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Tony Evers, Governor
Dan Hereth, Secretary

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

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

AGENDA

11:00 A.M.
(OR IMMEDIATELY FOLLOWING THE PHARMACY RULES COMMITTEE)

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-4)

B. Approval of Minutes of January 18, 2024 (5-11)

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements, and Recognition

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

F. Improving Pharmacist Workplace Satisfaction – Discussion and Consideration (12-19)
1) Presentation: 2022 NABP Report of the Work Group on Workplace Safety, Well-Being, and Working Conditions – Reggie Dilliard, NABP President

G. FDA Advisory Letter to NABP Concerning Compounded Semaglutides – Discussion and Consideration (20-23)

H. Administrative Rule Matters – Discussion and Consideration (24-41)

1) Preliminary Rule Draft: Phar 15, Relating to Pharmaceutical Compounding **(25-29)**
2) Emergency Rule Draft: Phar 8, Relating to Controlled Substances Requirements **(30-34)**
3) Adoption Order: Phar 7 and 10, Relating to Required Disclosures to Consumers **(35-38)**
4) Scope Statement: Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substances Prescription Transfers, and Remote Dispensing **(39-40)**
5) Pending or Possible Rulemaking Projects **(41)**

I. NABP Expedited Testing Solutions – Discussion and Consideration

J. Legislative and Policy Matters – Discussion and Consideration

K. Credentialing Matters – Discussion and Consideration

L. Liaison Reports – Discussion and Consideration

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

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

O. Pilot Program Matters – Discussion and Consideration

P. 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

Q. 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.).

R. Credentialing Matters
1) **Application Reviews (42-141)**
   a. C.N. – Pharmacy Technician

S. Deliberation on Division of Legal Services and Compliance Matters
1) **Administrative Warning (144-156)**
   a. 22 PHM 008 – E.S.P. **(144-146)**
   b. 23 PHM 060 – K.M.L. **(147-148)**
   c. 23 PHM 105 – A.A.K. **(149-150)**
   d. 23 PHM 105 – N.R.W. **(151-152)**
   e. 23 PHM 125 – C.L. **(153-154)**
   f. 23 PHM 142 – B.D.J. **(155-156)**
2) **Case Closings (157-222)**
   a. 22 PHM 044 – W. **(157-165)**
   b. 22 PHM 089 – CVS **(166-170)**
   c. 22 PHM 101 – CVS **(171-177)**
   d. 22 PHM 101 – M.H. **(171-177)**
   e. 22 PHM 117 – W. **(178-184)**
   f. 22 PHM 127 – W. **(185-190)**
   g. 23 PHM 018 – M.M.P. **(191-194)**
   h. 23 PHM 037 – E.S.P. **(195-198)**
   i. 23 PHM 105 – D.J.M. **(199-204)**
   j. 23 PHM 105 – W. **(199-204)**
   k. 23 PHM 125 – W. **(205-210)**
   l. 23 PHM 142 – W.R.H.P. **(211-214)**
   m. 23 PHM 148 – O.E. **(215-217)**
   n. 23 PHM 162 – H.P. **(218-222)**
3) **Proposed Stipulations, Final Decisions and Orders (223-234)**
   a. 22 PHM 044 – Erik C. Simonson **(223-228)**
   b. 22 PHM 120 – Triad Rx, Inc. **(229-234)**

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: APRIL 25, 2024

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

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, or reach the Meeting Staff by calling 608-267-7213.

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
MEETING MINUTES
JANUARY 18, 2024

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

EXCUSED: Christa Wilson

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

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 11:00 a.m. A quorum was confirmed with five (5) members present.

ADOPTION OF AGENDA

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

APPROVAL OF MINUTES OF OCTOBER 26, 2023

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to approve the Minutes of December 7, 2023, as published. Motion carried unanimously.

PUBLIC HEARING FOR CLEARINGHOUSE RULE 23-072 ON PHAR 1, 5, 7, 10, AND 19, RELATING TO REGISTRATION OF PHARMACY TECHNICIANS

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, to authorize the Chairperson to work with DSPS staff on responding to the Clearinghouse Report and drafting the Final Rule and Legislative Report for Clearinghouse Rule 23-072 (Phar 1, 5, 7, 10, and 19), Relating to Registration of Pharmacy Technicians. Motion carried unanimously.

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to authorize the Chairperson to approve the Legislative Report and Draft for Clearinghouse Rule 23-072 (Phar 1, 5, 7, 10, and 19), Relating to Registration of Pharmacy Technicians for submission to the Governor's Office and Legislature. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Election of Officers

Slate of Officers

NOMINATION: Anthony Peterangelo nominated the 2023 slate of officers to continue in 2024. All officers accepted their nominations.

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

The Slate of Officers was elected by unanimous voice vote.

ELECTION RESULTS	
Chairperson	John Weitekamp
Vice Chairperson	Tiffany O'Hagan
Secretary	Susan Kleppin

Appointments of Liaisons and Alternates

LIAISON APPOINTMENTS	
Credentialing Liaison(s)	Anthony Peterangelo, Tiffany O'Hagan, Christa Wilson
Education and Examinations Liaison(s)	Susan Kleppin *Alternate:* John Weitekamp
Monitoring Liaison(s)	Michael Walsh, Christa Wilson *Alternate*: Anthony Peterangelo
Professional Assistance Procedure (PAP) Liaison(s)	Anthony Peterangelo *Alternate*: Susan Kleppin
Travel Authorization Liaison(s)	John Weitekamp *Alternate:* Tiffany O'Hagan
Legislative Liaison(s)	Anthony Peterangelo, Tiffany O'Hagan, John Weitekamp
Pilot Program Liaison(s)	Tiffany O'Hagan, Anthony Peterangelo
Newsletter Liaison(s)	Christa Wilson *Alternate:* John Weitekamp
Website Liaison(s)	Michael Walsh

Appointed to Controlled Substances Board as per Wis. Stats. §15.405(5g)	John Weitekamp
PHARM Rep to SCAODA	Susan Kleppin *Alternate:* John Weitekamp
Variance Liaison(s)	Tiffany O'Hagan *Alternate:* Anthony Peterangelo
Inspection Liaison(s)	Susan Kleppin *Alternate:*
Phar 7.08(8) Approval Requests Liaison(s)	Susan Kleppin *Alternate:*
SCREENING PANEL APPOINTMENTS	
Screening Panel	John Weitekamp, Tiffany O'Hagan, Michael Walsh *Alternate:* Anthony Peterangelo
COMMITTEE MEMBER APPOINTMENTS	
Pharmacy Rules Committee	Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo, John Weitekamp

Delegation of Authorities

Review and Approval of 2023 Delegations

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to reaffirm all delegation motions from 2023 as reflected in the agenda materials. Motion carried unanimously.

Document Signature Delegations

MOTION: Michael Walsh moved, seconded by Susan Kleppin, in order to carry out duties of the Board, the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) has the ability to delegate signature authority for purposes of facilitating the completion of assignments during or between meetings. The members of the Board hereby delegate to the Executive Director, Board Counsel or DPD Division Administrator, the authority to sign on behalf of a board member as necessary. Motion carried unanimously.

Monitoring Delegations

Delegation of Authorities for Monitoring

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to adopt the "Roles and Authorities Delegated for Monitoring" document as presented in the January 18, 2024, agenda materials on pages 43-45. Motion carried unanimously.

Delegation to Department Attorneys to Approve Duplicate Legal Issue

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to delegate authority to Department Attorneys to approve a legal matter in connection with a renewal application when that same/similar matter was already addressed by the Board and there are no new legal issues. Motion carried unanimously.

Improving Pharmacist Workplace Satisfaction Delegation

MOTION: John Weitekamp moved, seconded by Tiffany O'Hagan, to designate Anthony Peterangelo to work with DSPS to identify topics of consideration and discussion related to improving pharmacist workplace satisfaction by the Pharmacy Examining Board. Motion carried unanimously.

Phar 7.08(8) Approval Request Liaison(s) Delegation

MOTION: John Weitekamp moved, seconded by Tiffany O'Hagan, to designate the Phar 7.08(8) Approval Request Liaison to serve as the liaison for review of Phar 7.08(8) approval requests. Motion carried unanimously.

Inspection Liaison(s) Delegation

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, to designate the Inspection Liaison(s) to address all issues related to the inspection of credentialed facilities. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Final Rule Draft: Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, to authorize the Chairperson to approve the Legislative Report and Draft for Clearinghouse Rule 23-054 (Phar 1, 5, 6, 7, and 8), Relating to Remote Dispensing for submission to the Governor's Office and Legislature. Motion carried unanimously.

Emergency Rule Draft: Phar 8, Relating to Controlled Substances Requirements

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to authorize John Weitekamp to approve the emergency rule revising Phar 8, relating to Controlled Substances Requirements for emergency rule submission to the Governor and publication in an official newspaper. Motion carried unanimously.

LEGISLATIVE AND POLICY MATTERS

2023 Senate Bill 705/2023 Assembly Bill 626

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to designate John Weitekamp as the legislative liaison to work with DSPS staff on matters related to 2023 Senate Bill 705/Assembly Bill 626. Motion carried unanimously.

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

MPJE Item Development Workshop, March 13-15, 2024, Mount Prospect, IL

MOTION: John Weitekamp moved, seconded by Michael Walsh, to designate Susan Kleppin and Tiffany O'Hagan to attend the MPJE Item Development Workshop, on March 13-15, 2024, in Mount Prospect, IL. Motion carried unanimously.

MPJE State-Specific Review, September 11-13, 2024, TBA

MOTION: John Weitekamp moved, seconded by Tiffany O'Hagan, to designate Susan Kleppin and Tiffany O'Hagan to attend the MPJE State-Specific Review, on September 11-13, 2024 (location to be announced). Motion carried unanimously.

CLOSED SESSION

MOTION: Michael Walsh moved, seconded by Susan Kleppin, 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; and John Weitekamp-yes. Motion carried unanimously.

The Board convened into Closed Session at 1:20 p.m.

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

Administrative Warnings

MOTION: Michael Walsh moved, seconded by Tony Peterangelo, to issue an Administrative Warning in the following DLSC Cases:
23 PHM 118 – S.S.P., Inc.
23 PHM 119 – E.P., LLC
23 PHM 120 – A.S.P.
Motion carried unanimously.

Case Closings

MOTION: Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to close the following DLSC Cases for the reasons outlined below:
22 PHM 063 – P.M.S. – No Violation (NV)
23 PHM 024 – K.M.O. – No Violation (NV)
23 PHM 025 – W. – No Violation (NV)
23 PHM 053 – W. – No Violation (NV)
23 PHM 087 – S.A.F. – No Violation (NV)
Motion carried unanimously.

Proposed Stipulations, Final Decisions and Orders

22 PHM 101, Jason D. Crawford, R.Ph.

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to adopt the Proposed Decision and Order in the matter of disciplinary proceedings against Jason D. Crawford, R.Ph., DLSC Case Number 22 PHM 101. Motion carried unanimously.

23 PHM 139, Paul A. Blazkovec

MOTION: Susan Kleppin moved, seconded by Tiffany O'Hagan, to adopt the Proposed Decision and Order in the matter of disciplinary proceedings against Paul A. Blazkovec, DLSC Case Number 23 PHM 139. Motion carried unanimously.

RECONVENE TO OPEN SESSION

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 1:57 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

DRAFT

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, 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: Susan Kleppin moved, seconded by Michael Walsh, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 1:59 p.m.

DRAFT

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski, Executive Director		**2) Date when request submitted:** 2/19/2024 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: 2/29/2024	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Improving Pharmacist Workplace Satisfaction – Discussion and Consideration 1) Presentation: 2022 NABP Report of the Work Group on Workplace Safety, Well-Being, and Working Conditions, NABP President, Reggie Dilliard	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☒ Yes Reggie Dilliard ☐ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>	
10) Describe the issue and action that should be addressed: NABP Chairperson Reggie Dilliard will attend the WI Pharmacy Examining Board to discuss NABP's 2022 Report on Workplace Safety. The report is attached.			
11) **Authorization** **Signature of person making this request**		**2/19/2024** **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.**

NABP
National Association of Boards of Pharmacy

Report of the Work Group on

Workplace Safety, Well-Being, and Working Conditions

NABP

Report of the Work Group on Workplace Safety, Well-Being, and Working Conditions

Members Present

Reginald B. “Reggie” Dilliard (TN), *chair*; Lee Ann Bundrick (SC), Jack W. “Jay” Campbell IV (NC), John Colaizzi, Jr (NJ), Kimberly Grinston (MO), Diane Halvorson (ND), Marty Hendrick (OK), Susan McCoy (MS), Brenda McCrady (AR), Steven Schierholt (OH), Kari Shanard-Koenders (SD), Jermaine Smith (MD), Mary Douglass Smith (SC), Theresa “Terry” Talbott (PA), Cyndi Vipperman (OR), and Jeanne Waggener (TX).

Others Present

Jeffrey J. Mesaros, *Executive Committee liaison;* Michael Ayotte, National Association of Chain Drug Stores (NACDS); Joni Cover, National Alliance of State Pharmacy Associations (NASPA); Rob Geddes, Albertsons; Brigid Groves, American Pharmacists Association (APhA), *Guests;* Lemrey “Al” Carter; Melissa Becker; William “Bill” Cover; Eileen Lewalski; Maureen Schanck; and Cameron Orr, *NABP staff*.

Introduction

The work group met on September 7-8, 2022, at NABP Headquarters in Mount Prospect, IL. This work group was established pursuant to Reggie Dilliard’s 2022-2023 presidential initiative, which focuses on facilitating a new pharmacy practice model that enhances and promotes patient safety while exploring a supportive environment for pharmacy professionals.

Review of the Work Group Charge

Work group members reviewed their charge and accepted it as follows:

1. Review barriers in existing statutes or regulations that limit patient access to medication and care;
2. Discuss opportunities to increase patient safety by enabling pharmacists to practice at the top of their education and training;
3. Determine other extrinsic factors that foster unsafe working environments when delivering patient care not already identified by the Task Force on Workplace Safety and Well-Being; and
4. Offer solutions to identified challenges.

Background and Discussion

The meeting began with comments from representatives of the various invited organizations. APhA presented an overview of findings from several APhA and APhA/NASPA initiatives pertaining to workplace issues and pharmacy staff well-being. Of note, it was relayed to the members that this is not a new problem, as there are publications dating back to May 1982 that discuss pharmacist well-being. It was shared that, as expected, the coronavirus disease 2019 (COVID-19) pandemic put a public spotlight on well-being and workplace concerns not only in pharmacy, but in all areas of health care. In response, APhA collaborated with NASPA to develop the *Pharmacist’s Fundamental*

Responsibilities and Rights document, which focuses on pharmacists' responsibilities and the workplace expectations needed to fulfill those responsibilities. The work group was informed that, as of August 30, 2022, 38 organizations have formally supported the document, including schools of pharmacy, state associations, two state boards of pharmacy, and national associations, including NABP, although the Association acknowledges that certain provisions pertaining specifically to business models may fall outside the regulatory purview of the boards of pharmacy. Another APhA/NASPA collaboration resulted in the Pharmacy Workplace and Well-being Reporting (PWWR) portal that serves as a safe place for individuals to submit reports concerning both positive and negative workplace experiences, which are then collected and analyzed by a patient safety organization to afford legal confidentiality protections. The members were informed that over 1,150 reports have been submitted since PWWR's launch in October 2021, and that aggregated data reports and findings are generated quarterly, which indicate the following key learnings:

- harassment by patients, coworkers, and pharmacy and non-pharmacy managers is a real problem;
- two-way lines of communication are not perceived to be open; and
- positive experiences have a long-term positive effect on well-being.

APhA also shared that they convened the 2022 Community Pharmacy Workplace Summit, which brought 47 stakeholders together to brainstorm ideas on addressing drivers impacting community pharmacy-based workplaces. Stakeholders included pharmacists, pharmacy technicians, student pharmacists, pharmacy employers, and pharmacy organizations, including NABP, who discussed challenges in serving community and individual health care needs, resulting in more than 20 key ideas that can be implemented to begin the necessary changes. In addition, the May 2022 final report of the 2021 APhA/NASPA National State-Based Pharmacy Workplace Survey was shared with the work group. The survey was offered nationally and through the individual state associations, and the results of more than 6,700 respondents from every state, the District of Columbia, and Puerto Rico indicated the following:

- A belief exists that there is not "an open mechanism" for pharmacists and pharmacy personnel to discuss workplace issues with management and if they try, it is not welcomed nor heard.
- Issues identified as factors likely to contribute to stress, potentially leading to medication errors and near misses, include:
    - increased demands, harassment, and bullying from patients/consumers;
    - concern due to insufficient and inadequately trained staff;
    - constant interruptions from telephone calls; and
    - inability to practice pharmacy in a patient-focused manner.
- Pharmacists want to spend more time with patients, but are unable to do so, which also causes distress.

Lastly, APhA shared the Pharmacy Professional Well-Being Index (WBI), which was originally invented by researchers at Mayo Clinic for physicians and was revised to include pharmacy

professionals in 2019. It consists of a 100% anonymous nine-question assessment that measures dimensions of distress and well-being. A WBI score that is greater than or equal to five indicates a risk of high distress, which is important because that increases the risk of having a low quality of life, burnout, high fatigue, intent to leave a current job, and most importantly, an increased risk of medication errors. As of September 1, 2022, the distress percent, which measures the percentage of individuals whose scores indicate that they are at risk for high distress, was 32.04%. It was noted to the members that there is consistency among all the above-mentioned tools regarding what is causing the most problems and that nearly one-third of those who are at risk for high distress are also at a twofold higher risk of medication errors.

Chain store representatives provided additional background information. Challenges for them included the increased workload that COVID-19 has introduced, including administration of vaccinations and tests, high employee turnover rates, harassment of pharmacy personnel by patients, reduced resources, and the inability to scale successful pilot projects due to the myriad of state pharmacy laws and rules. In addition, it is anticipated that the expanded scope of practice now allowed in many states thanks to the Public Readiness and Emergency Preparedness Act, will no longer be in place once waivers are rescinded unless those states enact and/or revise legislation to allow for the continued expanded scope of practice. Although these challenges are daunting, potential solutions discussed included implementation of shared services models, education to manage patient expectations, and improved communication efforts with frontline workers.

The NASPA representative reiterated the challenges already mentioned and agreed that PWWR is an instrumental mechanism for sharing both good and bad experiences by pharmacy personnel. Information gathered by NASPA indicates that there is not a shortage of pharmacists but rather a shortage of desirable practice settings, especially in rural areas, and unfortunately, the surveys indicate that there are problems in every setting.

All work group members were familiar with these concerns and concurred that COVID-19 certainly brought them to the forefront. As the fourth element of the charge was to offer solutions to the identified challenges, the members discussed approaches that could create meaningful change. Meeting participants agreed that current pharmacy workplace issues need to be addressed using a multipronged approach involving patient education and expanded training for pharmacists and pharmacy technicians, as well as through the adoption of less proscriptive regulations by boards of pharmacy to allow for easier integration of technology and alternative practice models. Members also emphasized that alleviating workload demands by means of the aforementioned strategies could help improve working conditions and expand the candidate pool for community pharmacy staffing by making it a more desirable practice setting. Despite the potential for improving working conditions through expanded practice scope and innovation, regulatory work group members voiced concern over continued complaints regarding working conditions being reported by licensees in states that have expanded pharmacy technician ratios and responsibilities, allowed remote operations, and implemented other strategies. Regulators also shared that pharmacists are reporting that they often face retaliation for making good faith reports to boards of pharmacy related to working conditions.

With that in mind, the work group determined that it is of utmost importance for NABP to play a crucial role in bringing pharmacy stakeholders together to identify solutions that will ultimately improve patient perceptions and outcomes as well as pharmacy working conditions. Such solutions should demonstrate support for pharmacists' ability to effectively provide patient care services and prevent inordinate delays and abrupt pharmacy closures due to lack of staff.

Members further agreed that one part of the solution, and an integral part in the development of a new pharmacy practice model, is to review and suggest modifications to outdated or unnecessary rules that create barriers to patient care. Specifically, they recommended that staff review the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to identify language that can create barriers to providing patient care and suggest revisions for the Committee on Law Enforcement/Legislation to review.

The work group concurred that boards of pharmacy can play a major role in addressing the pharmacy workplace challenges by encouraging pathways to innovation such as the use of more automation and shared services, while holding stakeholders accountable for ensuring innovation improves patient care. Industry representatives discussed the financial and regulatory burdens that often prevent chain pharmacies from introducing technological advancements to assist with workload demands, noting that the investment in new technology is often not worth the cost if it is only allowed in a few states. Members stressed that NABP should assist with this process and serve as a repository for pilot program and patient safety review data. This data can then be shared with state boards of pharmacy for evaluation and approval based on a pilot conducted in a single state, simplifying the process and improving access to pharmacy services for more patients.

As it was noted that patient expectations have changed and are negatively impacting working conditions, the work group agreed that there is much to do in this space. Communication to patients is lacking about reasonable pharmacy wait times for drug dispensing and clinical care, especially during high volume times. As such, members recommended that NABP encourage pharmacy stakeholders to amplify their current messaging to educate patients about pharmacy operations to manage expectations and depict pharmacists as health care professionals. Members also agreed that patient education should include messaging about the safety of pharmacy technology to foster uptake of innovative solutions that ease pharmacy burdens, such as kiosks, digital modes of communication, and remote pharmacy services.

The work group also identified schools and colleges of pharmacy as being integral stakeholders in developing a new pharmacy practice model, as enrollment has significantly decreased while the need for pharmacists has increased. If these trends continue, there will not be enough pharmacists to meet the health care needs of communities throughout the country, especially in more rural areas. Schools and colleges of pharmacy must join the discussion to improve the perception of community pharmacy practice and equip future graduates with the soft skills needed for difficult dialogues with patients, the knowledge to manage pharmacy staff, and the training to navigate competing priorities in a customer-facing role.

As pharmacy stakeholders envision and collaborate on a new pharmacy practice model, members identified some deliverables for consideration, such as providing pharmacy staff with opportunities to work from home with fewer interruptions to complete non-patient-facing tasks, including data entry, data verification, and third-party adjudication. Employers and state boards of pharmacy were also encouraged to support efforts to increase the use of call centers that provide patients the convenience and time to discuss concerns and ask questions, while freeing up staff in the community setting for more clinical tasks. The work group also suggested that central fill operations should be utilized to relieve busy pharmacies and that the central fill pharmacies should be permitted to mail medications directly to patients rather than having to ship them back to the originating pharmacy. Furthermore, all agreed that stakeholders should collaborate to identify and set meaningful standards for lunch breaks, shift lengths, the well-being of pharmacy personnel, and practice standards for clinical functions.

Lastly, along the lines of pharmacy staffing, the work group discussed the use of pharmacy technicians and how they should be used in ways that augment the role of the pharmacist, as it was reiterated many times that a pharmacist should never work alone in a pharmacy. Members recommended that NABP encourage boards of pharmacy to review and revise their regulations, if necessary, to utilize pharmacy technicians in an expanded capacity and allow for professional growth. For example, states should consider allowing technicians to accept new phoned-in prescriptions for legend drugs, verify the accuracy of filled prescriptions (tech-check-tech), and administer vaccinations. Additionally, the work group recommended that this review should also identify regulations that address duties to be performed only by a pharmacist to ascertain whether they can be safely and competently performed by non-pharmacist personnel and, if so, revise those regulations accordingly.

After careful review and consideration, the work group recommended that:

1. NABP collaborate with stakeholders to:
    a. identify new practice models that support pharmacists' ability to provide patient care services; and
    b. identify/set meaningful standards for staffing to include but not be limited to:
        i. lunch breaks/shift lengths;
        ii. well-being;
        iii. clinical functions;
        iv. use of automation technology; and
        v. use of pharmacy technicians.
2. NABP review the *Model Act* to identify model act language that can create barriers to care and suggest edits to submit to the Committee on Law Enforcement/Legislation.
3. NABP encourage industry stakeholders to amplify current messaging to educate patients about pharmacy operations to manage expectations.

4. NABP encourage boards of pharmacy to consider pathways to innovation such as automation and central fill, reimagine new delivery models that support pharmacists' ability to provide patient care services, and address staffing shortages.
5. NABP encourage boards of pharmacy to review and revise regulations to utilize pharmacy technicians to augment the role of the pharmacist and to identify current pharmacist-only duties that could be safely and competently performed by non-pharmacist personnel.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Whitney DeVoe, Board Counsel		**2) Date when request submitted:** 2/21/24 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: 2/29/24	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** FDA Advisory Letter to NABP Concerning Compounded Semaglutides – Discussion and Consideration	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** ☐ Yes ☒ No	**9) Name of Case Advisor(s), if applicable:**	
10) Describe the issue and action that should be addressed: Discussion of FDA advisory letter to NABP.			
11) Authorization Whitney DeVoe — **2/21/24** **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.			

U.S. FOOD & DRUG ADMINISTRATION

Oct. 10, 2023

Lemrey “Al” Carter, MS, PharmD, RPh
Executive Director/Secretary
National Association of Boards of Pharmacy
1600 Feehanville Dr.
Mount Prospect, IL 60056

Dear Dr. Carter:

The purpose of this letter is to bring to the attention of the National Association of Boards of Pharmacy information related to compounded drug products containing semaglutide or semaglutide salts (e.g., semaglutide acetate or semaglutide sodium).

Semaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist and the active ingredient in several FDA-approved drug products: Rybelsus (semaglutide) tablets, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; Ozempic (semaglutide) injection, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease; and Wegovy (semaglutide) injection, indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in certain adult and pediatric patients.

FDA is aware of increased interest in compounded semaglutide drug products. In some cases, compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product. However, compounded drugs, including compounded semaglutide drug products, are not FDA-approved and do not receive premarketing review for safety, efficacy, and quality. Ozempic and Wegovy currently appear on FDA’s drug shortage list. When a drug is in shortage, compounders may be able to prepare a compounded version of that drug if they meet certain conditions in the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA has received adverse event reports and complaints concerning these compounded drug products.

There are currently no FDA-approved products containing a semaglutide salt (e.g., semaglutide acetate or semaglutide sodium) as an active ingredient. Although FDA has carefully evaluated the chemical and pharmacologic properties of semaglutide in the context of the approved drug products, FDA is not aware of information regarding the chemical and pharmacologic properties of the semaglutide salts (e.g., semaglutide sodium or semaglutide acetate) or whether the semaglutide salts have the same safety or efficacy profile as semaglutide.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
w ww.fda.gov

Compounded Drug Products Containing Semaglutide Salts

FDA is not aware of any basis in the FD&C Act for compounding a drug using semaglutide salts such as semaglutide sodium and semaglutide acetate.

Sections 503A and 503B of the FD&C Act describe the conditions that must be satisfied for compounded human drug products to be exempt from certain sections of the FD&C Act, including the requirements of premarket approval and labeling with adequate directions for use. Among the conditions of sections 503A and 503B are restrictions on the bulk drug substances (active pharmaceutical ingredients or APIs) that may be used to compound human drug products.

Specifically, under section 503A (which applies to drugs products compounded outside an outsourcing facility registered by FDA, e.g., by licensed pharmacists in a State licensed pharmacy or a Federal facility, or by licensed physicians), the drug product must be compounded using bulk drug substances that (1) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are components of drugs approved by FDA; or (3) if such a monograph does not exist and the bulk drug substances are not components of a drug approved by FDA, appear on a list developed by FDA through regulations (the 503A Bulks List). Semaglutide salts are not the subject of an applicable USP or NF monograph, are not components of an FDA-approved drug product, and do not appear on the 503A Bulks List.

For compounded drug products to qualify for the exemptions under section 503B, they must be compounded in an outsourcing facility that does not compound drugs using bulk drug substances unless the bulk drug substance (1) appears on a list established by FDA identifying bulk drug substances for which there is a clinical need (the 503B Bulks List), or (2) the drug compounded from such bulk drug substances appears on FDA's drug shortage list at the time of compounding, distribution and dispensing. Semaglutide salts do not appear on the 503B Bulks List, nor do products containing semaglutide salts appear on FDA's drug shortage list.

Compounded Drug Products Containing Semaglutide

Semaglutide is a component of an FDA-approved drug product and appears on FDA's drug shortage list. Therefore, compounded drug products containing this API are potentially eligible for the exemptions under sections 503A or 503B of the FD&C Act, provided they meet all of the conditions in those sections. These sections describe the conditions that must be satisfied for compounded human drug products to be exempt from certain sections of the FD&C Act, including the requirements of premarket approval and labeling with adequate directions for use.

While compounded drug products containing semaglutide may be lawfully marketed under federal law, please be advised that FDA does not evaluate the safety, effectiveness, or quality of compounded drug products before such drugs are marketed. As stated, FDA has received an increased number of adverse event reports and complaints concerning these compounded drug

products.

We are also sending this letter to the Federation of State Medical Boards to facilitate communication among associations with shared goals regarding these matters.

We encourage you to share the information in this letter with your members. We look forward to continuing to work with you on matters related to drug compounding. If you have questions, please contact the Office of Compounding Quality and Compliance at compounding@fda.hhs.gov.

Sincerely,

F. Gail Bormel, RPh, JD
Director
CDER Office of Compounding Quality and Compliance

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
w ww.fda.gov

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**2/16/24** **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**

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

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
2/29/24	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Preliminary Rule Draft: Phar 15, Relating to Pharmaceutical Compounding** **2. Emergency Rule Draft: Phar 8, Relating to Controlled Substances Requirements** **3. Adoption Order: Phar 7 and 10, Relating to Required Disclosures to Consumers** **4. Scope Statement: Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substances Prescription Transfers, and Remote Dispensing** **5. Pending or Possible Rulemaking Projects**

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

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

Attachments:

1. Phar 15 Preliminary Rule Draft
2. Phar 8 EmR Rule Draft
3. Phar 7 and 10 Adoption Order
4. Phar 7 Scope Statement
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 — 02/16/24

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

Supervisor (if required) — **Date**

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

Directions for including supporting documents:

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

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal and recreate chapter Phar 15, relating to Compounding Pharmaceuticals.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.01 (16), Stats.

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

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

Section 450.02 (3) (d), Stats. says that the board "may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961."

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

Related statute or rule: N/A

Plain language analysis:
The Pharmacy Examining Board recently completed a revision to Wisconsin Administrative Code Chapter Phar 15 which became effective on August 1, 2022. The objective of this rule is to repeal and recreate the recent version of Phar 15 to incorporate by reference United States Pharmaceopeia (USP) General Chapters 795 and 797, published on November 1, 2022. The Board will also be incorporating USP General Chapter 800, published on December 1, 2019, as well as USP General Chapter 825, published on December 1, 2020.

DRAFT

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].

DRAFT

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.

DRAFT

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

TEXT OF RULE

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

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

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

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

(a) The pharmacist shall ensure that the flavoring agent is not more than 5 percent of the product's total volume.
(b) The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise documented.
(c) The pharmacist shall document the addition of flavoring as part of the prescription record. The documentation shall include the type of flavoring agent, manufacturer, lot number, and expiration date.
(d) A prescription is required before a pharmacist may add flavoring to an over-the-counter product.

(2) PHARMACEUTICAL COMPOUNDING - STERILE PREPARATIONS. USP-NF general chapter 797, official as of November 1, 2023, is incorporated by reference into this chapter.
(3) SAFE HANDLING OF HAZARDOUS DRUGS. USP-NF general chapter 800, official as of December 1, 2023, is incorporated by reference into this chapter.
(4) RADIOPHARMACEUTICALS. USP-NF general chapter 825, official as of December 1, 2020, is incorporated by reference into this chapter.

DRAFT

Note: Copies of the above standards are on file in the offices 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 licensee.

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

(END OF TEXT OF RULE)

DRAFT

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

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 (date).

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.

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.

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."

DRAFT

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].

DRAFT

In the Illinois Controlled Substances Act, the rules require that inventory of controlled substances be done annually, with an exact count for Schedule II drugs and an approximation for Schedule III and IV. Illinois also requires that a record of all written prescription orders received and verbal prescriptions filled, compounded or dispensed for controlled substances be retained for at least 5 years [Illinois Administrative Code Title 77 Chapter XV Part 3100 Section 3100.360]. Illinois also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance in an emergency where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. There does not appear to be a requirement that the prescriber follow up with a written prescription [Illinois Administrative Code Title 77 Chapter XV Part 3100 Section 3100.400].

Iowa: The Iowa Pharmacy Board requires a pharmacy to maintain controlled substance records for at least 2 years and to segregate Schedule I and II drug records from other controlled substance records [657 Iowa Administrative Code Chapter 10 Section 10.36]. Iowa also requires that pharmacies keep a perpetual inventory of all Schedule II drugs on hand [657 Iowa Administrative Code Chapter 10 Section 10.18]. Iowa only requires a pharmacist to report theft or loss of controlled substances to the Pharmacy Board if there is reason to believe that the theft was committed by a pharmacy board licensee, otherwise it is sufficient to merely report to the DEA [657 Iowa Administrative Code Chapter 10 Section 10.21]. Iowa also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. The prescriber must then provide a written prescription within 7 days [657 Iowa Administrative Code Chapter 10 Section 10.26].

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]. Inventory must be taken of all controlled substances at least annually and schedule II controlled substances must be stored separately [Michigan Administrative Rules R 338.3151]. Controlled substance records must be retained for at least 5 years. After two years from the date of dispensing, if the prescription is a hard copy and an electronic duplicate is made, the original hard copy may be destroyed [Michigan Administrative Rules R 338.3153]. Michigan also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. The prescriber must then provide a written prescription within 7 days [Michigan Administrative Rules R 338.3164 and 338.3165].

DRAFT

Minnesota: Minnesota requires a perpetual inventory of Schedule II substances which must be reconciled monthly [Minnesota Administrative Code Section 6800.4600]. 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]. All prescription information must be maintained for at least 2 years [Minnesota Administrative Code Section 6800.3100].

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.

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.

(END OF TEXT OF RULE)

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board

DRAFT

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 23-015)

ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 15.08 (5) (b), 450.13 (5m), 450.135 (8m), Stats.

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

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

Section 450.02 (3) (a), Stats. allows the board to "promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs."

Section 450.02 (3) (d), Stats. says that the board "may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961."

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

Related statute or rule: 2021 Wisconsin Act 9

Plain language analysis: The objective of the proposed rule is to revise Wisconsin Administrative Code chs. Phar 7 and 10, to bring the code into compliance with current statutory provisions as modified by 2021 Wisconsin Act 9. Section Phar 7.15 was created to outline the new consumer disclosure requirements created in 2021 Wisconsin Act 9. Additional requirements were also added to Phar 10.03 regarding unprofessional conduct of a licensee.

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

Comparison with rules in adjacent states:

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

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

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

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

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

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

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

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

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

Agency contact person:

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

TEXT OF RULE

SECTION 1. Phar 7.15 is created to read:

Phar 7.15 Consumer Disclosures.

(1) Each pharmacy shall post in a prominent place and maintain the consumer disclosures required in ss. 450.13 (5m) and 450.135 (8m), Stats.
(2) A link to the 100 most commonly prescribed generic drug product equivalents as determined by the Board, shall be maintained on the Department website as required in s. 450.13 (5m) (b), Stats.

> **Note:** Copies of the required consumer disclosures are located on the Department of Safety and Professional Service's website: https://dsps.wi.gov

(3) Pursuant to s. 450.13 (5m) (c), Stats., each pharmacy shall maintain and make available to the public a list of the drugs from the list in sub. (2) that are available for purchase at that pharmacy. The list shall be updated monthly, with all of the following information included:

(a) brand name.
(b) generic equivalent drugs and biological products.
(c) interchangeable biological products.
(d) retail price.

(4) The list required under sub. (3) may differ depending on whether the drugs on the list from sub. (2) are available for purchase at a specific pharmacy.

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

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

Phar 10.03 (21) Failure to comply with ss 450.13 (5m) or 450.135 (8m), Stats.

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

(END OF TEXT OF RULE)

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board

DRAFT

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 7

Relating to: Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, and Remote Dispensing

Rule Type: Permanent

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

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

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:
Wisconsin Administrative Code Phar 7 includes requirements for the practice of pharmacy. These requirements have the potential to become outdated on a regular basis. If the Board does not make regular updates via the permanent rules process, there will be inconsistencies between current pharmacy practice and what is required in the Wisconsin Administrative Code. This project will ensure that the Wisconsin Administrative Code continues to be current in the practice areas listed above.

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

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

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

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

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

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

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

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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:	Approved for implementation:
Authorized Signature	Authorized Signature
Date Submitted	Date Submitted

Pharmacy Examining Board
Rule Projects (updated 02/16/24)

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	Final Rule and Leg Report Submitted to Governor's Office on 2/6/24; Emergency Rule Effective 02/03/23-05/01/24	Governor's Office Approval and Submission to the Legislature for Review
23-054 (EmR 2213)	053-22	12/27/2024	Phar 1, 5, 6, 7 and 8	Remote Dispensing	Legislative Review; Emergency Rule Effective 11/01/22-05/01/24	Board Approval of Adoption Order at a Future Meeting
Not Assigned Yet	Not Assigned Yet	TBD	Phar 7	Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, and Remote Dispensing	Scope Statement Reviewed at 2/29/24 Meeting	Board Approval of Scope Statement for Publication and Submission to the Governor's Office for Review
23-015	102-21	05/01/2024	Phar 7 and 10	Consumer Disclosures	Adoption Order Reviewed at 02/29/24 Meeting	Submission for Publication; Anticipated Effective Date of 05/01/24
Not Assigned Yet	044-23	01/10/2026	Phar 8	Controlled Substances Requirements	Discussion of Emergency Ruel Timeline at 2/29/24 Meeting	Drafting Preliminary Permanent Rule
Not Assigned Yet	007-23	07/23/2025	Phar 15	Compounding Pharmaceuticals	Review of Preliminary Rule Draft at 02/29/24 Meeting	Board Approval of Permanent Preliminary Rule Draft for Posting for EIA Comment and Submission to Clearinghouse for Review
23-031	097-21	04/18/2024	Phar 18	Third Party Logistics Providers	Legislative Review	Board Approval of Adoption Order at a Future Meeting