and to create. [s. 1.01 (1) (b), Manual.]

### 4. Adequacy of References to Related Statutes, Rules and Forms

The "Statutes Interpreted" section of the rule analysis incorrectly lists "450.11m", which does not correspond to a statute. Did the board intend to instead cite s. 450.11 (1m), Stats.?

### 5. Clarity, Grammar, Punctuation and Use of Plain Language

a. In SECTION 1 of the proposed rule, creating s. Phar 8.03 (3), the word "judgement" as used should be spelled "judgment" to conform with other uses of the term "professional judgment" within rules promulgated by the board. Additionally, the plural "Pharmacists are to" should be revised to the singular "A pharmacist may". The singular form is consistent with other rules promulgated by the board, and is the preferable format when regulating classes of people who individually must comply with the regulation. [s. 1.05 (1) (c), Manual.]

b. In SECTION 3 of the proposed rule, repealing and recreating s. Phar 8.07, consider revising the provision to be phrased using the active voice. For example, it could provide that: "A pharmacist may partially dispense a controlled substance in accordance with federal law.". [s. 1.05 (1) (d), Manual.]

# State of Wisconsin
# Department of Safety & Professional Services

## AGENDA REQUEST FORM

| | | |
|---|---|---|
| 1) Name and title of person submitting the request:<br>Brad Wojciechowski, Executive Director | | 2) Date when request submitted:<br>10/11/2024<br>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting |
| 3) Name of Board, Committee, Council, Sections:<br>Pharmacy Examining Board | | |
| 4) Meeting Date:<br>10/24/2024 | 5) Attachments:<br>☐ Yes<br>☒ No | 6) How should the item be titled on the agenda page?<br>Education and Examination Matters – Discussion and Consideration<br>1) Appearance: Al Carter, Executive Director, NABP – MPJE Pilot Program, and UPJE Update |
| 7) Place Item in:<br>☒ Open Session<br>☐ Closed Session | 8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*<br>☐ Yes <Appearance Name(s)><br>☐ No | 9) Name of Case Advisor(s), if applicable:<br><Click Here to Add Case Advisor Name or N/A> |
| 10) Describe the issue and action that should be addressed: | | |
| 11) Authorization<br>  <br>10/11/2024<br>Signature of person making this request — Date<br><br>Supervisor (Only required for post agenda deadline items) — Date<br><br>Executive Director signature (Indicates approval for post agenda deadline items) — Date | | |
| Directions for including supporting documents:<br>1. This form should be saved with any other documents submitted to the Agenda Items folders.<br>2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.<br>3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting. | | |

# Pilot Summary

**E-Profile and Eligibility**

| Rostered Students | e-Profiles | | MPJE Eligibilities |
|---|---|---|---|
| 120 | 86 | 72% % of Rostered | 86 |

**Timeframes**

| Pilot Purchase to Registration | Historic Purchase to Registration | Max Pilot Exams Taken | Max Historic Exams Taken |
|---|---|---|---|
| 37 Days | 46 Days | September | June |

**Exams**

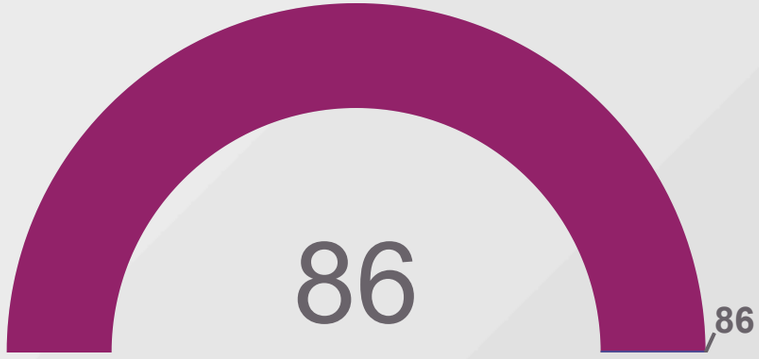
| Exams Scheduled | Exams Taken | Released Results | |
|---|---|---|---|
| 28 | 34 | 34 | 26 PASS<br>8 FAIL |

**Results**

| Pilot Passing Rate | 2023 Passing Rate |
|---|---|
| 76% | 80.4% |

# Eligibility Overview

**Distinct Pilot Students with Eligibility Applications**




MPJE

**2025**
Year

**86**
Elig Applications

**67**
ATTs

**86**
Eligibility Granted

| College | Eligibility Applied Students | Pilot Students | Roster |
|---|---|---|---|
| Concordia Univ Wisconsin | 14 | 14 | 39 |
| Medical Coll of Wisconsin | 29 | 29 | 35 |
| Univ of Wisconsin-Madison | 43 | 43 | 46 |
| **Total** | **86** | **86** | **120** |

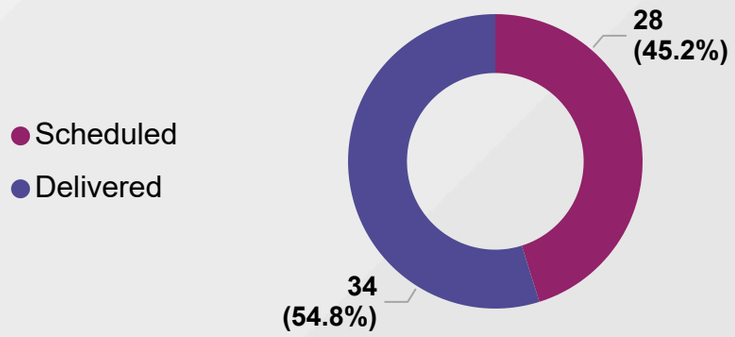
| Year | Applications |
|---|---|
| **2024** | |
| May | 24 |
| June | 39 |
| July | 14 |
| August | 5 |
| September | 4 |
| October | 4 |
| **Total** | **86** |

# Pearson VUE

1/30/2025
Latest Exam

10/10/2024
Latest Registration

## MPJE Registered Students by Status

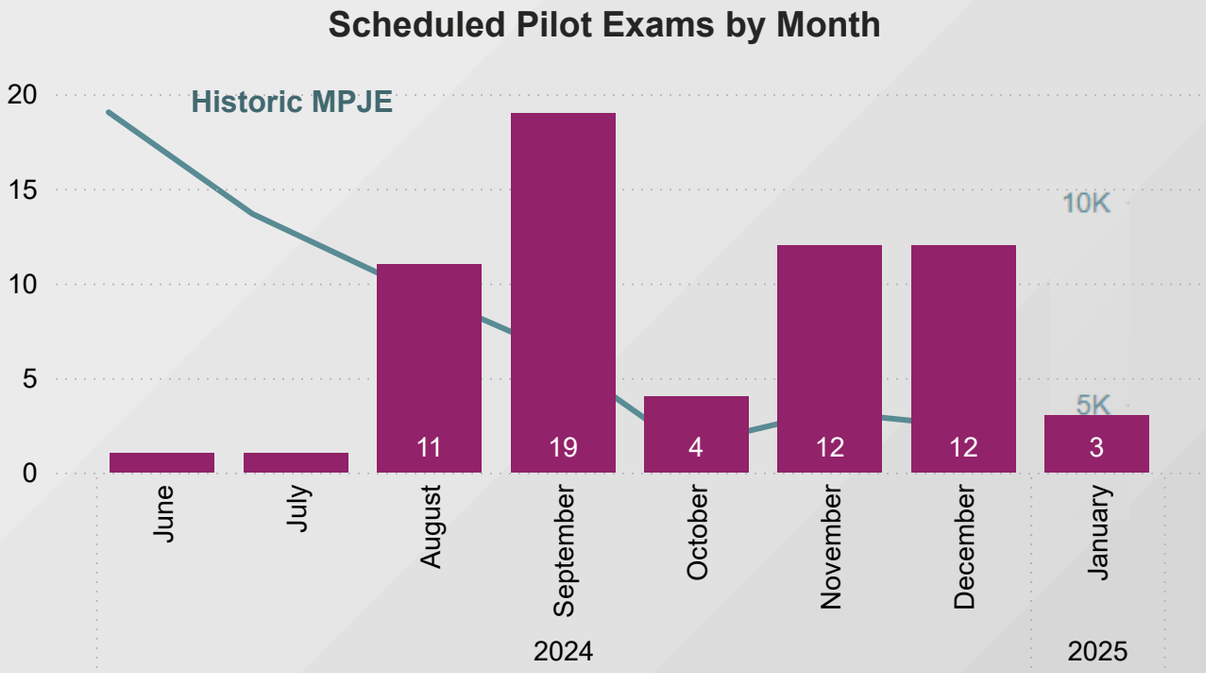



| Scheduled | No Shows | Delivered |
|---|---|---|
| 28 | 0 | 34 |

| College | Scheduled | Delivered | Eligible Students |
|---|---|---|---|
| Concordia Univ Wisconsin | 5 | 5 | 14 |
| Medical Coll of Wisconsin | 13 | 8 | 29 |
| Univ of Wisconsin-Madison | 10 | 21 | 43 |
| **Total** | **28** | **34** | **86** |

# Scheduling

Table View




| | Pilot Average Days | Historic Average Days |
|---|---|---|
| Grant to Purchase | 15 | 14 |
| Purchase to Registration | 37 | 46 |
| Registration to Exam | 86 | 57 |

# Results

Exams Taken

34

Unreleased Results

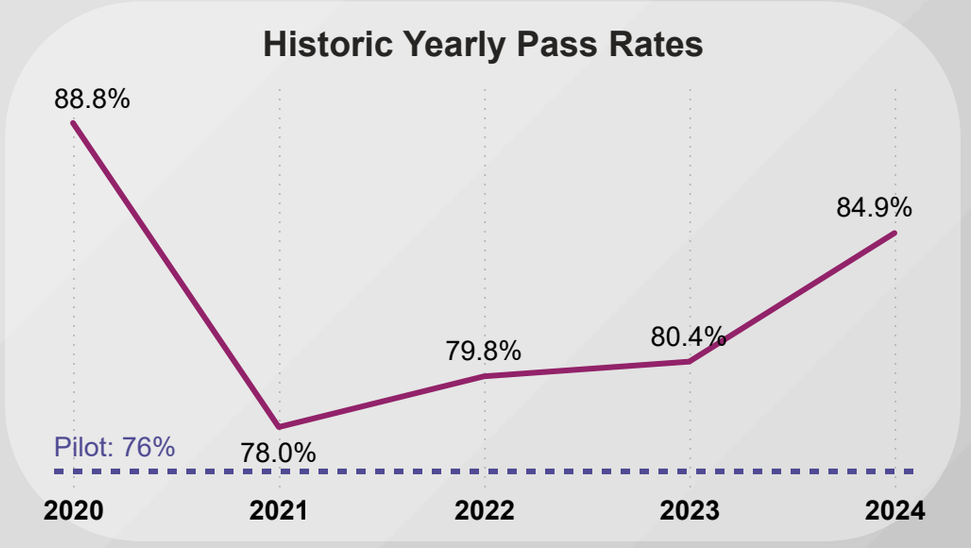
0

Released Results

| | |
|---|---|
| FAIL | 8 |
| PASS | 26 |
| **Total** | **34** |

Pilot Passing Rate

76%



NABP
National Association of Boards of Pharmacy

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Mount Prospect, IL 60056

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help@nabp.pharmacy

***Item Development***

- The Multistate Pharmacy Jurisprudence Examination®(MPJE®) items are written to map to the Competency Areas (exam blueprint). The competencies and blueprint are updated once every 3 to 5 years or more frequently as necessary to ensure that current regulatory and legislative changes in pharmacy practice are reflected in the content areas assessed on the MPJE and to ensure that the weight for each area is appropriate.

- Weights that are assigned to each area relate to the importance of the application of knowledge and skills captured from the MPJE practice analysis conducted according to psychometric industry standards by surveying state boards to determine the relative risk to the pharmacist, the patient, and the public.

- NABP recruits volunteer subject matter experts (SMEs), that are board members and/or board staff from all practice settings, to participate in item writing (MPJE Item Development Workshops). Item writers are nominated by the participating jurisdictions' Board.

- Item writers are typically Board staff or board members who serve as SMEs on the state's rules and regulations.

- In some cases, Boards may nominate an item reviewer that is not a board member or staff, such as a law firm attorney or a representative from a local state association if there is no conflict of interest.

- A dedicated NABP team is available to provide year-round support for both the development and review of MPJE questions from a jurisdiction's item pool.

- Detailed item development training is provided both virtually and in-person during the Item Development process and is designed to streamline items by following strict NABP item writing guidelines and editorial standards.

- An additional behind-the-scenes overview of the MPJE item development process can be found by clicking here.

***Item Review***

- Item analysis is conducted by NABP Psychometricians as an ongoing monitoring process of items' statistical performance based on psychometric thresholds for item difficulty and discrimination. When necessary, the Competency Assessment Department will outreach to boards on any items that need further review to ensure rules or regulation changes are properly reflected on the exam.

- A yearly MPJE State-Specific Review (SSR) meeting is hosted for participating jurisdictions during which content review of a jurisdiction's item pool is prioritized based on Competency Areas impacted by various rule or regulation change(s)

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and/or item analysis results.

- All edited and newly written items must go through a rigorous review process by the MPJE Review Committee (MRC) which validates exam content to ensure that they meet specific standards before it enters the editorial and final testing phases.

- NABP's criteria by which it selects its MPJE Review Committee members is strictly followed to promote consistency among the review committees and to maintain the quality of its exams. Review committee members must be a pharmacist, pharmacy board attorney, or pharmacy board staff member familiar with state and federal laws and regulations, who serve as SMEs on the regulatory aspects of the profession. All MPJE items are reviewed by the MRC members before they are used in published exams.

***Exam Content***

- Exam content includes federal and state-specific items, which are not differentiated as such.

- Jurisdiction-specific content is tailored to reflect terminology and characteristics unique to each participating state's rules and regulations, however the development of the exam is ***standardized*** across all participating jurisdictions.

- The MPJE is a fixed-length computer adaptive test (CAT) delivered to match a candidate's ability level.

- State-specific exams are built utilizing Psychometric standards following the *Standards for Educational and Psychological Testing* (AERA et al., 2014), which consider item type and difficulty to support the MPJE Competency Areas, also known as the Blueprint.

- Candidates are administered 100 operational (scored) items and 20 pretest (unscored) items. Pre-test items are not factored in as these are only used to analyze an item's performance.

- Both the operational and the pretest item pools are composed of multiple-choice, multiple- response (select all that apply), and multiple responses (K type), with the majority being multiple-choice items. K-type and multiple-response questions are being phased out from the MPJE exam.

***Exam Updates***

- NABP partners with the Member Relations Government Affairs (MRGA) team to continuously monitor regulatory and legislative changes that may impact the content of the MPJE. NABP will reach out to the boards to review identified exam content to discuss the potential impact to the MPJE and mask any items that need to be immediately removed from the exam.

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- Exam content updates are a continual process to ensure representation of contemporary pharmacy practice and account for changes in state rules and regulations.

- Given the ever-changing landscape of pharmacy, once alerted by a state Board, NABP staff can remove content from a state's exam immediately ensuring the most up-to-date evaluation process.

- Boards should notify NABP at the end of the rule promulgation process as soon as a new rule or regulation has been passed/approved and adopted.

- Boards can notify NABP at any time throughout the year if there is a rule change that may impact their exam. NABP staff are available to support ad hoc reviews or updates that can be made outside of the yearly state-specific review process.

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# Uniform Pharmacy Jurisprudence Exam (UPJE)

## District 1 and 2 Meeting

## Oct 7, 2024

# Uniform Pharmacy Jurisprudence Exam (UPJE) *Overview*

## Purpose

- The goal of the UPJE in those states that adopt it is for a pharmacist to take ***one pharmacy jurisprudence exam*** to demonstrate their competency. Candidates who pass the UPJE would ***meet the law examination requirement*** in all states that recognize it and would be eligible for licensure in any of those states without taking another law exam so long as all other licensing requirements are met.

## Exam Development Process and Implementation

- UPJE Steering Committee met again in January 2024.
- The goal of the committee will be to review the development process.
    - Examination development will include an examination review committee to drive the examination purpose, scope, and timeline.
- Targeting launch in 2026 – more information was shared at the 2024 NABP Annual Meeting.

*NABP will continue to operate and support the MPJE for states that choose not to adopt the UPJE.*

## Background

- ***Resolution 118-3-22*** at the 118 Annual Meeting, May of 2022, the membership approved NABP establishing a National Standardized Pharmacy Jurisprudence Examination steering committee.

- The ***UPJE Steering Committee*** met in June 2023 to:
    - Determine the architectural framework for the examination development.
    - Discuss expectations and obligations from the boards of pharmacy for development, maintenance, and usage of the examination.
    - Examine the components necessary for developing state-specific continuing pharmacy education modules.

# UPJE Development Timeline

## Q1 2024

Steering Committee Meeting Jan 2024

Review June 2023 Report from initial Steering Committee meeting

Align on next steps

## Q2/Q3 2024

Recruit UPJE Review Committee (URC)

Initial URC Meeting

Draft Competency Statements

## 2025

Practice Analysis (JTA)

Competency Statements (Exam Blueprint)

Item Development Workshop

URC Meeting

Pretest (Stats)

Standard Setting

## 2026

**LAUNCH**

# UPJE Exam Development – *Key Takeaways*

- **Purpose**: jurisprudence exam for use by the boards of pharmacy to consider candidate exam results for the purpose of licensure eligibility in participating jurisdiction(s).
- The UPJE is envisioned as an additional resource for boards, rather than a sole mandate.
- The URC will:
  - Review exam purpose, score, timeline of project
  - Define core competencies
  - Review resources (pharmacy practice law)
  - Establish comprehensive exam blueprint (a.k.a. competency statements / exam content outline)
- The UPJE is **not** a federal law exam (e.g., Federal Drug Law Examination (FDLE))
- The exam will be designed to assess knowledge of applicable "universal" laws and regulations to ensure pharmacist competency and to protect states' public health and patient safety.
  - *Optional State-Specific "Plus Module"* could be required for new licensees as a supplementary assessment of idiosyncratic aspect of states' laws and regulations.
  - The "Plus Module" will be independently administered by the state.
  - Candidates could be held accountable by the state board and subject to disciplinary action if they do not follow state-specific laws.

# UPJE Core Concepts

**Area 1**

- Self-regulation in pharmacy
- Approaches to regulation
- Reasons to regulate professions
- State boards of pharmacy
- Federal Agencies (FDA, DEA, HHS, etc)
- State Regulation of Long-Term Care Facilities
- State Hospital Pharmacy Licensure Issues

**Area 2**

- Licensing
- Licensing of pharmacists
- Licensing/permitting of pharmacies
- Licensing of wholesale drug distributors
- Licensing of non-pharmacist personnel
- Licensing durable medical equipment facilities
- Automation
- CE/competency
- Nonresident (mail-order) pharmacies
- Nonresident (internet) pharmacies

**Area 3**

- Grounds for discipline
- Unprofessional/unethical conduct
- Due process/administrative procedure
- Absence of a pharmacist
- Reinstatement of a license
- Impaired pharmacist programs
- Actions against a pharmacy license/ registration/permit

**Area 4**

- Standards of practice
- Practice of pharmacy defined
- Counseling requirements
- Collaborative practice agreements/ prescriptive authority/state protocols
- Emergency refill authorization
- Applicable US Pharmacopeia chapters
- Supervision of non-pharmacist personnel
- Liability and malpractice
- Prescription monitoring programs
- Continuous quality improvement programs*

*The committee considered including this item in a separate Area 5.

# Sample UPJE Questions

A pharmacist is presented with a refill request for a two month supply of semaglutide tablets that has exceeded its authorized refills. The pharmacist has attempted to contact the prescriber without success. The pharmacist:

a) can not dispense any medication to the patient
b) is authorized to dispense an emergency supply of medication
c) must transmit or fax the prescriber a refill request in order to dispense additional medication
d) should prepare a new prescription order with refills listing the pharmacist as the prescriber

Which scenario should the pharmacist consider providing an emergency refill to a patient that has no more medication and the prescriber is not available to issue a new prescription?

a) A patient with cancer that takes OxyContin for pain
b) A patient that takes indomethacin for mild acute pain
c) A patient that takes citalopram for depression
d) A patient with seasonal allergies that takes CLARINEX® (desloratadine)

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# Thank you

# State of Wisconsin
# Department of Safety & Professional Services

## AGENDA REQUEST FORM

| 1) Name and title of person submitting the request: | 2) Date when request submitted: |
|---|---|
| **Nilajah Hardin**<br>**Administrative Rules Coordinator** | **10/11/24**<br>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting |

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

Pharmacy Examining Board

| 4) Meeting Date: | 5) Attachments: | 6) How should the item be titled on the agenda page? |
|---|---|---|
| **10/24/24** | ☒ Yes<br>☐ No | **Administrative Rule Matters – Discussion and Consideration**<br>1. **Scope Statement: Phar 1, 6, 7, and 10, Relating to Pharmacy Workplace Conditions**<br>2. **Administrative Code Note: Phar 7. 085 – Delivery Drivers**<br>3. **Preliminary Rule Draft: Phar 15, Relating to Compounding Pharmaceuticals**<br>4. **Pending or Possible Rulemaking Projects** |

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

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

Attachments:

1. Phar 1, 6, 7, and 10 Scope Statement
2. Admin. Code Note for Phar 7.085
3. Phar 15 Preliminary Rule Draft
4. ASHP USP 795 Standard Operating Procedures
5. 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 — 10/24/24

**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.**

# STATEMENT OF SCOPE

## PHARMACY EXAMINING BOARD

**Rule No.:** Phar 1, 6, 7, and 10

**Relating to:** Pharmacy Workplace Conditions

**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 amend requirements in Wisconsin Administrative Code to increase workplace satisfaction and safety for pharmacy staff.

**3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:**
Wisconsin Administrative Code Chapters Phar 1, 6, 7, and 10 currently outline requirements for authority and definitions, pharmacy licenses and equipment, pharmacy practice, and unprofessional conduct. These areas could be expanded upon to include requirements that improve working conditions for pharmacy staff. An alternative to amending these provisions is that the administrative code will continue to be silent on the issue of workplace conditions in the pharmacy profession.

**4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):**
15.08 (5) (b), Stats., states that the Board "[s]hall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."

450.02 (2), Stats., states that "[t]he board shall promulgate rules that do all of the following:
(a) The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.
(b) Define the activities that constitute the practice of a pharmacy technician for purposes if the registration requirement under s. 450.68."

450.02 (3) (b), Stats., states "[t]he board may promulgate rules establishing security standards for pharmacies."

450.02 (3) (d), Stats., states "[t]he board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961."

450.02 (3) (e), Stats., states "[t]he board may promulgate rules establishing minimum standards for the practice of pharmacy."

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

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

Authorized Signature

Date Submitted

Approved for implementation:

Authorized Signature

Date Submitted

**Phar 7.085 Delivery by common carrier or delivery services.** Utilization of common carrier or delivery services to deliver a prescription to a location of the patient's choice from the pharmacy which fills the prescription to the patient or patient's agent shall ensure all of the following:

**(1)** The delivery method is appropriate to prevent drug adulteration.

**(2)** The patient or patient's agent is provided a method by which the patient or patient's agent can notify the pharmacy as to any irregularity in the delivery of the prescription drug product or device, including all of the following:

**(a)** Timeliness of delivery.

**(b)** Condition of the prescription drug upon delivery.

**(c)** Failure to receive the proper prescription drug product or device.

**(3)** Any prescription drug product or device which is compromised or lost shall be replaced by the pharmacy at no additional cost to the patient. If the timeliness of the replacement will lead to an interruption in therapy, a pharmacist at the dispensing pharmacy shall take steps to mitigate patient harm.

Note: A delivery driver engaged solely in the delivery of a prescription in compliance with this section does not need to be registered as a pharmacy technician.

**History:** CR 19-145: cr. Register December 2020 No. 780, eff. 1-1-21.

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.

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TEXT OF RULE

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

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

**Phar 15.01 Definitions.** In this chapter:
**(1)** "USP-NF" means the United States Pharmacopeia-National Formulary published by the United States Pharmacopeial Convention.

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

(a) The pharmacist shall ensure that the flavoring agent is not more than 5 percent of the product's total volume.
(b) The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless 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.

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(END OF TEXT OF RULE)

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USP <795>

# LIST OF STANDARD OPERATING PROCEDURES

Standard operating procedures (SOPs) must be reviewed initially and at least every 12 months by the designated person(s) to ensure that they reflect current practices, and the review must be documented. Any changes or alterations to an SOP must be made only by a designed person(s) and must be documented. Revisions to SOPs must be communicated to all personnel involved in these processes and procedures, and personnel should document acknowledgement of the communication.

**Total SOPs required: 20**

## INTRODUCTION AND SCOPE (2)

- **Practices Not Subject to the Requirements in This Chapter**
  - The following practices are not considered compounding and are not required to meet the requirements of this chapter. Handling of nonsterile HDs should additionally comply with USP Chapter <800>. Refer to facility SOPs for additional safe practices (e.g., labeling).
    - Nonsterile radiopharmaceuticals
    - Reconstitution
    - Repackaging
    - Splitting tablets
    - Administration
- **Oversight by Designated Person(s)**
  - The designated person(s) must be identified in the facility's SOPs.

## PERSONNEL TRAINING AND EVALUATION (2)

- **Personnel Training and Evaluation**
  - Other personnel, who do not compound and only perform functions such as in process checks, final verification, or dispensing of compounded nonsterile preparations (CNSPs), must undergo training as required by the facility's SOPs.
  - In addition to the initial and annual competency training and evaluation described in this section, the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel.

## PERSONAL HYGIENE AND GARBING (2)

- **Garb and Glove Requirements**
  - Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs.
  - The facility's SOPs must describe cleaning and sanitization procedures for reusing goggles, respirators, and other reusable equipment.

## BUILDINGS AND FACILITIES (2)

- **Compounding Area**
  - » An area must be designated for nonsterile compounding. The method of designation must be described in the facility's SOPs.
  - » The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s).

## EQUIPMENT AND COMPONENTS (4)

- **Equipment**
  - » Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients, added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented.
- **Components**
  - » The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP.
- **Component Receipt**
  - » The following information must be documented (see 14. Documentation) according to the facility's SOPs: receipt date, quantity received, supplier name, lot number, expiration date, and results of any in-house or third-party testing performed.
- **Component Spill and Disposal**
  - » The management and documentation of nonhazardous components spills and disposal must be described in the facility's SOPs.

## MASTER FORMULATION AND COMPOUNDING RECORDS (1)

- **Creating Master Formulation Records**
  - » Any changes or alterations to the master formulation records must be approved and documented according to the facility's SOPs.

## LABELING (1)

- **Labeling**
  - » Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups.

## QUALITY ASSURANCE AND QUALITY CONTROL (4)

- **Quality Assurance and Quality Control**
  - » A facility's quality assurance (QA) and quality control (QC) programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction.
  - » The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program.
- **Complaint Handling**
  - » Compounding facilities must develop and implement SOPs for handling complaints.
- **Adverse Event Reporting**
  - » Adverse events potentially associated with the quality of CNSPs must be reported in accordance with the facility's SOPs and all laws and regulations of the applicable regulatory jurisdiction.

## CNSP PACKAGING AND TRANSPORTING (2)

- **Packaging of CNSPs**
  - The facility's SOPs must describe packaging of CNSPs.
- **Transporting of CNSPs**
  - If transporting CNSPs, the facility must have written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed.

*Special acknowledgment to* **Sarah Hall, PharmD (candidate)***, UNC Eshelman School of Pharmacy, and* **Kevin Hansen, PharmD, MS, BCSCP***, Director of Pharmacy, Compounding Services and Data Analytics, Cone Health, for the development of this resource, and to* **Patricia Kienle, RPh, MPA, BCSCP, FASHP***, Director, Accreditation and Medication Safety, Cardinal Health, and* **Michael Ganio, PharmD, MS, BCSCP, FASHP***, Senior Director, Pharmacy Practice and Quality, ASHP, for peer-review.*

*Kevin and Patti are members of the USP Compounding Expert Committee, but this resource is not affiliated with or endorsed by USP.*

**Pharmacy Examining Board**
**Rule Projects (updated 10/11/24)**

| 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 | Not Assigned Yet | TBD | Phar 1. 6, 7, and 10 | Pharmacy Workplace Conditions | Scope Statement Reviewed at 10/24/24 Meeting | Scope Statement Submission to Governor for Approval and Administrative Register for Publication |
| Not Assigned Yet | 089-24 | 05/05/2027 | Phar 7 | Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check | Drafting | Board Approval of Preliminary Rule Draft for EIA Comment and Clearinghouse Review |
| 24-070 (EmR 2411) | 044-23 | 01/10/2026 | Phar 8 | Controlled Substances Requirements | Emergency Rule Effective 10/01/24-02/27/25; Public Hearing Held at 10/24/24 Meeting | Drafting of Final Permanent Rule and Legislative Report and Submission to Governor for Approval |
| 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:**<br>Brad Wojciechowski, Executive Director | | **2) Date when request submitted:**<br>9/30/2024<br>**Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting** |
| **3) Name of Board, Committee, Council, Sections:**<br>Pharmacy Examining Board | | |
| **4) Meeting Date:**<br>10/24/2024 | **5) Attachments:**<br>☐ Yes<br>☒ No | **6) How should the item be titled on the agenda page?**<br>Speaking Engagements, Travel, or Public Relation Requests, and Reports<br>1) Travel Request: NABP Member Forum, December 4-5, 2024 – Mount Prospect, IL |
| **7) Place Item in:**<br>☒ Open Session<br>☐ Closed Session | **8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)*<br>☐ Yes <Appearance Name(s)><br>☒ No | **9) Name of Case Advisor(s), if applicable:**<br><Click Here to Add Case Advisor Name or N/A> |

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

At this year's Member Forum, board of pharmacy attendees will discuss important regulatory issues during closed sessions. Attendees will also receive updates about enhancements, changes, and newly released NABP programs and services. The forum provides board members with an opportunity to collaborate and network with other board members.

**11) Authorization**

9/30/2024

| | |
|---|---|
| **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.