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Tony Evers, Governor
Dan Hereth, Secretary

HYBRID (IN-PERSON/VIRTUAL)
PHARMACY EXAMINING BOARD
N208, 4822 Madison Yards Way, Madison
Contact: Brad Wojciechowski (608) 266-2112
August 13, 2026

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 June 18, 2026 (5-9)

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements and Recognition
1. Recognition: John Weitekamp, Pharmacist Member (Resigns: 8/13/2026)

E. Administrative Matters – Discussion and Consideration
1. Department, Staff and Board Updates
2. **Election of Officers, Appointment of Liaisons and Alternates (10-11)**
3. Board Members – Term Expiration Dates
   a. Esser, Paul T. – 7/1/2029
   b. O'Hagan, Tiffany M. – 7/1/2028
   c. Peterangelo, Anthony – 7/1/2027
   d. Sokn, Erick – 7/1/2029
   e. Weitekamp, John G. – 7/1/2026
   f. Wilson, Christa – 7/1/2029

F. Legislative and Policy Matters – Discussion and Consideration

G. Administrative Rule Matters – Discussion and Consideration (12-31)
1. Update on Phar 7 Final Rule Draft
2. Pending or Possible Rulemaking Projects

H. Interdisciplinary Advisory Committee – Discussion and Consideration (32)
1. Ketamine Guidance Document Review

I. Guidance on Compounding Pharmacies, Phar 15, and Semaglutide/Tirzepatide Production – Discussion and Consideration (33-56)

1. Draft Guidance Document Review and Discussion
2. Public Comment Review and Discussion

J. Report from Pharmacy Consultant – Discussion and Consideration

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

L. Newsletter Matters – Discussion and Consideration

M. Credentialing Matters – Discussion and Consideration

N. National Association of Boards of Pharmacy Matters – Discussion and Consideration

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

P. Liaison Reports – Discussion and Consideration

Q. 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

R. 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.).

S. Credentialing Matters

1. Application Review

a. C.Z. – Initial Application (IA-907370) **(57-97)**
b. B.S.O. – Wholesale Distributor Applicant (IA-672656) **(98-632)**
c. D.U.I.D.S. – Out-of-State Pharmacy (IA-691701) **(633-669)**
d. E.C.S. – Initial Application (IA-852652) **(670-1279)**
e. K.B. – Pharmacy Technician (IA-940749) **(1280-1286)**

T. Deliberation on Division of Legal Services and Compliance Matters

1. Administrative Warnings

a. 25 PHM 0713 – P.J.S. **(1287-1293)**
b. 25 PHM 0181 – K.M. **(1294-1304)**

2. Case Closings

a. 23 PHM 146 – A.R. **(1305-1315)**
b. 24 PHM 0126 – C.M.M.P. **(1316-1318)**
c. 25 PHM 0156 – W.P. **(1319-1322)**
d. 25 PHM 0173 – H.X. **(1323-1328)**
e. 25 PHM 0181 – T.L.A. and W. **(1329-1338)**

3. Proposed Stipulations, Final Decisions and Orders

a. 25 PHM 0173 – CVS Pharmacy #8525 **(1339-1344)**

U. Deliberation on Proposed Final Decision and Orders

1. Tiffany Sullivan, Respondent – (DHA Case Number SPS-25-0081/DLSC Case Number 25 PHM 0030) **(1345-1351)**

V. Monitoring Matters

1. Daniel VandeWalle – Modification Request **(1352-1372)**

W. 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

X. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: OCTOBER 15, 2026

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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
JUNE 18, 2026

PRESENT: Paul Esser, Anthony Peterangelo, Erick Sokn, John Weitekamp, Christa Wilson

ABSENT: Tiffany O'Hagan

STAFF: Brad Wojciechowski, Executive Director; Joseph Ricker, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Tracy Drinkwater, Board Administrative Specialist; 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: Erick Sokn moved, seconded by Anthony Peterangelo, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF APRIL 16, 2026

MOTION: Paul Esser moved, seconded by Anthony Peterangelo, to approve the Minutes of April 16, 2026, as published. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Scope Statement: Phar 1, 5, 6, 7, 8, 10, 15, and 19, Relating to Remote Dispensing Sites

MOTION: Christa Wilson moved, seconded by Anthony Peterangelo, to designate the Chairperson to approve the Scope Statement revising Phar 1, 5, 6, 7, 8, 10, 15, and 19, Relating to Remotely Supervised Pharmacies, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on the Scope Statement, the Chairperson is authorized to approve the required notice of hearing. Motion carried unanimously.

REPORT FROM PHARMACY CONSULTANT

MOTION: Christa Wilson moved, seconded by Anthony Peterangelo, to request DSPS Staff draft a Scope Statement on Phar 1 and 12 to 14, relating to Licensure and Inspection Requirements. Motion carried unanimously.

MOTION: Erick Sokn moved, seconded by Anthony Peterangelo, to request DSPS Staff draft a Scope Statement on Phar 1 and 6, relating to Remodeling. Motion carried unanimously.

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

Travel Request: MPJE State-Specific Review – September 16-18, 2026 – Mt. Prospect, IL

MOTION: John Weitekamp moved, seconded by Paul Esser, to designate Tiffany O'Hagan and Christa Wilson to attend the MPJE State-Specific Review on September 16-18, 2026, in Mt. Prospect, IL. Motion carried unanimously.

Travel Request: Executive Officers and Members Forum – September 28-October 1, 2026 – Mt. Prospect, IL

MOTION: Paul Esser moved, seconded by Anthony Peterangelo, to designate Brad Wojciechowski to attend the NABP Executive Officers and Members Forum on September 28-October 1, 2026, in Mt. Prospect, IL. Motion carried unanimously.

Travel Request: NABP District IV Meeting – October 14-16, 2026 – Ada, OH

MOTION: Paul Esser moved, seconded by Christa Wilson, to designate Tiffany O'Hagan, to attend the NABP District IV Meeting on October 14-16, 2026, in Ada, OH. Motion carried unanimously.

CLOSED SESSION

MOTION: John Weitekamp moved, seconded by Paul Esser, 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: Paul Esser-yes; Erick Sokn-yes; Anthony Peterangelo-yes; John Weitekamp-yes; and Christa Wilson-yes. Motion carried unanimously.

The Board convened into Closed Session at 12:32 p.m.

CREDENTIALING MATTERS

Application Review

B.P. – Wholesale Distributor Applicant (IA-692754)

MOTION: Anthony Peterangelo moved, seconded by Christa Wilson, to authorize Board Counsel to request additional information from Wholesale Distributor Applicant IA-692754. Motion carried unanimously.

C.B. – Pharmacy Technician (IA-397000)

MOTION: Paul Esser moved, seconded by Christa Wilson, to approve the Pharmacy Technician application IA-397000, once all requirements are met. Motion carried unanimously.

J.S.J. – CE Waiver Review (IA-956137)

MOTION: Erick Sokn moved, seconded by Anthony Peterangelo, to deny the CE Waiver Review IA-956137. **Reason for Denial**: Wis. Stat. § 450.085(2) and Wis. Admin. Code § Phar 16.02(2). Motion carried unanimously.

M.D. – Third-Party Logistics Provider (Out-of-State)

MOTION: Anthony Peterangelo moved, seconded by Erick Sokn, to approve the Third-Party Logistics Provider (Out-of-State) application of M.D., once all requirements are met. Motion carried unanimously.

M.D.S.D. – Third-Party Logistics Provider (Out-of-State)

MOTION: Anthony Peterangelo moved, seconded by Erick Sokn, to approve the Third-Party Logistics Provider (Out-of-State) application of M.D.S.D., once all requirements are met. Motion carried unanimously.

W.F.P. – Exception Request

MOTION: Anthony Peterangelo moved, seconded by Erick Sokn, to deny the Exception Request for W.F.P.. **Reason for Denial**: Wis. Stat. § 450.02(3m). Motion carried unanimously.

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

Case Closings

MOTION: Paul Esser moved, seconded by Erick Sokn, to close the following DLSC Cases for the reasons outlined below:

1. 24 PHM 022 – P.A.B. – Lack of Jurisdiction (L2), H.P.1. – No Violation, H.P.16. – Insufficient Evidence
2. 24 PHM 0120 – B.M.N. – Lack of Jurisdiction (L2)
3. 24 PHM 0164 – M.S.P. – No Violation
4. 25 PHM 0066 – R.N.A.M. – Insufficient Evidence
5. 25 PHM 0178 – W. – No Violation
6. 26 PHM 0010 – P.M. – No Violation
7. 26 PHM 0035 – H.A.Z. – No Violation

Motion carried unanimously.

Proposed Stipulations, Final Decisions and Orders

23 PHM 146 – Janisha E. Toney and 23 PHM 146 – Rikysha N. Williams

MOTION: Erick Sokn moved, seconded by Christa Wilson, to delegate to Al Rohmeyer, Department Chief Legal Counsel, the authority to preside over and resolve DLSC Case Numbers 23 PHM 146 – Janisha E. Toney and 23 PHM 146 – Rikysha N. Williams. Motion carried unanimously.

MOTION: Christa Wilson moved, seconded by Erick Sokn, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of the following cases:

1. 24 PHM 022 – Hayat Pharmacy 16
2. 24 PHM 022 – Xiaoang Xing
3. 24 PHM 0159 – Accutome, Inc.

Motion carried unanimously.

RECONVENE TO OPEN SESSION

MOTION: Paul Esser moved, seconded by Erick Sokn, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 1:44 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: Christa Wilson moved, seconded by Erick Sokn, 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: Christa Wilson moved, seconded by Erick Sokn, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 1:48 p.m.

PHARMACY EXAMINING BOARD
2026 Officers and Liaisons

2026 OFFICERS	
Chairperson	John Weitekamp
Vice Chairperson	Tiffany O'Hagan
Secretary	Anthony Peterangelo

Appointments of Liaisons and Alternates

LIAISON APPOINTMENTS	
Credentialing Liaison(s)	Anthony Peterangelo, Tiffany O'Hagan, Christa Wilson
Education and Examinations Liaison(s)	Erick Sokn *Alternate:* John Weitekamp
Monitoring Liaison(s)	Anthony Peterangelo *Alternate*: Erick Sokn
Professional Assistance Procedure (PAP) Liaison(s)	Anthony Peterangelo *Alternate*: Erick Sokn
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)	Christa Wilson
Appointed to Controlled Substances Board as per Wis. Stats. §15.405(5g)	John Weitekamp
PHARM Rep to SCAODA	Erick Sokn

	Alternate: John Weitekamp
Variance Liaison(s)	Tiffany O'Hagan *Alternate:* Anthony Peterangelo
Inspection Liaison(s)	Erick Sokn *Alternate:* Tiffany O'Hagan
SCREENING PANEL APPOINTMENTS	
Screening Panel	John Weitekamp, Tiffany O'Hagan, Erick Sokn, Paul Esser *Alternate:* Anthony Peterangelo
COMMITTEE MEMBER APPOINTMENTS	
Pharmacy Rules Committee	Erick Sokn, Tiffany O'Hagan, Anthony Peterangelo, John Weitekamp
OTHER APPOINTMENTS	
Interdisciplinary Advisory Council	John Weitekamp *Alternate:* Christa Wilson

Updated 2/26/2026

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:
Jake Pelegrin **Administrative Rules Coordinator**	**8/3/26** **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?
8/13/26	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** 1. Update on Phar 7 Final Rule Draft 2. Pending or Possible Rulemaking Projects

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

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

Attachments:
-Phar 7 signed final rule draft
-Draft scope statement on Phar 1 and 12 to 14 - Licensure and Inspection for Manufacturers and Distributors
-Draft scope statement on Phar 1 and 6 - Facilities, Floor Design, and Remodeling
-Rules progress chart

11) Authorization

Jake Pelegrin 8/3/26

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	**:**	**REPORT TO THE LEGISLATURE**
PHARMACY EXAMINING BOARD	**:**	**CR 25-073**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

The objective of this rule was to update requirements in Wisconsin Administrative Code Phar 7 to align with current pharmacy practice in the areas of electronic prescriptions, prescription labelling, CPR for pharmacists, controlled substance prescription transfers, remote dispensing, and the definition of a managing pharmacist. Additionally, the rule will implement the statutory changes from 2023 Wisconsin Act 27 by updating requirements for epinephrine delivery systems. This rule updates chapter Phar 7 as follows:

- A definition for "HIPAA" was added to Phar 7.01
- Phar 7.01 (2) was repealed
- Phar 7.02 (4) was amended to include prescriptions sent via secure texting platforms
- Phar 7.02 (5) was amended to include additional requirements for alterations to a prescription
- Phar 7.04 (1) (a) (intro.) was amended so that the section applies to all prescription transfers
- Phar 7.04 (3) was repealed and recreated to include compliance with 21 CFR 1306, the Board will also submit a request to incorporate this standard by reference to the Attorney General as required by the rulemaking process
- Phar 7.05 (2) (a) 4. was amended to say "epinephrine delivery system"
- Phar 7.05 (5) was created to add requirements about labelling non-patient specific compounded preparations
- Phar 7.07 (2) was amended to reflect that final check may involve other pharmacy personnel besides the pharmacist
- Phar 7.08 (1) (a) was amended to include that a prescription that has not been previously dispensed by that pharmacy or a pharmacy in the same computer system
- Phar 7.16 is created to require CPR training and basic life support for all pharmacists who administer drug product or devices or vaccines
- Phar 7.40 (2) was repealed
- Phar 7.42 (2) (intro) was amended to include an updated statute on remote dispensing
- Phar 7.43 (4) (d) was created to clarify that no vaccines or drug product or devices shall be administered at a remote dispensing site

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

The Pharmacy Examining Board held a public hearing on December 18, 2025, on CR 25-073. The following people either testified at the hearing, or submitted written comments:

- Mike Gillard, PharmD, BCPS, FPSW
- Kellen Dorff, PharmD, RPh
- Danielle Womack, Vice President of Public Policy and Advocacy for the Pharmacy Society of Wisconsin (PSW)
- Deeb Eid, PharmD, RPh, FMPLP, Director of Government Affairs at Empower Pharmacy

The Pharmacy Examining Board summarizes the comments received either by hearing testimony or by written submission as follows:

- Mike Gillard disagrees with the addition of Phar 7.43 (4) (d) which prohibits vaccinations at remote dispensing sites
- Kellen Dorff disagrees with the change to Phar 7.04 (3) if the intent of the change is to restrict the electronic transfer of initial fill schedule II controlled substance prescriptions
- The PSW submitted the following comments:
    - The reference in section Phar 7.02 (5) (c) should be updated to Phar 7.05 (2) to avoid ambiguity
    - Section Phar 7.04 (1) (a) still limited controlled substance transfers, even though section Phar 7.04 (3) was repealed and recreated
    - The second sentence in section Phar 7.07 (2) should be modified to read "If sub. (1) (a) or (b) is completed by a pharmacy product verification technician under s. Phar 7.14, the prescription record shall identify the pharmacy product verification technician performing the check. If sub. (1) (a) or (b) is completed through automated technology under s. Phar 7.55, the prescription record shall delegate the supervising pharmacist under s. Phar 7.55 (1) (b)."
    - The prohibition on vaccines at remote dispensing sites in section Phar 7.43 (4) (d) should be removed
- Empower Pharmacy submitted the following comments:
    - Section Phar 7.05 (5) should be amended to read "the label shall include the practitioner's name in place of the patient's name and follow requirements for labeling referenced by the Compounding Quality Act Title 1, section 503B."

The Pharmacy Examining Board made the following modifications to its rule-making proposal based on public comments:

- Section Phar 7.04 (1) (a) (intro.) was updated to read "A transfer of prescription order information between pharmacies licensed in this state or another state, may occur if all of the following conditions are satisfied:"
- Section Phar 7.05 (5) was updated to read:

Phar 7.05 (5) Notwithstanding sub. (2), compounded preparations prepared by a 503B pharmacy, dispensed or distributed to a practitioner pursuant to a non-patient specific order to be administered by a practitioner or a practitioner's agent shall comply with ch. Phar 15. The pharmacy shall affix a label to any compounded preparation prepared in this manner that includes all of the following:

(a) The name, address, and phone number of the compounding pharmacy.

(b) The name, strength, and dosage form of the compounded drug and a listed of active ingredients and strengths. If the number of active ingredients would prohibit proper labelling, then the pharmacist shall provider to the practitioner a complete list of the active ingredients and strengths, including those listed on the label.

(c) The pharmacy's lot number and a beyond-use date.

(d) The quantity or amount in the container.

(e) The appropriate ancillary instructions, such as storage instructions, cautionary statements, or hazardous drug warning labels when appropriate.

(f) The statement "For Office Use Only – Not for Resale."

- Section Phar 7.07 (2) was updated to read: "For all prescription drug products or devices dispensed by a pharmacist, the prescription record shall identify the individual responsible for each part of the final check.."

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 5b: "In Section 2, consider whether any clarity is lost by removing the definition of "managing pharmacist" while continuing to use the term throughout the chapter, especially when the use of the term is in conjunction with "supervising pharmacist" which is a defined term."

Response: The Board rejects this comment and would like to note that "managing pharmacist" is already defined in chapter Phar 1 and the definitions in that chapter apply to chapters Phar 1 to 19. Therefore, there is no need to define the term again in chapter Phar 7.

All of the remaining recommendations suggested in the Clearinghouse Report have been accepted in whole.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS: N/A

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 25-073)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 7.01 (2) and 7.40 (2); renumber and amend Phar 7.02 (5); amend Phar 7.02 (4), 7.04 (1) (a) (intro.), 7.05 (2) (a) 4., 7.07 (2), 7.08 (1) (a), and 7.42 (2) (intro); to repeal and recreate Phar 7.04 (3); and to create Phar 7.01 (1a), 7.02 (5) (a) and (b), 7.05 (5), 7.16, and 7.43 (4) (d) , relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.02 (2) and (5);450.09 (1) and (2) (b) 2.; and 450.11, Stats.

Statutory authority: ss. 15.08 (5) (b); 450.02 (2) and (5); and 450.02 (3) (a), (b), (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 (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."

Section 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."

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

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

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

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

Related statute or rule: s. 961.31, Stats.

Plain language analysis: The objective of this rule was to update requirements in Wisconsin Administrative Code Phar 7 to align with current pharmacy practice in the areas of electronic prescriptions, prescription labelling, CPR for pharmacists, controlled substance prescription transfers, remote dispensing, and the definition of a managing pharmacist. Additionally, the rule will implement the statutory changes from 2023 Wisconsin Act 27 by updating requirements for epinephrine delivery systems. This rule updates chapter Phar 7 as follows:

- A definition for "HIPAA" was added to Phar 7.01
- Phar 7.01 (2) was repealed
- Phar 7.02 (4) was amended to include prescriptions sent via secure texting platforms
- Phar 7.02 (5) was amended to include additional requirements for alterations to a prescription
- Phar 7.04 (1) (a) (intro.) was amended so that the section applies to all prescription transfers
- Phar 7.04 (3) was repealed and recreated to include compliance with 21 CFR 1306, the Board will also submit a request to incorporate this standard by reference to the Attorney General as required by the rulemaking process
- Phar 7.05 (2) (a) 4. was amended to say "epinephrine delivery system"
- Phar 7.05 (5) was created to add requirements about labelling non-patient specific compounded preparations
- Phar 7.07 (2) was amended to reflect that final check may involve other pharmacy personnel besides the pharmacist
- Phar 7.08 (1) (a) was amended to include that a prescription that has not been previously dispensed by that pharmacy or a pharmacy in the same computer system
- Phar 7.16 is created to require CPR training and basic life support for all pharmacists who administer drug product or devices or vaccines
- Phar 7.40 (2) was repealed
- Phar 7.42 (2) (intro) was amended to include an updated statute on remote dispensing
- Phar 7.43 (4) (d) was created to clarify that no vaccines or drug product or devices shall be administered at a remote dispensing site

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 on August 29, 2024 at 11:00am. No comments were received.

Comparison with rules in adjacent states:

Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of Pharmacy in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Pharmacy Practice Act contains various requirements on licensure, dispensing, and practice. Some of those requirements include that a prescription includes electronically transmitted orders for drugs from a licensed health care prescriber. Additionally, an electronically transmitted prescription means a prescription issued with an electronic signature and is transmitted and stored via electronic means. In Illinois, "remote prescription processing" includes outsourcing certain prescription services to a remote pharmacy. Such services may include entering prescription or patient data into a pharmacy system, drug regimen review, getting refill authorizations and communicating with prescribers, and transferring prescription information. Remote prescription processing may only occur between pharmacies that share a common electronic file or have technology that allows information to be sufficiently processed. Outside of remote prescription processing, Illinois licensees may also engage in "telepharmacy" under certain conditions. In this context, "telepharmacy" means the practice of pharmacy by a pharmacist through telecommunications or other technology. A pharmacy engaged in the practice of telepharmacy shall use an automated pharmacy system and be under the supervision of a pharmacist in charge [225 Illinois Complied Statutes ch. 85 ss. 3, 25.10, and 25.15].

The Illinois Department of Financial and Professional Regulation is also responsible for the promulgation of rules to implement certain sections of the Illinois Pharmacy Practice Act. These rules in the Illinois Administrative Code include that a "remote consultation site" means a site separate from a pharmacy where prescriptions that were filled at that pharmacy are stored and dispensed by a pharmacy technician or student pharmacist under remote supervision of a pharmacist who is located at the home pharmacy. A "remote dispensing site" means a site separate from the home pharmacy where a supply of prescriptions drugs is kept and prescriptions are filled and dispensed by a pharmacy technician or student pharmacist under the remote supervision of a pharmacist who is located at the pharmacy. Additionally, any compounded drug for

office use must have a label with the name, address, and phone number of the compounding pharmacy; the name, strength, and dose of the compounded drug; the pharmacy's lot number and a beyond-use date; quantity or amount; storage instructions or hazardous drug warning labels; and a statement that says "For Office Use Only – Note for Resale." Illinois pharmacies are required to have a Pharmacist-in-Charge, similar to a Managing Pharmacist in Wisconsin, who is responsible for supervision of the activities all employees that relate to the practice of pharmacy, of the method for storage and safekeeping of drugs, of the pharmacy recordkeeping system. The Pharmacist-in-Charge is responsible for the security of the pharmacy along with the pharmacy owner [Illinois Administrative Code ss. 1330.10, 1330.640, and 1330.660].
The Illinois Pharmacy Practice Act Statute and its related Administrative Rules do not appear to address cardiopulmonary resuscitation (CPR) training for pharmacists, epinephrine delivery systems, controlled substance prescription transfers, initial patient consultation, prescription alteration, or final check.

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. Chapter 155A of the Iowa Code contains various statutes regarding pharmacy practice including requirements for a prescription. In Iowa, a prescription is required to be submitted electronically unless it qualifies for an exemption. Some of the exemptions include, a prescription for a device, for a compounded preparation with two or more components, for an opioid antagonist, and for an emergency situation. Exempted prescriptions may be submitted in writing as an original signed by the prescriber, by facsimile, or orally. For prescription alteration, a pharmacist may use professional judgement when making a therapeutic substation to a prescribed drug, unless the prescription includes "dispense as written"[Iowa Code ch. 155A ss. 155A.27 and 155A. 32].
The Iowa Administrative Code also includes various pharmacy practice rules. Some of those requirements include rules for controlled substance prescription transfers, telepharmacy, labelling of non-patient specific compounded prescriptions, and patient consultation. In Iowa, transfers of controlled substance prescriptions is allowed pursuant to 21 CFR 1306 and are limited to authorization by the pharmacist at the patient's request. Telepharmacy requirements include that a telepharmacy site must have a managing pharmacy located in Iowa and an on-site pharmacist at least 16 hours per month. A pharmacist may provide remote supervision of pharmacy personnel at a telepharmacy site. Requirements for labelling of non-patient specific compounded prescriptions include the name, strength, dosage form and quantity; name of each active ingredient; pharmacy name, address, and phone number; preparation and beyond-use date; storage and handling instructions; lot or control number; a statement identifying the prescription as a compounded drug and whether it is sterile; and a statement that the prescription is not for distribution or is limited to direct patient administration. Patient consultation is required prior to dispensing any new or changed prescription. A pharmacist will counsel the patient on matters that the pharmacist determines will enhance drug therapy [481 Iowa Administrative Code ch. 552 ss. 552.8, 552.16, 552.18, 552.21, and 552.23].The Iowa Board of Pharmacy's Administrative Rules and related Statutes do not appear to address CPR training for

pharmacists, managing pharmacist requirements, or final check.
The statutory requirements for epinephrine auto-injectors are located under the Department of Health and Human Services - Public Health chapter instead of the Iowa Board of Pharmacy. In Iowa, a person who is authorized to administer epinephrine must be an employee or agent of a "facility" as defined by statute. Licensed healthcare professionals are to use the name of the facility when prescribing epinephrine auto-injectors. The facility may have a prescription for and maintain a supply of epinephrine auto-injectors at a secure location [Iowa Code ch. 135 s. 135.185].

Michigan: The Michigan Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Michigan. Act 368 Article 15 Part 177 of the Michigan Compiled Laws includes the regulations for pharmacy in Michigan, among several other occupations. Those regulations include requirements for electronic prescriptions, epinephrine delivery systems, remote dispensing, and pharmacist-in-charge requirements. In Michigan, an electronically transmitted prescription is a prescription communicated via electronic means, such as computer to computer or computer to facsimile machine, but does not include a prescription transmitted by telephone or facsimile machine. For prescribing auto-injectable epinephrine, or an epinephrine delivery system in Wisconsin, a pharmacist may dispense to an authorized entity. Authorized entities include a school board, a person or governmental entity that operates where allergens that can cause anaphylaxis may be present such as an amusement park, religious institution or recreation camp, and an entity eligible under the laws enforcement and firefighter access to epinephrine act. The pharmacist shall use the name of the authorized entity as the name of the patient for the prescription of the auto-injectable epinephrine. Requirements for a remote pharmacy include that both a parent pharmacy and an associated remote pharmacy must have a common owner, both be licensed as pharmacies, and located in the state of Michigan. A remote pharmacy cannot be within 10 miles of another pharmacy unless a waiver has been granted by the Michigan Board. If a pharmacist is not on site at a remote pharmacy, the pharmacist in charge of the parent pharmacy shall ensure that there is a pharmacist overseeing pharmacy technicians at the remote pharmacy via video and a telepharmacy system. A pharmacist cannot oversee 3 or more remote pharmacies at the same time. For a Pharmacist in Charge, or managing Pharmacist in Wisconsin, they are responsible for supervising the practice of pharmacy at the pharmacies they are assigned to. A Pharmacist in Charge may not supervise more than 3 pharmacies at one time, including remote pharmacy sites [Michigan Compiled Laws ss. 333.17703, 333.17742a and b, 333.17744a, and 333.17748].
Additional pharmacy practice regulations are also located in the Michigan Administrative Rules and include requirements on patient consultation. Patient consultation includes that a pharmacist is required to provide consultation on a prescription orally and in-person, except when the patient is not present at the pharmacy. The pharmacist providing the information printed or electronically also satisfies the consultation requirement. Consultation is to be provided with refills if the pharmacist deems it to be appropriate [Michigan Administrative Rules R 338.589 (4)].
The Michigan Board of Pharmacy's statutes and related administrative rules do not appear to address CPR training for pharmacists, labelling of non-patient specific

compounded prescriptions, controlled substance prescription transfers, prescription alteration, and final check.

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Minnesota. Chapter 151 of the Minnesota Statutes, the Pharmacy Practice and Wholesale Distribution Act, includes pharmacy regulations. In Minnesota, an electronic prescription order is allowed if it has that practitioner's electronic signature. The electronic prescription should contain the same information as any other prescription order [Minnesota Statutes 151.01 (16a)].
Part 6800 of the Minnesota Administrative Code also includes regulations for pharmacy in Minnesota. Some of those regulations include requirements for a Pharmacist-in-Charge, controlled substance prescription transfers, patient consultation, In Minnesota, a Pharmacist-in-Charge is responsible for supervising and establishing the procedures for all pharmacy employees. They also are required to supervise the method of storage of drugs and the record keeping system for pharmacy transactions. A Pharmacist-in-Charge may not be designated to supervise more than one pharmacy. For controlled substance prescription transfers, schedule III-V transfers are allowed pursuant to the requirements of the Drug Enforcement Administration. Schedule II controlled substance prescriptions cannot be transferred. For patient consultation, every pharmacy is required to have a procedure for consultation that allows for oral communication between the patient and the pharmacist about the patient's drug therapy. The pharmacist shall initiate the consultation for any new prescription. The consultation must be in person, whenever applicable, but can be supplemented with written information [Minnesota Administrative Rules part 6800, sections 6800.0910, 6800.2400, 6800.3120].
The Minnesota Board of Pharmacy's statutes and related administrative rules do not appear to address labelling of non-patient specific compounded prescriptions, CPR training for pharmacists, epinephrine delivery systems, remote dispensing, prescription alteration, and final check.

Summary of factual data and analytical methodologies: The Pharmacy Examining Board reviewed Wisconsin Administrative Code chapter Phar 7 and made updates where needed.

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 will be attached upon completion.

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

Agency contact person:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; 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 December 18, 2025, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 7.01 (1m) is created to read:

Phar 7.01 (1m) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

SECTION 2. Phar 7.01 (2) is repealed.

SECTION 3. Phar 7.02 (4) is amended to read:

Phar 7.02 (4) VERBAL PRESCRIPTION AND PRESCRIPTION VIA SECURE TEXTING PLATFORM. Verbal prescription orders may be received at a pharmacy via a direct conversation, telephone answering device or voice mail. Prescription orders via text may be received at a pharmacy through a HIPAA compliant secure texting platform. The verbal prescription or prescription order via secure texting platform shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information.

SECTION 4. Phar 7.02 (5) is renumbered to 7.02 (5) (intro) and amended to read:

Phar 7.02 (5) ALTERATIONS. Any alterations that modify the original intent of a prescription shall be documented including the identification of the pharmacist responsible for the alteration and the practitioner or practitioner's delegate who authorized the alteration. If an alteration does not modify the original intent of the prescription, the pharmacist shall use their professional judgement when determining whether it is necessary to contact the practitioner or practitioner's delegate before performing the following alterations to an initial fill of a non-controlled substance prescription:

SECTION 5. Phar 7.02 (5) (a) and (b) are created to read:

Phar 7.02 (5) (a) Changing the quantity, dosage, or directions for use of the medication if doing so does not alter the intended treatment parameters.

(b) Changing the dosage form, with patient consent, if the form dispensed contains the identical amount of the active ingredients as the dosage prescribed and if doing so does not alter the intended treatment parameters.

SECTION 6. Phar 7.04 (1) (a) (intro.) is amended to read:

Phar 7.04 (1) (a) A transfer of prescription order information between pharmacies licensed in this state or another state, ~~for the purpose of original or refill dispensing of non-controlled substances and refills of controlled substances,~~ may occur if all of the following conditions are satisfied:

SECTION 7. Phar 7.04 (3) is repealed and recreated to read:

Phar 7.04 (3) CONTROLLED SUBSTANCES. The transfer of controlled substance prescriptions is allowed consistent with 21 CFR 1306.

SECTION 8. Phar 7.05 (2) (a) 4. is amended to read:

Phar 7.05 (2) (a) 4. For an epinephrine ~~auto-injector~~ delivery system prescribed under s. 118.2925 (3) or 255.07 (2), Stats., the name of the school, authorized entity, or other person specified under s. 255.07 (3), Stats.

SECTION 9. Phar 7.05 (5) is created to read:

Phar 7.05 (5) Notwithstanding sub. (2), compounded preparations prepared by a 503B pharmacy, dispensed or distributed to a practitioner pursuant to a non-patient specific order to be administered by a practitioner or a practitioner's agent shall comply with ch. Phar 15. The pharmacy shall affix a label to any compounded preparation prepared in this manner that includes all of the following:

(a) The name, address, and phone number of the compounding pharmacy.

(b) The name, strength, and dosage form of the compounded drug and a listed of active ingredients and strengths. If the number of active ingredients would prohibit proper labelling, then the pharmacist shall provider to the practitioner a complete list of the active ingredients and strengths, including those listed on the label.
(c) The pharmacy's lot number and a beyond-use date.
(d) The quantity or amount in the container.
(e) The appropriate ancillary instructions, such as storage instructions, cautionary statements, or hazardous drug warning labels when appropriate.
(f) The statement "For Office Use Only – Not for Resale."

SECTION 10. Phar 7.07 (2) is amended to read:

Phar 7.07 (2) For all prescription drug products or devices dispensed by a pharmacist, the prescription record shall identify the ~~pharmacist~~ individual responsible for each part of the final check. ~~If sub. (1) (a) or (b) is completed by a pharmacy product verification technician under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the pharmacy product verification technician performing the check.~~

SECTION 11. Phar 7.08 (1) (a) is amended to read:

Phar 7.08 (1) (a) Has not been dispensed previously to the patient by that pharmacy or a pharmacy within the same shared computer system.

SECTION 12. Phar 7.16 is created to read:

Phar 7.16 Additional Certification for Pharmacists. Every licensed pharmacist who administers drug product or devices or vaccines pursuant to s. 450.035, Stats., shall maintain current certification in cardiopulmonary resuscitation and basic life support.

SECTION 13. Phar 7.40 (2) is repealed.

SECTION 14. Phar 7.42 (2) (intro) is amended to read:

Phar 7.42 (2) An automated direct-to-patient dispensing system in a secure and professionally appropriate environment in any of the locations under s. ~~450.062 (1) to (4)~~450.09 (2) (b) 1. a. to d., Stats., may operate for purposes of practitioner dispensing. The supervising practitioner will ensure all of the following requirements are met:

SECTION 15. Phar 7.43 (4) (d) is created to read:

Phar 7.43 (4) (d) No vaccines or drug product or devices shall be administered at a remote dispensing site.

SECTION 16. 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)

This Proposed Order of the Pharmacy Examining Board is approved for submission to the Governor and Legislature.

Dated 4/28/2026

Agency John Weitekamp

Member
Pharmacy Examining Board

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

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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

2. Date
09/18/25

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 7

4. Subject
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

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

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

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

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 $17,600.00 in one-time staffing costs to implement the rule. The estimated need for 0.2 limited term employee (LTE) is for updating applications, updating LicensE, legal and supervisor review, training on new requirements and procedures, promulgation of rules. The one-time estimated costs cannot be absorbed in the currently appropriated agency budget.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit of implementing the rule is an updated Wisconsin Administrative Code Chapter Phar 7 that is in line with current practice in the Pharmacy profession. The alternative to implementing this rule is that the chapter will remain unedited.

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16. Long Range Implications of Implementing the Rule

The long range implications of implementing the rule are increased safety in pharmacy practice in Wisconsin.

17. Compare With Approaches Being Used by Federal Government

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..

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

Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of Pharmacy in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Pharmacy Practice Act contains various requirements on licensure, dispensing, and practice. Some of those requirements include that a prescription includes electronically transmitted orders for drugs from a licensed health care prescriber. Additionally, an electronically transmitted prescription means a prescription issued with an electronic signature and is transmitted and stored via electronic means. In Illinois, “remote prescription processing” includes outsourcing certain prescription services to a remote pharmacy. Such services may include entering prescription or patient data into a pharmacy system, drug regimen review, getting refill authorizations and communicating with prescribers, and transferring prescription information. Remote prescription processing may only occur between pharmacies that share a common electronic file or have technology that allows information to be sufficiently processed. Outside of remote prescription processing, Illinois licensees may also engage in “telepharmacy” under certain conditions. In this context, “telepharmacy” means the practice of pharmacy by a pharmacist through telecommunications or other technology. A pharmacy engaged in the practice of telepharmacy shall use an automated pharmacy system and be under the supervision of a pharmacist in charge [225 Illinois Complied Statutes ch. 85 ss. 3, 25.10, and 25.15].

The Illinois Department of Financial and Professional Regulation is also responsible for the promulgation of rules to implement certain sections of the Illinois Pharmacy Practice Act. These rules in the Illinois Administrative Code include that a “remote consultation site” means a site separate from a pharmacy where prescriptions that were filled at that pharmacy are stored and dispensed by a pharmacy technician or student pharmacist under remote supervision of a pharmacist who is located at the home pharmacy. A “remote dispensing site” means a site separate from the home pharmacy where a supply of prescriptions drugs is kept and prescriptions are filled and dispensed by a pharmacy technician or student pharmacist under the remote supervision of a pharmacist who is located at the pharmacy. Additionally, any compounded drug for office use must have a label with the name, address, and phone number of the compounding pharmacy; the name, strength, and dose of the compounded drug; the pharmacy’s lot number and a beyond-use date; quantity or amount; storage instructions or hazardous drug warning labels; and a statement that says “For Office Use Only – Note for Resale.” Illinois pharmacies are required to have a Pharmacist-in-Charge, similar to a Managing Pharmacist in Wisconsin, who is responsible for supervision of the activities all employees that relate to the practice of pharmacy, of the method for storage and safekeeping of drugs, of the pharmacy recordkeeping system. The Pharmacist-in-Charge is responsible for the security of the pharmacy along with the pharmacy owner [Illinois Administrative Code ss. 1330.10, 1330.640, and 1330.660].

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

more than 3 pharmacies at one time, including remote pharmacy sites [Michigan Compiled Laws ss. 333.17703, 333.17742a and b, 333.17744a, and 333.17748].
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The Michigan Board of Pharmacy's statutes and related administrative rules do not appear to address CPR training for pharmacists, labelling of non-patient specific compounded prescriptions, controlled substance prescription transfers, prescription alteration, and final check.

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Minnesota. Chapter 151 of the Minnesota Statutes, the Pharmacy Practice and Wholesale Distribution Act, includes pharmacy regulations. In Minnesota, an electronic prescription order is allowed if it has that practitioner's electronic signature. The electronic prescription should contain the same information as any other prescription order [Minnesota Statutes 151.01 (16a)].
Part 6800 of the Minnesota Administrative Code also includes regulations for pharmacy in Minnesota. Some of those regulations include requirements for a Pharmacist-in-Charge, controlled substance prescription transfers, patient consultation, In Minnesota, a Pharmacist-in-Charge is responsible for supervising and establishing the procedures for all pharmacy employees. They also are required to supervise the method of storage of drugs and the record keeping system for pharmacy transactions. A Pharmacist-in-Charge may not be designated to supervise more than one pharmacy. For controlled substance prescription transfers, schedule III-V transfers are allowed pursuant to the requirements of the Drug Enforcement Administration. Schedule II controlled substance prescriptions cannot be transferred. For patient consultation, every pharmacy is required to have a procedure for consultation that allows for oral communication between the patient and the pharmacist about the patient's drug therapy. The pharmacist shall initiate the consultation for any new prescription. The consultation must be in person, whenever applicable, but can be supplemented with written information [Minnesota Administrative Rules part 6800, sections 6800.0910, 6800.2400, 6800.3120].
The Minnesota Board of Pharmacy's statutes and related administrative rules do not appear to address labelling of non-patient specific compounded prescriptions, CPR training for pharmacists, epinephrine delivery systems, remote dispensing, prescription alteration, and final check.

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)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
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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

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
26-013	002-25	07/13/2027	Phar 1. 6, 7, and 10	Pharmacy Workplace Conditions	Permanent rule effective 6/1/2026.	Permanent rule effective 6/1/2026.
25-073	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	Final rule draft is finished and signed. The request for incorporation of standards is with the Attorney General for approval. Need approval for this before next step.	Submittal of the final rule draft to the Governor and Legislature.
			Phar 1, 5, 6, 7, 8, 10, 15, and 19	Remotely Supervised Pharmacies	Governor's review of scope statement.	Publication of scope statement in the Administrative Register.
			Phar 1 and 12 to 14	Licensure and Inspection for Manufacturers and Distributors	Board review of scope statement.	Approval of scope statement or further discussion at next meeting.
			Phar 1 and 6	Facilities, Floor Design, and Remodeling	Board review of scope statement.	Approval of scope statement or further discussion at next meeting.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski, Executive Director		**2) Date when request submitted:** 8/3/2026 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: 8/13/2026	**5) Attachments:** ☐ Yes ☒ No	**6) How should the item be titled on the agenda page?** Interdisciplinary Advisory Committee – Discussion and Consideration 1) Ketamine Guidance Document Review	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes <Appearance Name(s)> ☐ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>	
10) Describe the issue and action that should be addressed:			
11) **Authorization** 8/3/2026 **Signature of person making this request** — **Date** **Supervisor (Only required for post agenda deadline items)** — **Date** **Executive Director signature (Indicates approval for post agenda deadline items)** — **Date**			
Directions for including supporting documents: 1. This form should be saved with any other documents submitted to the Agenda Items folders. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

Revised 03/2021

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:
Brad Wojciechowski, Executive Director	7/30/2026
	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?
8/13/2026	☒ Yes ☐ No	Guidance on Compounding Pharmacies, Phar 15, and Semaglutide/Tirzepatide Production – Discussion and Consideration

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 applicable:
☒ Open Session ☐ Closed Session	☐ Yes <Appearance Name(s)> ☐ No	<Click Here to Add Case Advisor Name or N/A>

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

11) Authorization

	7/30/2026
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

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Tony Evers, Governor
Dan Hereth, Secretary Designee

PUBLIC AGENDA REQUEST FORM

Instructions:

1. Fill out this form, and then save to your device.
2. Return to the "Suggest an Agenda Item" page and select the appropriate Board or Council from the Board/Council list.
3. Attach your completed "Public Agenda Request" form and send.

First Name: Kerry

Last Name: Zimdars

Association/Organization: N/A

Subject: Scheduling GLP-1 RAs

Issue to Address:

Glucagon-like peptide-1 (GLP-1) receptor agonists use has increased rapidly in recent years (3). While approved for use for diabetes and weight management, patients without any medical indication and those with contraindications to its use are also frequently, inappropriately seeking out these medications. In my personal practice, I see patients go from doctor to doctor, trying to find someone who will ignore their contraindications and prescribe them this medication anyway, just as patients may seek classically addictive substances like opioids or benzodiazepines. It is also too common that I recommend that a patient not take a GLP-1 RA medication based on their personal contraindications, and their response is to then seek out the medication via an online app, despite these concerns for harm exceeding benefit. With ease of access to these medications via online apps, that prescribe without sufficient screening or oversight (6), eating disorder rates and underweight/frailty rates are increasing (2, 4, 1).

Driven by the misleading and unrealistic 'beauty ideal' that the manufacturer commercials pressure patients with; which fuels body dysmorphia, harmful mental attachments akin to dependence and addiction, eating disorders, and frailty; the current capacity for miss-use by patients is far too high. The long-term effects of these medications, especially when used for weight loss, are not known, and with ongoing increased use, new significant adverse events continue to come to light (8, 5, 7). Our medical system's history provides ample examples of the harms that come from widely utilizing a medication without a full understanding of its risk profile or possible addiction and misuse profile, such as thalidomide, opioids, benzodiazepines, and fenfluramine-phentermine.

As such, I urge that GLP-1 RAs be classified as a controlled substance in Wisconsin to ensure that we are protecting patients by requiring the necessary level of prescriber oversight while utilizing these medications.

Citations

1. Dangoor, Natasha. “The GLP-1 Revolution Comes with a Catch: Muscle Wasting.” *The Wall Street Journal*, 17 May 2026, www.wsj.com/health/pharma/glp-1-weight-muscle-loss-frailty-ca277a24.
2. “Eating Disorders and GLP-1 RAs.” *NEDC*, National Eating Disorder Collaboration, 2023, nedc.com.au/eating-disorders/other-learning/eating-disorders-and-glp-1ra. Accessed 6 June 2026.
3. EHRN. “Epic Research.” *Epic Research*, 2026, epicresearch.org/articles/glp-1-use-has-more-than-quadrupled-since-2021-as-obesity-rates-continue-to-show-signs-of-declines. Accessed 6 June 2026.
4. João Carlos Locatelli, et al. “Incretin-Based Weight Loss Pharmacotherapy: Can Resistance Exercise Optimize Changes in Body Composition?” *Diabetes Care*, 30 Apr. 2024, https://doi.org/10.2337/dci23-0100.
5. “Optic Neuropathy and Other Hidden Ocular Risks of GLP-1 RA Weight Loss Drugs.” *Neurology Advisor*, 3 July 2025, www.neurologyadvisor.com/features/naion-hidden-ocular-risks-of-glp-1-ra-semaglutide-weight-loss-drugs/.
6. Rowland, Christopher, and Ariana Eunjung Cha. “People with Eating Disorders Are Taking GLP-1s, and Doctors Are Alarmed.” *The Washington Post*, 23 May 2026, www.washingtonpost.com/health/2026/05/23/weight-loss-drugs-pose-dangers-people-with-eating-disorders/.
7. T Joseph Mattingly, Emeka Elvis Duru, Rena M Conti, Adverse events administering glucagon-like peptide-1 receptor agonists: a cross-sectional study, *Health Affairs Scholar*, Volume 4, Issue 2, February 2026, qxag023, https://doi.org/10.1093/haschl/qxag023
8. “Update on FDA’s Ongoing Evaluation of GLP-1 RAs and Suicidality.” *U.S. Food and Drug Administration*, FDA, 2026, www.fda.gov/drugs/drug-safety-communications/update-fdas-ongoing-evaluation-reports-suicidal-thoughts-or-actions-patients-taking-certain-type.

May 22, 2026

Eli Lilly and Company

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Via Email

Dan Hereth, Secretary
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John G. Weitekamp, Chairperson
Department of Safety and Professional Services
Pharmacy Examining Board
PO Box 8366
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RE: Compounding Guidance Regarding GLP-1s and Similar Products

Dear Secretary Hereth, Chairperson Weitekamp, and members of the Pharmacy Examining Board:

I write on behalf of Eli Lilly and Company ("Lilly") to urge the Wisconsin Pharmacy Examining Board (the "Board") to issue guidance clarifying the Board's rules regarding the compounding of glucagon-like peptide-1 receptor agonist drug products ("GLP-1s") and other similar products.

As a medicine company headquartered in Indiana, Lilly has been at the forefront of drug innovation and drug quality for nearly 150 years. At Lilly, patient safety is at the heart of everything we do. We believe our commitment to patient safety aligns with the Board's longstanding dedication to public health and the effective regulation of the practice of pharmacy in Wisconsin. We aim to partner with the Board in its efforts to protect Wisconsin patients and advance public health.

We understand that there was discussion at the Board's meeting on April 16, 2026 about the need for additional guidance for pharmacies engaged in compounding, including discussion of a guidance document issued by the Ohio Board of Pharmacy[1] (the "Ohio Guidance") that could provide a potential framework for this Board. As you know, compounded drugs are not tested in clinical trials and are not approved by the U.S. Food and Drug Administration ("FDA"). Compounded drugs are intended to be used solely when a patient's unique clinical needs cannot

[1] Ohio Board of Pharmacy, "Compounding of Glucagon-like Peptide-1 Drug Products (GLP-1) in Ohio" issued July 17, 2025, *available at*: https://www.pharmacy.ohio.gov/documents/pubs/special/compounding/compounding%20of%20glp-1%20drug%20products%20in%20ohio.pdf.

be met by an approved medicine, but the reality today is that many compounding pharmacies are mass-marketing and mass-producing standard formulations of drugs that do not have any assurances of safety or efficacy. All too often, these mass-compounded drugs have been produced under insanitary or other violative conditions that have exposed American patients to unnecessary and unacceptable risks.[2]

Lilly commends the Board's commitment to clarifying the regulatory requirements for compounded drugs. The Ohio Guidance provides a strong foundation from which this Board can build, however, we believe certain aspects of the Ohio Guidance can be improved to ensure that compounding pharmacies do not mass-produce copies of approved medicines. Our recommendations are explained in greater detail below.

I. The Need for Board Guidance

As you know, the Board has not issued compounding guidance specific to the GLP-1 category of drugs to date. While the Wisconsin Administration Code includes a framework for drug compounding practices generally, it does not include necessary language to combat the illegal mass compounding of GLP-1 drug products that is proliferating today.[3] We believe that the absence of such regulations and guidance from the Board will inevitably lead to enforcement gaps, potentially exposing Wisconsin patients to serious safety risks in the meantime.

II. The Board Should Adopt Guidance Similar to Ohio Guidance

The Ohio Guidance provides important information about the status of GLP-1 drugs and the ability (or lack thereof) of Ohio pharmacies, prescribers, and outsourcing facilities to compound essentially copies of commercially available drug products like tirzepatide and semaglutide. It is appropriately grounded in both the federal Food, Drug and Cosmetic Act ("FD&C Act") and Ohio state law, and its core provisions are readily adaptable to Wisconsin law and this Board's regulatory structure. We encourage the Board to adopt the following elements of the Ohio Guidance:

- **Prohibition on Compounding Tirzepatide and Semaglutide:** Compounding pharmacies and outsourcing facilities may not compound "copies" of tirzepatide and semaglutide. This aligns with recent statements from FDA, which have reiterated that mass compounding of tirzepatide and semaglutide is not permitted and that neither compound is on the 503B bulks list or FDA's shortage list.[4]

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[2] U.S. Food and Drug Administration, "Form 483 to Revive Rx LLC dba Revive Rx Pharmacy" (Mar. 27, 2026) ("Microbial contamination was present in the ISO 5 area and area adjacent to production areas."); U.S. Food and Drug Administration, "Form 483 to SCA Pharmaceuticals, LLC" (Mar. 13, 2026) ("Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed."); U.S. Food and Drug Administration, "Form 483 to OSRX, Inc." (Nov. 14, 2025) ("Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed."); U.S. Food and Drug Administration, "Form 483 to Medi-Fare Drug" (June 6, 2025) ("Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.").

[3] *See* Wis. Admin. Code § 15 et seq.

[4] *See, e.g.*, U.S. Food and Drug Administration, "FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize" issued Apr. 1, 2026, *available at*: https://www.fda.gov/drugs/drug-alerts-and-

- **Categorical Prohibition on Retatrutide and Cagrilintide:** Retatrutide and cagrilintide are not components of an FDA-approved drug, do not appear on the FDA's 503A or 503B bulk drug lists, lack USP/NF monographs, and have not been found to be safe and effective for any condition. These are currently investigational products and should not be prescribed or compounded, as FDA has reinforced in its own guidance.[5]

- **Documentation of Significant Difference:** Prescribers should clearly document and compounders should verify the specific reason that a compounded drug is purportedly necessary (i.e., the significant difference). Making relatively small changes to a compounded drug product that do not cause a clinically significant difference for a patient is not sufficient to enable a 503A pharmacy to compound a product that is essentially a copy of a commercially available drug.

- **Compliance with USP Standards and State Law:** Compounding should comply with applicable United States Pharmacopoeia ("USP") Chapters on compounding and state law. Requiring compliance with the USP Chapters on compounding would help reduce some of the risks associated with compounded drugs, and help promote consistency and coordination between the states.

- **Pharmaceutical-grade API Sourcing:** All active pharmaceutical ingredients ("API") used in compounding must be pharmaceutical-grade product, accompanied by a valid certificate of analysis, and sourced from an FDA-registered manufacturing establishment. Ensuring APIs are pharmaceutical-grade and properly sourced helps to ensure the API is appropriate for human use and minimizes the risk of impurities that could lead to patient harm. The importance of this requirement is underscored by a recent FDA Warning Letter issued to Harbin Jixianglong Biotech Co., Ltd. ("Harbin"), a Chinese manufacturer that had its Green List status revoked after FDA found Harbin had shipped relabeled semaglutide API purchased from non-approved suppliers into the United States, in what

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statements/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize; Dr. Marty Makary (@DrMakaryFDA), post issued Apr. 10, 2026 at 12:03 p.m., *available at:* https://x.com/drmakaryfda/status/2042634670827803119?s=46 ("FDA continues to see unapproved GLP-1s being mass marketed. These drugs can be risky and ineffective. We'll continue to go after companies that are violating our regulations."); U.S. Food and Drug Administration, "FDA Warns 30 Telehealth Companies Against Illegal Marketing of Compounded GLP-1s" issued Mar. 3, 2026, *available at*: https://www.fda.gov/news-events/press-announcements/fda-warns-30-telehealth-companies-against-illegal-marketing-compounded-glp-1s ("compounders should not try to compound drugs in a way that circumvents FDA's approval process").

[5] U.S. Food and Drug Administration, "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss" issued Feb. 4, 2026, *available at*: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss ("Retatrutide and cagrilintide cannot be used in compounding under federal law. Additionally, these are not components of FDA-approved drugs and have not been found safe and effective for any condition. The agency has issued warning letters to companies distributing active pharmaceutical ingredients, such as retatrutide and certain other GLP-1 drugs.").

FDA described as an attempt to circumvent safeguards associated with the Import Alert, and had released tirzepatide API without validated analytical methods, adequate stability studies, or appropriate endotoxin and microbial testing.[6] FDA's findings illustrate that even Green List entities will ship research grade API that has not been produced according to acceptable quality standards for human use.

III. Opportunity to Address Gaps in Ohio's Guidance

While the Ohio Guidance provides a strong foundation, it leaves gaps that compounders have already begun to exploit in other states. We encourage the Board to address these gaps proactively, protecting Wisconsin patients from substandard and potentially dangerous compounded drugs while providing clear, enforceable rules for the pharmacy community.

a. FDA's Shortage List Is Not the Appropriate Test of Commercial Availability for a 503A Pharmacy

Lilly supports aligning the Board's approach with the federal prohibition on compounding drugs that are essentially copies of commercially available medicines. However, as a federal district court recently explained, the phrase "commercially available" is different from, and cannot be interchanged with, the concept of a drug shortage.[7] Congress did not intend for compounding pharmacies (as opposed to registered outsourcing facilities) to be able to copy approved medicines during a shortage.[8] It follows that the legal test for "commercial availability" is simply whether the approved drug is on the market at all. Unless and until an approved medicine has been discontinued altogether, it is neither appropriate nor lawful for compounding pharmacies operating under Section 503A to regularly make their own copies of such drug. Guidance from the Board should affirmatively clarify that a product is considered "commercially available" if it is available on the market, and that a drug's presence on FDA's shortage list does not alter that determination.

Further, guidance from the Board should reiterate that minor modifications, such as adding ingredients like vitamin B12 or making small dosage adjustments, do not permit compounding pharmacies to circumvent this prohibition. FDA considers compounded products to be "essentially copies" when they contain the same APIs in similar strengths and are administered the same way, unless there is a documented, patient-specific clinical need for a

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[6] U.S. Food and Drug Administration, "Warning Letter, Harbin Jixianglong Biotech Co., Ltd." issued May 1, 2026, *available at*: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/harbin-jixianglong-biotech-co-ltd-723330-05012026.

[7] *See Eli Lilly and Co. v. Revive Rx, LLC*, No. H-23-3521, slip op. (S.D. Tex. Dec. 5, 2025) ("A product is 'commercially available' if it is 'able to be bought and sold by people.' Although a shortage exists 'when the demand or projected demand for the drug within the United States exceeds the supply of the drug,' manufacturers may still sell, and at least some consumers may still purchase, the drug in shortage.") (citations omitted).

[8] *See id.* ("Congress's decision to allow outsourcing facilities under 503B, but not other pharmacists under 503A, to compound during a shortage balances consumer safety and medical need. Congress allowed more heavily-regulated facilities, which are more likely to produce safe pharmaceuticals, to increase production during a shortage.").

significant difference.[9] The Board's guidance should explicitly prohibit "sham personalization" practices that attempt to justify mass compounding based on negligible changes absent a prescriber's determination of clinical necessity.[10]

b. Adopt FDA's Position on "Regularly or in Inordinate Amounts"

Section 503A of the FD&C Act permits a pharmacy to compound drugs that are essentially copies of commercially available products only if it does not do so "regularly or in inordinate amounts." This standard has long lacked a clear and enforceable definition. FDA's April 2026 clarification statement helps address any ambiguity by stating that the agency does not intend to take action against a compounder filing four or fewer prescriptions of an essentially-copy compounded drug product per calendar month.[11]

Lilly recommends that the Board incorporate this standard into Wisconsin guidance, providing licensees with a clear and administrable threshold. This will also provide the Board with an explicit basis for enforcement against compounders who exceed the limit.

c. Require a "Clinically" Significant Difference Standard and Documentation

The Ohio Guidance states that a prescription order must include a determination of "significant difference" for the individual patient by the prescriber between the compounded formulation and the commercially available drug product. In addition to incorporating this important element of the Ohio Guidance, Lilly encourages the Board to incorporate two additional elements that would meaningfully strengthen this requirement.

First, the Board should specify that the required difference must be in response to an identified medical need and must produce a "clinically" significant difference. Compounders have exploited this ambiguity by adding small amounts of B12 and other vitamins or making minor dosage adjustments to their knockoff GLP-1s—modifications that produce no meaningful clinical benefit for patients[12]—as pretext to mass compound drugs that are essentially copies of

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[9] U.S. Food and Drug Administration, "FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize" issued Apr. 1, 2026, *available at*: https://www.fda.gov/drugs/drug-alerts-and-statements/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

[10] Importantly, FDA recently concluded that there was no clinical need to compound tirzepatide, semaglutide, or liraglutide from bulk drug substances, because there is no basis to conclude that the FDA-approved medicines are "medically unsuitable" for patients and that alternative dosages, forms of administration, or combination versions are needed. *See* U.S. Food and Drug Administration, "List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act" issued May 1, 2026, *available at*: https://www.federalregister.gov/documents/2026/05/01/2026-08552/list-of-bulk-drug-substances-for-which-there-is-a-clinical-need-under-section-503b-of-the-federal.

[11] U.S. Food and Drug Administration, "FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize" issued Apr. 1, 2026, *available at*: https://www.fda.gov/drugs/drug-alerts-and-statements/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

[12] Brad Jordan, et al., "A Novel, Widespread Impurity in Mass-Compounded Tirzepatide/B12 Products: Potential Patient Safety Implications" published Apr. 30, 2026, *available at*: https://www.tandfonline.com/doi/full/10.1080/14740338.2026.2663185 ("Our testing identified a widespread and

FDA-approved medicines. A clinically significant difference standard will help to combat this sham "personalization," while still allowing for compounding for patients with a genuine, documented clinical need that a commercially available product cannot meet.

Second, the Board should require that the clinically significant difference be verified and documented by the dispensing pharmacist. Pharmacist verification creates an additional check against sham "personalization" to ensure that patients only receive compounded drugs when FDA-approved medicines cannot meet their needs.

* * *

Lilly appreciates the opportunity to comment on these important matters. Once more, we applaud the Board's efforts to improve the practice of pharmacy and protect Wisconsin patients. We further urge the Board to pair the adoption of new guidance with increased enforcement to ensure meaningful compliance and to safeguard patient safety. If you have any questions, we would be happy to provide additional information.

Sincerely,

Brad Jordan, Ph.D.
Associate Vice President
Regulatory Policy & Strategy
Eli Lilly and Company

cc: Members of the Pharmacy Examining Board

previously unidentified impurity in compounded tirzepatide-B12 products resulting from a chemical reaction between tirzepatide and certain analogs of B12."); *see also* U.S. Food and Drug Administration, "List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act" issued May 1, 2026, *available at*: https://www.federalregister.gov/documents/2026/05/01/2026-08552/list-of-bulk-drug-substances-for-which-there-is-a-clinical-need-under-section-503b-of-the-federal.

Via Email May 20, 2026

Chairperson John Weitekamp
Board Member Erik Sokn
Executive Director Brad Wojciechowski
Board Counsel Gretchen Mrozinski
Wisconsin Pharmacy Examining Board
PO Box 8366
Madison, WI 53708-8366

Dear Chairperson Weitekamp, Board Member Sokn, Executive Director Wojciechowski, and Counsel Mrozinski:

Thank you for working to protect Wisconsin patients from unlawfully compounded GLP-1 products. I am writing on behalf of Novo Nordisk Inc. ("NNI") in support of the Wisconsin Pharmacy Examining Board's forthcoming GLP-1 compounding guidance ("the Guidance"). We greatly appreciate the Board's efforts, including in the April 2026 Wisconsin Pharmacy Today newsletter, to inform its licensees of their compliance obligations regarding compounding of GLP-1 drugs. The Board's action on this is timely given recent important FDA statements on the lack of a clinical need for GLP-1 products compounded with the bulk drug substances semaglutide, liraglutide, and tirzepatide under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA), which we believe is highly relevant to compounding with these substances under section 503A of the FDCA.[1] We offer recommendations below for the Board's consideration as you develop the Guidance, which include references to GLP-1 guidance in other states that may be useful inputs.

Novo Nordisk is a global healthcare company with a 100-year history of innovation, committed to preventing, treating, and ultimately curing diabetes, and to improving the lives of those living with other serious chronic conditions, including hemophilia, growth disorders, and obesity. NNI is the only company in the United States with FDA-approved medicines containing semaglutide. Semaglutide is the foundational molecule that serves as the primary ingredient for NNI's well-known, prescription only medicines: Ozempic®, Wegovy®, and Rybelsus®.[2]

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[1] FDA, List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act, 91 Fed. Reg. 23431 (May 1, 2026).

[2] Ozempic® (semaglutide) injection is indicated to improve glycemic control in adults with type 2 diabetes, to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease, and to reduce the risk of kidney disease worsening, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes and chronic kidney disease. *See* OZEMPIC®, Full Prescribing Information (May 2026). Wegovy® (semaglutide) injection is indicated for chronic weight management in adults and pediatric patients ages 12 years and older with obesity or adults with overweight with at least one weight-related comorbid condition. Wegovy® is also indicated to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight and for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis ("MASH"), formerly known as nonalcoholic steatohepatitis ("NASH") with moderate to advanced liver fibrosis in adults. *See* WEGOVY®, Full Prescribing Information (May 2026). Wegovy® (semaglutide) tablets are indicated in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight, and to reduce excess body weight and maintain weight reduction long term in adults with obesity or in adults with overweight in the presence of at least one weight-related comorbid condition. *Id.* Rybelsus® (semaglutide) tablets

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As the only company with FDA-approved medicines containing semaglutide, NNI is deeply concerned about the serious public health risks associated with mass manufacturing under the guise of compounding. Over the last several years, there has been an overwhelming opportunistic surge of compounding, particularly of GLP-1 medicines such as semaglutide.[3] In the wake of significant demand for injectable semaglutide medicines, the compounding industry began to mass produce these drugs. Although the injectable semaglutide shortage ended over a year ago, and even though there are multiple approved semaglutide medicines available to patients, many compounding entities continue to produce semaglutide drugs and attempt to evade compounding laws by selling versions of these drugs with unnecessary and pretextual changes to doses, routes of administration, and ingredients.

These practices far exceed the intent of the legal framework for compounding and unnecessarily expose patients to unapproved drugs. One medical expert described the mass compounding of GLP-1 drugs as "the largest uncontrolled, unconsented human experiment of our time."[4] Unlawful and unsafe compounding schemes and an influx of imported, substandard active pharmaceutical ingredients ("API") contribute to this serious public health problem.

Risks to patients with the mass expansion of GLP-1 compounding are real. NNI testing of compounded injectable semaglutide samples found peptide-related impurities up to 86.2% total.[5] One oral compounded semaglutide product contained almost 75% total impurities. Peptide-related impurities can cause the formation of anti-drug antibodies that can impact the effectiveness of semaglutide drugs, including FDA-approved semaglutide medicines, as well as interfere with the role that native GLP-1 plays in the body. Testing has revealed myriad other safety and effectiveness risks as well, including significant super- and sub-potency, ingredients banned by FDA for use in compounding, and unapproved drug-drug combinations where interactions affect the stability and structure of semaglutide.[6]

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are indicated to improve glycemic control in adults with type 2 diabetes and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes who are at high risk for these events. *See* RYBELSUS® Full Prescribing Information (Jan. 2026).

[3] The semaglutide bulk drug substance used by pharmacy compounders is not the same semaglutide used in Novo Nordisk's FDA-approved medicines. Novo Nordisk manufactures its semaglutide in yeast using recombinant DNA technology, whereas the compounders use bulk drug substances that are generally manufactured by chemical synthesis. Furthermore, the semaglutide used in Novo Nordisk's FDA-approved medicines is manufactured exclusively by the Novo Nordisk entities listed in the new drug applications for these medicines. For the purposes of this letter, we will refer to the compounded products as containing "semaglutide," even though these bulk drug substances are meaningfully different from Novo Nordisk's semaglutide.

[4] *See* The Obesity Society, *FDA-Approved vs. Compounded GLP-1s: Comparing Safety, Quality, and Transparency*, at 9:51–9:58 (Mar. 19, 2025) (statement of Angela Fitch, MD, immediate past president of The Obesity Society); *see also Restoring Trust in FDA: Rooting Out Illicit Products: Hearing Before the H. Comm. on Oversight & Gov't Reform*, 119th Cong. 11–12 (2025) (statement of David Kessler, former FDA Commissioner) ("In my opinion . . . we have been conducting a reckless national experiment with compounded new weight loss drugs, the GLP-1s.").

[5] Supplement to Citizen Petition from Novo Nordisk Inc. to No. FDA-2024-P-5378 at 3, 25 (Jan. 12, 2026).

[6] *See* Nomination from Covington & Burling LLP on Behalf of Novo Nordisk Inc. to No. FDA-2017-N-2562 (Oct. 22, 2024) (nomination of semaglutide products to the 503A and 503B DDC Lists); Supplement from Novo Nordisk, Inc. to its Citizen Petition to Docket No. FDA-2024-P-5378 (Apr. 22, 2025); Supplement from Novo Nordisk Inc. to its Citizen Petition to Docket No. FDA-2024-P-5378 (Jan. 12, 2026); Morten Hach et al., *Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-on GLP-1 Polypeptide Drugs*, 41 Pharm. Rsch. 1991 (2024); Eli Lilly & Company, *An open letter from Eli Lilly and Company warning of potential patient safety risks associated with tirzepatide compounded with vitamin B12* (Mar. 12, 2026).

To help protect Wisconsin patients from these risks, we urge the Board to ensure that the Guidance clarifies the narrow circumstances in which GLP-1 drugs may be compounded and distributed. At a high level, it is important that the Guidance make clear that, now that the GLP-1 shortages and FDA's associated enforcement discretion periods have ended:

- Pharmacies and physicians may not compound semaglutide products for patients who can take FDA-approved semaglutide medicines.
- Compounders must compound with pharmaceutical-grade API accompanied by a valid certificate of analysis from an FDA-registered API manufacturer.
- Semaglutide products compounded by an outsourcing facility may no longer be distributed or dispensed, regardless of when they were compounded.

I. Consistent with Federal Law and Recent State Guidance, Wisconsin Should Clarify the Narrow Circumstances in Which Pharmacies May Compound Versions of FDA-Approved GLP-1 Drugs

A. Federal Restrictions

Because compounded drugs are riskier than FDA-approved products, there is widespread agreement that a compounded product "should only be used for patients whose medical needs cannot be met by an available FDA-approved drug."[7] Recognizing this principle, section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA)[8] prohibits pharmacies from compounding drugs unless the compounded products meet all the conditions in the section.

One of the conditions of section 503A is that a compounded product must be "necessary" for "an identified individual patient." "Necessary" does not mean mere preference, and FDA has said in guidance that a compounded drug is not appropriate under section 503A if a patient can take a commercially available drug.

Another condition of section 503A is that pharmacies may not compound regularly or in inordinate amounts drugs that are "essentially copies" of a commercially available drug product. Under the law, a drug is "essentially a copy of a commercially available drug product" unless a prescriber determines that there is a change between the compounded drug and the comparable commercially available drug that makes a significant difference for an individual, identified patient.

As FDA has stated in guidance, the section 503A copies restrictions are intended to ensure that pharmacists do not compound drug products for patients who could use a commercially available drug product.[9] Per FDA guidance, the documentation of the prescriber

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[7] FDA, FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated With Compounded Injectable Semaglutide Products (July 26, 2024).

[8] 21 U.S.C. § 353a.

[9] *See* FDA, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry* 3 (Jan. 2018), https://www.fda.gov/files/drugs/published/Compounded-Drug-Products-That-Are-Essentially-Copies-of-a-

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determination must make clear that the prescriber identified the relevant change between the compounded drug and the commercially available drug, as well as the significant difference that the change will produce for the patient.[10]

On May 1, 2026, FDA took an important step to address unlawful mass compounding of GLP-1 drugs by issuing a notice proposing to not include semaglutide, tirzepatide, and liraglutide on the 503B Bulks List.[11] In support of this notice, FDA provided a thorough scientific analysis confirming there is no medical basis or clinical need for outsourcing facilities to compound using these bulk drug substances. FDA's analysis specifically states that there is no clinical need for certain compounded products, including compounded semaglutide products with other active ingredients (like vitamin B-6), with different strengths (including microdoses and higher doses), or with different routes of administration (like sublingual or buccal) compared to FDA-approved semaglutide medicines. In addition, FDA did not identify any basis to conclude that the ingredients, strengths, or routes of administration of commercially available and FDA-approved GLP-1 medicines including Ozempic® and Wegovy®, caused those products to be medically unsuitable for patients. FDA further explained that it does not consider "convenience," "cost," or "preference" when assessing "clinical need."

We believe that FDA's recent 503B bulks list notice is also highly relevant to compounding of GLP-1s under section 503A. On FDA's website addressing "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss," FDA clearly states that "[c]ompounded drugs should only be used in patients whose medical needs cannot be met by an FDA-approved drug."[12] In its notice, FDA did not identify any patient population whose medical needs cannot be met by an FDA-approved semaglutide medicine. Accordingly, in our view, the compounded semaglutide products that FDA discusses in the notice—which include semaglutide compounded with vitamins, as microdoses and macrodoses, and in sublingual and buccal routes of administration—cannot be "necessary," or produce a "significant difference," for an "identified individual patient" under section 503A.

Applying FDA's findings in its notice to section 503A would reinforce that compounding is meant to be a rare and limited exception to FDA's gold-standard drug approval framework, which ensures that medicines in the United States are safe and effective. By design, non-FDA-approved compounded drugs are intended to be a last resort when there is no available FDA-

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Commercially-Available-Drug-Product-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf.

[10] *See also* Kan. State Bd. of Pharmacy, *Statement on Compounding and Dispensing of Compounded GLP-1 and GIP Receptor Agonists* at 3 (last updated Apr 22, 2026) ("If a change is made to the commercially available product for an identified individual patient and the prescribing practitioner has determined that the change will produce a significant difference for that patient, there is still a minimum threshold. The FDA has stated that 'if a prescription identifies only a patient name and drug product formulation, this would not be sufficient to establish that the prescriber made the determination described by section 503A(b)(2). Note also that the significant benefit that the prescriber identifies must be produced by the change the compounder will make to a commercially available drug product (i.e., a change in drug product formulation). Other factors, such as a lower price, are not sufficient to establish that the compounded drug product is not essentially a copy of the commercially available drug product.'").

[11] 91 Fed. Reg. at 23431.

[12] FDA, *FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss* (Feb. 4, 2026).

approved medication that can meet an individual patient's clinical need. They should not be made available for convenience, preference, or some tangential, possible benefit.

B. Kansas Guidance

Recently, the Kansas State Board of Pharmacy updated its Statement on Compounding and Dispensing of Compounded GLP-1 and GIP Receptor Agonists to clarify that "FDA requires the compounded product be 'necessary' and not merely preference."[13] The Kansas BOP also made a number of additional clarifying statements regarding documentation of medical need to address a growing problem. In recent years, there has been an uptick in pharmacies mass-marketing fixed formulations, including unnecessary strengths, routes of administration and ingredient combinations, without any legitimate prescriber determination of medical need. To drive use of these formulations, some compounders are using check-the-box forms, preprinted or prepopulated prescription pads, and other preprinted or prespecified statements that do not explain how a compounded product provides a significant therapeutic difference for each individual patient based on the particular patient's medical need. Kansas recently addressed this concern by adding the following explanation to its statement on GLP-1 compounding:

> Pre-printed, pre-populated, check-box, or boilerplate prescriptions may not meet the requirements for pharmacist and pharmacy compounding. Furthermore, pharmacist or pharmacy-initiated requests for compounded formulations do not meet the requirement of a prescriber's clinical determination. These do not provide sufficient documentation of a specific medical need for an individual patient, and do not adequately explain how a change in a compounded product results in a clinically significant therapeutic response from the commercially available product.[14]

These statements by the Kansas BOP may be of interest to Wisconsin as it considers the content of its guidance.

C. Wisconsin Guidance

As the Wisconsin Board recognized in its recent newsletter, "[i]n the GLP-1 space, the FDA has issued warnings about compounded GLP-1 drugs and made it clear that compounded products cannot simply replicate FDA-approved GLP-1 drugs when those approved [drugs] are no longer considered in shortage."[15] To prevent compounders from unnecessarily exposing patients to the risks of unapproved compounded GLP-1 products, the Guidance should clarify that compounding can occur only when there is an individual medical need that cannot be met by a commercially available FDA-approved product. The Guidance should require the pharmacy to have documentation that explains why the FDA-approved product is not medically suitable, and how the compounded product produces a clinically significant therapeutic response in the patient that addresses the medical unsuitability. The Guidance should point to FDA's notice as a

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[13] Kan. State Bd. of Pharmacy, *Statement on Compounding and Dispensing of Compounded GLP-1 and GIP Receptor Agonists* at 2 (last updated Apr. 22, 2026).

[14] *Id.* at 3.

[15] Wis. Pharmacy Examining Bd., Wisconsin Pharmacy Today at 1 (Apr. 2026).

reference for pharmacies to use to evaluate the documentation it receives from the prescribers to assess compliance with federal and state law. The Guidance should also clarify that prepopulated prescription or check-the-box forms are not sufficient documentation of a specific medical need.

Potential Language:

Q: Under what circumstances are compounded GLP-1s "necessary for the identified patient"?

Under section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA), a compounded product must be "necessary for the identified patient." FDA recently issued a Federal Register notice proposing to exclude semaglutide, liraglutide, and tirzepatide bulk drug substances from the list of bulk drug substances that may be used in compounding by outsourcing facilities under section 503B of the FDCA. FDA's notice states that there is no clinical need for the proposed compounded products, which include compounded semaglutide products with other active ingredients (like vitamin B-6), different strengths (including microdoses and higher doses), or different routes of administration (like sublingual or buccal) compared to FDA-approved semaglutide medicines. FDA did not identify any basis to conclude that the ingredients, strengths, or routes of administration of the FDA-approved GLP-1 medicines caused those products to be medically unsuitable for patients. FDA further explained that it does not consider "convenience," "cost," or "preference" when assessing "clinical need." Pharmacies should refer to this notice when assessing whether a compounded GLP-1 is necessary for an identified patient under section 503A of the FDCA.

Q: Can GLP-1s be compounded or distributed if a GLP-1 medication is commercially available?

Under section 503A of the FDCA and Wisconsin law, compounding "drug products that are essentially copies of a commercially available drug product" (e.g., by a pharmacy or prescriber) regularly or in inordinate amounts is prohibited unless either of the following exceptions occurs:

(1) A drug is not commercially available (i.e., the drug product has been discontinued and is no longer marketed); ***OR***

(2) The compounded drug includes a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the commercially available product.

Q: Does a compounder need to obtain prescriber documentation of the specific reason that the compounded drug would produce a significant difference from the commercially available drug product?

Yes. If a compounder (e.g., pharmacy or physician) intends to rely on such a determination to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder must ensure that the determination is documented on the prescription or order. The documentation should explain a clinical reason why an FDA-approved drug cannot be used (excluding cost and convenience), how the compounded product

is different from the drug approved by FDA in a way that produces a clinically significant therapeutic response in the patient, and how that therapeutic response addresses why a patient cannot take an FDA-approved drug. Compounders should retain such documentation for at least five years. This documentation should not consist of check-the-box prepopulated, or other boilerplate forms or statements; patient-completed forms or patient-generated online orders that later receive a prescriber signature; or documentation that states the patient needs a compounded drug that combines two commercially available drugs, when these commercially available drugs could be taken separately.

Q: Does combining a GLP-1 with co-actives like cyanocobalamin (a form of vitamin B12) satisfy the "necessary for the identified patient" and "significant difference" requirements?

No. According to FDA's website titled "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss," compounded drugs should only be used in patients whose medical needs cannot be met by an FDA-approved drug.[16] Under section 503A of the FDCA, a compounded product must be "necessary for the identified patient." When FDA assessed whether there is a clinical need for an outsourcing facility to compound GLP-1s with pyridoxine (vitamin B6) or an antiemetic, FDA did not identify an attribute of the approved products that made them medically unsuitable (e.g., why a patient could not receive an FDA-approved GLP-1 product and separately an FDA-approved pyridoxine product or antiemetic).[17] Likewise, there is no reason why a patient cannot receive an FDA-approved GLP-1 product and separately an FDA-approved cyanocobalamin product. Therefore, a compounded GLP-1 and cyanocobalamin product are not necessary for an identified patient.

Also under section 503A of the FDCA, a compounded product cannot be essentially a copy of a commercial available drug product that is compounded regularly or in inordinate amounts. FDA considers a compounded drug product to be essentially a copy of a commercially available drug product if the compounded drug product contains the same APIs as two or more commercially available drug products in the same, similar, or easily substitutable strength and if the commercially available drug products can be used (regardless of how they are labeled) by the same route of administration prescribed for the compounded drug, unless there is documentation as described in Q[#] above. There is no clinically significant difference that can be documented for a patient taking semaglutide and cyanocobalamin together that cannot be achieved from taking commercially available semaglutide and cyanocobalamin products separately. FDA has stated that "a compounded drug product that combines semaglutide API and another API, [including] vitamin B12 (cyanocobalamin), [is] essentially a copy of a commercially available drug product when the[] drug products are used by the same route of administration [and] the drug products are the same, similar, or easily substitutable strength."[18]

[16] FDA, *FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss* (Feb. 4, 2026).

[17] FDA, List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act, 91 Fed. Reg. 23431 (May 1, 2026).

[18] FDA, FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize (Apr. 1, 2026).

II. The Guidance Should Explain the Requirements on the Use of Bulk Drug Substances and the Prohibition on Compounding under Insanitary Conditions

Federal law places important requirements on the use of bulk drug substances in compounding that the guidance should reiterate. These include specific circumstances under which a bulk drug substance may be used, and requirements about their quality.

Under section 503A, a licensed pharmacist or licensed physician that compounds the drug product must only use bulk drug substances[19] 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 drug substances that are components of drugs approved by the Secretary of the Department of Health and Human Services (Secretary); or
>
> (3) If such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A.[20]

Bulk drug substances used in compounding under section 503A must also meet certain other requirements, including: (1) the bulk drug substance must be manufactured by an establishment registered under section 510 of the FDCA[21] and (2) the bulk drug substance must be accompanied by a valid certificate of analysis (COA).[22]

Moreover, the law prohibits compounding under insanitary conditions under section 501(a)(2)(A) of the FDCA.[23] That section deems a drug to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health[.]" In guidance, FDA has made clear that insanitary conditions include "[u]sing active ingredients, inactive ingredients, or processing aids, that have or may have higher levels of impurities compared to compendial or

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[19] A *bulk drug substance* is defined as meaning "the same as 'active pharmaceutical ingredient' as defined in [21 C.F.R. §] 207.1." 21 C.F.R. § 207.3. *Active pharmaceutical ingredient* is defined as "any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body," but the term "does not include intermediates used in the synthesis of the substance." *See* section 21 U.S.C. § 353a(b)(1)(A) and 21 C.F.R. § 207.3. FDA has interpreted "an applicable USP or NF monograph" to mean an official USP or NF *drug substance* monograph. *See* the preamble of the final rule "List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act," 84 Fed. Reg. 4696, 4705 (Feb. 19, 2019).

[20] *See* 21 U.S.C. § 353a(b)(1)(A)(i).

[21] 21 U.S.C. § 360.

[22] *See* 21 U.S.C. § 353a(b)(1)(A).

[23] 21 U.S.C. § 351(a)(2)(A).

pharmaceutical grade equivalents," including "ingredients with potentially harmful impurities [and] ingredients labeled with 'not for pharmaceutical use' or an equivalent statement[.]"[24]

Potential Language:

Q: What requirements apply to compounding a GLP-1 drug from a bulk drug substance (active pharmaceutical ingredient)?

A pharmacy may only compound using bulk drug substances that:

1) Comply with the standards of an applicable United States Pharmacopoeia (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 drug substances that are components of drugs approved by the FDA; or

3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the FDA, that appear on FDA's list of bulk drug substances that can be used in compounding pursuant to section 503A(b)(1)(A)(i)(III) of the FDCA (the 503A Bulks List).

A pharmacy must also ensure that the API used in compounding is manufactured by an API manufacturer registered with the FDA under section 510 of the FDCA, is a pharmaceutical-grade product, and is accompanied by a valid certificate of analysis describing the identity and content of the substance as well as individual impurities identified by chemical name and amount present. Moreover, ingredients labeled with 'not for pharmaceutical use' or an equivalent statement may not be used in compounding.

III. The Guidance Should Explain that the Continued Distribution and Dispensing of Semaglutide Products Compounded by Outsourcing Facilities is Unlawful

Semaglutide products compounded by outsourcing facilities may not be legally dispensed or distributed, regardless of when they were made, because these products do not meet the conditions of section 503B. Under section 503B of the FDCA, a drug compounded by an outsourcing facility is exempt from three sections of the FDCA (i.e., the requirements for drug approval, adequate directions for use, and drug supply chain security) so long as it meets ***all*** of the conditions listed in section 503B.[25] The exemptions and conditions under section 503B of the FDCA apply to "a drug," not an entity.[26] When a ***drug*** compounded by an

[24] *See* FDA, *Insanitary Conditions at Compounding Facilities: Guidance for Industry* (Nov. 2020).

[25] *See* 21 U.S.C. § 353b(a).

[26] *Id.* ("Sections 352(f)(1), 355, and 360eee-1 of this title shall not apply to ***a drug*** compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met") (emphasis added).

outsourcing facility does not satisfy all of the conditions of 503B, it is an unapproved new drug and misbranded. This means that no entity may legally distribute or dispense that drug.

One of the conditions for a drug product compounded by an outsourcing facility to be eligible for the exemptions under section 503B is that the outsourcing facility must not compound drug products using a bulk drug substance unless (1) it appears on FDA's 503B Bulks List or (2) "the drug compounded . . . appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, ***and*** dispensing." Semaglutide does not appear on the 503B Bulks List, and FDA removed injectable semaglutide products from its Drug Shortage List on February 21, 2025.[27] Since that date, it has been unlawful for an outsourcing facility to compound drugs using semaglutide bulk drug substance and for any person to distribute or dispense a semaglutide drug product compounded by an outsourcing facility.[28]

A drug compounded by an outsourcing facility that does not meet any of the conditions listed in section 503B is an unapproved new drug and misbranded. Section 301 of the FDCA prohibits a person from introducing in interstate commerce, delivering for introduction, or causing the introduction or delivery for introduction into interstate commerce any drug that violates FDA's premarket approval requirements or is misbranded.[29] This means that any outsourcing facility, pharmacy, or other entity distributing a drug compounded by an outsourcing facility that does not meet all the conditions in section 503B would be introducing an unapproved new drug and misbranded drug into interstate commerce in violation of federal law.

The Kansas State Board of Pharmacy recently issued a statement clarifying that semaglutide products compounded by outsourcing facilities are not currently eligible for the exemptions under section 503B. Specifically, Kansas stated:

> Tirzepatide and semaglutide do not appear on the 503B Bulks List, nor do they appear on FDA's drug shortage list. Therefore, no salt form of semaglutide or tirzepatide may be used in a compounded drug product. Human drug products compounded with tirzepatide or semaglutide do not currently qualify for the exemptions and human drug products compounded with tirzepatide or semaglutide would not be exempt from the

[27] On April 24, 2025, a court in the United States District Court for the Northern District of Texas denied an attempt to reverse FDA's decision to remove semaglutide injection products from the Drug Shortage List. *See Outsourcing Facilities Assoc. v. FDA*, 4:25-cv-00174-P (N.D. Tex. Apr. 24, 2025) (opinion & order denying preliminary injunction). On June 13, 2025, the Court upheld FDA's decision, and dismissed the compounders' case on June 17, 2025. *Outsourcing Facilities Assoc. v. FDA*, 4:25-cv-00174-P (N.D. Tex. June 13, 2025) (opinion & order denying plaintiffs' motion for summary judgment and granting FDA's motions for summary judgment); *Outsourcing Facilities Assoc. v. FDA*, 4:25-cv-00174-P (N.D. Tex. June 17, 2025) (final judgment dismissing case with prejudice). OFA appealed the decision, and the appeal is pending before the Fifth Circuit Court of Appeals.

[28] Exercising enforcement discretion, FDA announced that, for outsourcing facilities, it did "not intend to take action against compounders for violations of the [FDCA] arising from conditions that depend on semaglutide injection products' inclusion on FDA's drug shortage list" until May 22, 2025. FDA, *FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize* (Feb. 21, 2025).

See also Kan. State Bd. of Pharmacy, *Statement on Compounding and Dispensing of Compounded GLP-1 and GIP Receptor Agonists* at 2 (last updated Apr. 22, 2026).

[29] *See* 21 U.S.C. § 331(a), (d).

requirements of FDA premarket approval and labeling with adequate directions for use and DSCSA requirements.[30]

We are aware of outsourcing facilities that unlawfully compounded semaglutide products after the shortage and enforcement discretion periods ended. We are also aware of telehealth companies and pharmacies that unlawfully distributed 503B compounded semaglutide products after the shortage and enforcement discretion periods ended. We therefore request that the Guidance make clear that these activities are unlawful.

Potential Language:

Q: Can an outsourcing facility compound semaglutide?

No. One of the conditions for a drug product compounded by an outsourcing facility to be eligible for the exemptions under section 503B of the FDCA is that the outsourcing facility must not compound drug products using a bulk drug substance unless (1) it appears on FDA's 503B Bulks List or (2) "the drug compounded . . . appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing." Semaglutide does not appear on the 503B Bulks List or on the section 506E shortage list, so it is unlawful for an outsourcing facility to compound semaglutide drug products.

Q: Can a prescriber clinic or pharmacy continue to dispense compounded semaglutide that was previously purchased from an outsourcing facility prior to the end of the injectable semaglutide shortage and associated FDA enforcement discretion period?

No. A prescriber clinic or pharmacy (including a mail order pharmacy) which previously purchased a semaglutide drug compounded by an outsourcing facility prior to the end of the injectable semaglutide shortage and associated enforcement discretion period may not continue to dispense and distribute the compounded drug.

The exemptions and conditions under section 503B of the FDCA apply to "a drug," not to the clinic, pharmacy, or outsourcing facility that distributes or dispenses the drug. Compounded semaglutide drug products do not meet the conditions of section 503B because semaglutide injection products are no longer in shortage and semaglutide is not on the 503B Bulks List. When a drug compounded by an outsourcing facility does not satisfy all of the conditions of section 503B, it is an unapproved new drug and a misbranded drug, and no one may legally distribute or dispense it—including a prescriber clinic or a pharmacy.

Finally, we recommend that the Guidance reiterate the point made in its newsletter, that "dispensing a compounded GLP-1 drug may carry risk of non-compliance under both state (Wis. Admin. Code ch. Phar 15) and federal law." We suggest the Guidance also make clear that licensees and registrants who fail to follow federal law, as described in the Guidance, have

[30] *See* Kan. State Bd. of Pharmacy, *Statement on Compounding and Dispensing of Compounded GLP-1 and GIP Receptor Agonists* at 2 (last updated Apr. 22, 2026).

engaged in unprofessional conduct and are therefore subject to discipline under Wis. Stat. Ann. § 450.10.

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We appreciate the Board's dedication to safeguarding patient health and upholding high standards to protect patients' health and safety. Thank you for the opportunity to provide feedback on the Guidance. We would be pleased to provide additional input or clarification of our feedback if needed.

Sincerely,

Gabrielle Cosel
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To: Wisconsin Pharmacy Examining Board
From: Wisconsin Aesthetic Provider Coalition
Date: February 12, 2026
RE: Considerations & Position Statement on Guidance on Compounding Pharmacies, Phar 15, and Semaglutide/Tirzepatide Production

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On behalf of the Wisconsin Aesthetic Provider Coalition (WAPC), we respectfully submit this position statement regarding the prescribing and compounding of GLP-1/GIP's, including semaglutide and tirzepatide.

Our coalition represents licensed healthcare providers who are committed to patient safety, regulatory compliance, and evidence-based medical decision-making. We believe it is critical that Wisconsin patients continue to have access to legally prescribed medications dispensed through pharmacies that are properly licensed by the State of Wisconsin and federally under 503A or 503B, including pharmacies physically located outside the state that hold active Wisconsin licensure.

Safe Access to GLP-1/GIP Therapies in Wisconsin

Access to GLP-1/GIP medications matter *especially* in Wisconsin because obesity is one of the state's biggest public-health drivers — and GLP-1s directly target many of the health risks Wisconsinites are facing.
Wisconsin's health data shows why medications like GLP-1s/GIPs are getting so much attention.

- Around 32–41% of Wisconsin adults have obesity, and about 68% live with excess weight overall. (citation 4)

- Some research measuring height/weight directly found rates as high as ~39% obese, higher than national averages in certain populations. (citation 5)

- Rates vary drastically by ZIP code, with some areas reaching 67% obesity prevalence, especially in rural communities. (citation 6)
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That matters because obesity is strongly linked to diabetes, heart disease, cancer, and chronic illness — conditions that already strain Wisconsin healthcare systems and employers.
Bottom line: When a third to nearly half of adults have obesity, medications that can safely reduce weight and metabolic risk, have a significant population impact. This has numerous public health benefits, including significant reductions in cardiovascular events and hospitalizations among obese patients (citation 1), anti-inflammatory benefits that may lower risks tied to heart disease and metabolic complication (citation 2), and lower risks for cancers and diabetes. (citation 3)

Framework for Prescribing and Dispensing GLP-1/GIP Medications

Prescribing Authority

Physicians (MDs/DOs), physician assistants and nurse practitioners may prescribe GLP-1/GIP medications within their scope of practice. Consistent with this framework, the administration of prescribed GLP-1/GIP's medications by nurses or advanced practice providers occurs within the scope of their respective professional licenses, or pursuant to appropriate physician delegation, and does not itself constitute the independent practice of pharmacy.

Compounding & Pharmacy Standards

We support the use of compounding pharmacies that operate under state and federal regulatory frameworks designed to promote safety and quality. Licensed Wisconsin pharmacies, whether physically located within the state or located outside Wisconsin but holding an active Wisconsin pharmacy license—play a critical role in ensuring medication safety and regulatory compliance. These pharmacies operate under Wisconsin licensure requirements and are subject to oversight by the Wisconsin Pharmacy Examining Board. Providers prescribing medications through these pharmacies do so with the understanding that dispensing occurs in accordance with Wisconsin law. Our organization endorses partnerships with pharmacies that:

- Hold appropriate state licensure and comply with applicable pharmacy regulations (503A / 503B)
- Follow USP <795>, <797>, and <800> standards where applicable
- Utilize sterile compounding practices when required

- Maintain clear quality assurance, testing, and traceability procedures

Importantly, providers have direct access to licensed pharmacists practicing at these Wisconsin-licensed pharmacies for consultation, medication clarification, patient counseling coordination, and regulatory compliance. This access supports appropriate prescribing, enhances patient safety, and ensures adherence to all applicable state requirements, regardless of the physical location of the pharmacy.

Clinical Responsibility

Prescribers exercise independent clinical judgment when recommending compounded medications, based on patient-specific assessment, clinical evidence, risk–benefit analysis, and informed consent.

Providers are responsible to educate patients about the nature of compounded medications, including the fact that compounded drugs are not FDA-approved in the same manner as commercially manufactured pharmaceuticals.

Position Summary

- Licensed prescribers should retain the authority to prescribe GLP1's/GIP medications based on individual patient needs and clinical judgment.
- Pharmacies licensed by the State of Wisconsin—including those physically located outside the state—should be permitted to dispense prescribed medications to Wisconsin patients in accordance with existing state and federal regulations.
- Providers should be able to rely on access to licensed pharmacists at Wisconsin-licensed pharmacies to support safe prescribing and dispensing practices.
- Regulatory actions should focus on enforcement of existing pharmacy and prescribing standards rather than restricting access to care.
- Any policy changes should be evidence-based, transparent, and developed with meaningful input from practicing healthcare providers.

Limiting the ability of licensed providers to prescribe medications dispensed by Wisconsin-licensed pharmacies would interfere with the provider–patient relationship and reduce access to care for patients across the state. Such restrictions may disproportionately affect patients who face barriers related to cost, availability, or geographic access to care.

We strongly support regulatory oversight that ensures patient safety while preserving access to medically appropriate treatment options and respecting the professional judgment of licensed providers. We appreciate the Board's commitment to public health and welcome continued dialogue to ensure that Wisconsin's regulatory framework remains balanced, practical, and patient-centered.

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