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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison
Contact: Brad Wojciechowski (608) 266-2112
December 18, 2025

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

AGENDA

11:00 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-4)

B. Approval of Minutes of October 16, 2025 (5-10)

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements and Recognition
1. Introduction: Paul Esser, Public Member (Succeeds: Walsh)

E. Administrative Matters – Discussion and Consideration
1. Department, Staff and Board Updates
2. **Election of Officers, Appointments of Liaisons and Alternates, Delegation of Authorities**
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. Walsh, Michael – 7/1/2024
   f. Weitekamp, John G. – 7/1/2026
   g. Wilson, Christa – 7/1/2029

F. 11:00 A.M. Public Hearing for Clearinghouse Rule 25-073 on Phar 7, 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 (11-23)
1. Review Public Hearing Comments and Respond to Clearinghouse Report

G. Legislative and Policy Matters – Discussion and Consideration

H. Administrative Rule Matters – Discussion and Consideration (24-30)

1. Preliminary Rule Draft: Phar 1, 6 ,7, and 10, Relating to Pharmacy Workplace Conditions **(25-29)**
2. Pending or Possible Rulemaking Projects **(30)**

I. Speaking Engagements, Travel, or Public Relation Requests, and Reports – Discussion and Consideration (31)

1. Consider Attendance: 122nd NABP Annual Meeting – May 12-15, 2026 – Boston, MA

J. Implement 2021 Wisconsin Act 9 – Top 100 Most Prescribed Drugs – Discussion and Consideration (32-35)

K. Guidance on Compounding Pharmacies, Phar 15, and Semaglutide/Tirzepatide Production – Discussion and Consideration (36-94)

L. Newsletter Matters – Discussion and Consideration

M. Interdisciplinary Advisory Committee – Discussion and Consideration

N. Credentialing Matters – Discussion and Consideration (95)

1. Remote Dispensing Site Application Update

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

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

Q. Liaison Reports – Discussion and Consideration

R. 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

S. 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.).

T. Credentialing Matters

1. Application Review

a. B.S.O. – Wholesale Distributor Application (IA- 672656) **(96-611)**
b. B.P. – Wholesale Distributor Application (IA- 692754) **(612-647)**
c. C.W. – Wholesale Distributor Application (IA- 695214) **(648-685)**
d. C.S.B. – Pharmacy Technician Application (IA- 397000) **(686-718)**
e. R.P.M. – Pharmacist Application (IA- 104328) **(719-731)**

2. Inspection Report Review

a. P. – Inspection Report Review Follow Up **(732-799)**

U. Deliberation on Division of Legal Services and Compliance Matters

1. Administrative Warnings

a. 24 PHM 0071 – E.P. **(800-806)**
b. 24 PHM 0071 – K.C.T. **(807-813)**
c. 24 PHM 0157 – J.L.T. **(814-815)**

2. Case Closings

a. 23 PHM 104 – J.A.H. **(816-820)**
b. 23 PHM 147 – A.R. **(821-827)**
c. 24 PHM 012 – W. **(828-834)**
d. 24 PHM 0109 – A.P.L. **(835-837)**
e. 24 PHM 0116 – W. **(838-843)**
f. 24 PHM 0133 – M.D. **(844-848)**
g. 24 PHM 0133 – M.D.C.R. **(849-855)**
h. 24 PHM 0143 – M.M.P. **(856-861)**
i. 24 PHM 0157 – C.V.S. and P.L.R. **(862-882)**
j. 24 PHM 0161 – F.D.C. and L.A.G. **(883-890)**
k. 24 PHM 0178 – C.V.S. and S.J.W. **(891-898)**
l. 25 PHM 0012 – M.F.P. **(899-903)**
m. 25 PHM 0077 – P., P.L., P. and P.L. **(904-910)**
n. 25 PHM 0117 – W.P. **(911-915)**

3. Proposed Stipulations, Final Decisions and Orders

a. 24 PHM 0137 – Daniel L. Zatarski **(916-922)**
b. 24 PHM 0143 – Julie A. Harer **(923-928)**

V. 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

W. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: FEBRUARY 26, 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
OCTOBER 16, 2025

PRESENT: Tiffany O'Hagan; Anthony Peterangelo, Erick Sokn, Michael Walsh, John Weitekamp, Christa Wilson

STAFF: Brad Wojciechowski, Executive Director; Jameson Whitney, 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 11:05 a.m. A quorum was confirmed with six (6) members present.

ADOPTION OF AGENDA

Amendments to the Agenda:
Moving R.4.a. 24 PHM 0163 – R.S.H.M. to R.3.b. 24 PHM 0163 – Richard S.H. Moresco.
Striking Petition for Authorization to Request Extension of Time from agenda.

MOTION: Michael Walsh moved, seconded by Erick Sokn, to adopt the Agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF AUGUST 21, 2025

MOTION: Erick Sokn moved, seconded by Anthony Peterangelo, to approve the Minutes of August 21, 2025, as published. Motion carried unanimously.

INTRODUCTIONS, ANNOUNCEMENTS, AND RECOGNITION

Recognition: Michael Walsh, Public Member (Resigns: 10/16/2025)

MOTION: John Weitekamp moved, seconded by Anthony Peterangelo, to recognize and thank Michael Walsh for their years of dedicated service to the Board and State of Wisconsin. Motion carried unanimously.

Recognition: Whitney DeVoe, DPD/DSPS

MOTION: John Weitekamp moved, seconded by Michael Walsh, to recognize and thank Whitney DeVoe for their years of dedicated service to the Board and State of Wisconsin. Motion carried unanimously.

ADMINISTRATIVE MATTERS

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)	Christa Wilson, Anthony Peterangelo *Alternate*:
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 *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

ADMINISTRATIVE RULE MATTERS

Emergency Rule Draft: Phar 1, 6 ,7, and 10, Relating to Pharmacy Workplace Conditions

MOTION: Anthony Peterangelo moved, seconded by Erick Sokn, to authorize the Chairperson to approve the emergency rule revising Phar 1, 6, 7, and 10, relating to Pharmacy Workplace Conditions for emergency rule submission to the Governor and publication in an official newspaper. Motion carried unanimously.

Scope Statement: Phar 1 and 7, Relating to Patient Drug Information Monographs

MOTION: Erick Sokn moved, seconded by John Weitekamp, to table the Scope Statement revising Phar 1 and 7, relating to Patient Drug Information Monographs. Motion carried unanimously.

CLOSED SESSION

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, 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: Tiffany O'Hagan-yes; Erick Sokn-yes; Anthony Peterangelo-yes; Michael Walsh-yes; John Weitekamp-yes; and Christa Wilson-yes. Motion carried unanimously.

The Board convened into Closed Session at 11:54 a.m.

CREDENTIALING MATTERS

Application Review

A.H.D. – Pharmacy Technician (IA-577820)

MOTION: Christa Wilson moved, seconded by Michael Walsh, to approve the Pharmacist Technician application IA-577820. Motion carried unanimously.

A.P. – Pharmacy (Out-of-State) (IA-652819)

MOTION: Erick Sokn moved, seconded by Tiffany O'Hagan, to approve the Pharmacy (Out-of-State) application IA-652819, once all requirements are met. Motion carried unanimously.

B.V.S. – Pharmacy (Out-of-State) (IA-672331)

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to authorize Board Counsel to request additional information from Applicant IA-672331. Motion carried unanimously.

V.I. – Third-Party Logistics Provider (Out-of-State)

MOTION: Erick Sokn moved, seconded by Michael Walsh, to deny the Third-Party Logistics Provider (Out-of-State) application for V.I.. **Reason for Denial**: Wis. Stats. § 450.075(3)(c), requirements for designated representative not met. Motion carried unanimously.

W.S.P. – Pharmacy (Out-of-State) (IA-642122)

MOTION: Michael Walsh moved, seconded by Erick Sokn, to approve the Pharmacy (Out-of-State) application IA-642122, once all requirements are met. Motion carried unanimously.

Inspection Report Review

P. – Pharmacy (Out-of-State) (IA-582662)

MOTION: John Weitekamp moved, seconded by Christa Wilson, to authorize Board Counsel to request additional information from Applicant IA-582662. Once the additional information is received the Liaison may act on the application. Motion carried unanimously.

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

Administrative Warnings

25 PHM 0081 – A.R.

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to issue an Administrative Warning in the matter of A.R. DLSC Case Number 25 PHM 0081. Motion carried unanimously.

Case Closings

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

1. 24 PHM 016 – M.D.C. – Prosecutorial Discretion (P2)
2. 24 PHM 0104 – W. – No Violation
3. 24 PHM 0139 – T.P. – Insufficient Evidence
4. 24 PHM 0174 – C.N.A. – Prosecutorial Discretion (P2)
5. 25 PHM 0034 – O.M.D. – No Violation
6. 25 PHM 0051 – C.P. – Prosecutorial Discretion (P2)
7. 25 PHM 0065 – E.S.P. – Prosecutorial Discretion (P2)

Motion carried unanimously.

Proposed Stipulations, Final Decisions and Orders

25 PHM 0083 – Anazao Health Corporation

MOTION: Michael Walsh moved, seconded by John Weitekamp, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Anazao Health Corporation, DLSC Case Number 25 PHM 0083. Motion carried unanimously.

24 PHM 0163 – Richard S.H. Moresco

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Richard S.H. Moresco, DLSC Case Number 24 PHM 0163. Motion carried unanimously.

RECONVENE TO OPEN SESSION

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

The Board reconvened into Open Session at 1:25 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

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

The meeting adjourned at 1:27 p.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**12/5/25** 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?
12/18/25	☒ Yes ☐ No	**11:00 A.M. Public Hearing for Clearinghouse Rule 25-073 on Phar 7, 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** **1. Review Public Hearing Comments and Respond to Clearinghouse Report**

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

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

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

11) Authorization

Nilajah D. Hardin — 12/5/25

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.

Revised 03/2021

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 7.01 (2) and 7.40 (2); renumber and amend Phar 7.02 (5); amend Phar 7.02 (4), 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) to (c), 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; 450.10; and 450.11 Stats.

Statutory authority: ss. 15.08 (5) (b); 450.02 (2); 450.02 (3) (a), (b), (d), and (e); and 450.02 (5). 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 (3) was repealed and recreated
- 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 (1a) is created to read:

Phar 7.01 (1a) "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) to (c) 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.

(c) Adding missing information on a prescription label required under s. Phar 7.05 (2) (a).

SECTION 6. 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 7. 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 8. Phar 7.05 (5) is created to read:

Phar 7.05 (5) Notwithstanding sub. (2), compounded preparations 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 and meet all of the following:

(a) The order shall include the name and address of the practitioner, drug, strength, quantity, and the purpose of the compounded preparation.

(b) The label shall include the practitioner's name in place of the patient's name and state "For practitioner Administration Only – Not for Dispensing or Distribution." If the sterility or integrity of the compounded preparation is not maintained after the initial opening of the container, the label shall state "Single-Dose Only."

(c) The pharmacist shall record the name and address of the location the compounded preparation was dispensed or distributed, and the lot number and beyond-use date of all preparations dispensed or distributed to the practitioner.

SECTION 9. 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 10. 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 11. 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 12. Phar 7.40 (2) is repealed.

SECTION 13. 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 14. 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 15. 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)

LCRC
FORM 2

Wisconsin Legislative Council

RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

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

CLEARINGHOUSE RULE **25-073**

AN ORDER to repeal Phar 7.01 (2) and 7.40 (2); to renumber and amend Phar 7.02 (5); to amend Phar 7.02 (4), 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) to (c), 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.

Submitted by **PHARMACY EXAMINING BOARD**

09-18-2025 RECEIVED BY LEGISLATIVE COUNCIL.

10-06-2025 REPORT SENT TO AGENCY.

SG:PW

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

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

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☑ NO ☐

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☑ NO ☐

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

Wisconsin Legislative Council
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE RULE 25-073

Comments

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

2. Form, Style and Placement in Administrative Code

a. In the statutory interpreted section of the analysis, consider whether s. 450.10, Stats., is necessary to include. The proposed rule does not appear to interpret any provisions of this statute.

b. In SECTION 1, consider changing the subsection from "(1a)" to "(1m)" to be consistent with s. 1.10 (3) (c), Manual.

c. In SECTION 6, consider whether the reference to Code of Federal Regulations material meets the definition of a standard, and if not, then consider whether it should be reproduced in full, as part of the text of the rule. [s. 1.14 (7) (c), Manual.]

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

a. In SECTION 8, consider whether the label for the compounded preparations should include more information than what is in par. (b). By using the term, "notwithstanding", the provision would not require any information specified in s. Phar. 7.05 (2). Also, consider whether any of the information recorded by the pharmacist in par. (c) should be included on the label, such as the lot number.

b. 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.

c. In the statutes interpreted section of the analysis, add a period after the "2" in "450.09 (1) and (2) (b) 2;". Also, add a comma before "Stats.".

d. In the statutory authority section of the analysis, consider placing s. 450.02 (5), Stats., with s. 450.02 (2), Stats. Also, use a comma rather than a period before "Stats.".

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**12/5/25** **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?
12/18/25	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Preliminary Rule Draft: Phar 1, 6 ,7, and 10, Relating to Pharmacy Workplace Conditions** **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:

1. Phar 1, 6, ,7 10 Preliminary Rule Draft
2. Rule Projects Chart

Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx

11) Authorization/

Nilajah D. Hardin — 12/5/25

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

Supervisor (if required) — **Date**

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

Directions for including supporting documents:

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

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

An order of the Pharmacy Examining Board to amend Phar 10.03 (2), (13), and (17) and create Phar 6.09, relating to Pharmacy Workplace Conditions.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.02 (2) and 450.02 (3) (d) and (e), Stats.

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

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

Section 450.02 (2), Stats., states that "[t]he board shall promulgate rules that do all of the following:
(a) Define 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. 450.068."

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

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

Section 450.02 (3) (e), Stats., states "[t]he board may promulgate rules…[e]stablishing 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: None.

Plain language analysis: The objective of the proposed rule is to amend requirements in the Wisconsin Administrative Code to increase public safety by improving working conditions in pharmacies. The Board achieved this objective by creating Phar 6.09, which consists of requirements related to working conditions in pharmacies. The Board also amended Phar 10.03 (2), (13), and (17) to include that they now also apply as unprofessional conduct for the pharmacy license.

Summary of, and comparison with, existing or proposed federal regulation: None.

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 public hearing on February 20, 2025, on Scope Statement 002-25. The following people either testified at the hearing, or submitted written comments:

- Rachel Ver Velde, Associate Vice President of Government Relations and Senior Political Advisor, Wisconsin Manufacturers & Commerce (WMC)

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

- WMC commented that there is a lack of information in the statement of scope regarding the description of existing policies relevant to the rule, new policies proposed, and analysis of policy alternatives. The WMC further commented that this lack of information meant that their members could not comment on the scope statement.

The Pharmacy Examining Board did not make any modifications to Scope Statement 002-25 based on public comment.

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 pharmacy working conditions. In Illinois, a pharmacy cannot require any pharmacy staff to work more than 12 continuous hours per day. A pharmacy shall also allow pharmacists who work 6 continuous hours or longer to take at least one 30-minute break and one 15-minute break during that 6-hour period. If the pharmacy has a private break room, a pharmacist who qualifies for breaks shall have access to this room. The pharmacy may choose to close when the pharmacist is on break. If the pharmacy does not close, the pharmacist on break must remain within the pharmacy or the building where the pharmacy is located. Only prescriptions that have received final

verification by a pharmacist may be dispensed while a pharmacist is on break. Additionally, a license may be revoked or have disciplinary action taken against it for failing to provide a working environment that protects the health and safety of a patient. This includes failure to employ sufficient pharmacy staff, provide breaks, and enough time for pharmacists to complete their professional duties [225 Illinois Compiled Statutes ch. 85 ss. 15.1 and 30].

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. The Iowa Administrative Code includes various pharmacy practice rules. Some of those requirements include standards for pharmacies such as adequate drug storage under sanity conditions, policies and procedures for pharmacy operation, equipment as needed to serve patient needs maintained pursuant to manufacturer recommendations, and the current pharmacist's license displayed within view of the public. Additionally, in Iowa unprofessional conduct includes negating a patient's freedom of choice in pharmacy services and breaching the public trust in terms of the practice of pharmacy [481 Iowa Administrative Code ch. 552 ss. 552.2 and 552.11].

Michigan: The Michigan Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Michigan. Many pharmacy practice regulations are located in the Michigan Administrative Rules and include requirements for pharmacies. In Michigan, pharmacies are required to be equipped with the necessary facilities to provide efficient services [Michigan Administrative Rules R 338.537].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Minnesota. Part 6800 of the Minnesota Administrative Code includes regulations for pharmacy in Minnesota. Some of those regulations include requirements for pharmacy work conditions. In Minnesota, a pharmacy cannot require pharmacists or pharmacy technicians to work more than 12 hours per day including breaks. Those working more than 6 hours per day are allowed a 30-minute uninterrupted break. If a pharmacy chooses to stay open while the pharmacist is on break, the pharmacist needs to stay within the pharmacy or within the establishment for emergencies. Only prescriptions that have been approved by the pharmacist to be dispensed without counseling may be sold while the pharmacist is on break. These work conditions do not apply to an emergency situation that necessitates longer working hours or no breaks to minimize immediate patient health risks. Additionally, it is unprofessional conduct for a pharmacist or pharmacy to engage in practice that causes a danger to the patient or public [Minnesota Administrative Rules part 6800, sections 6800.2160 and 6800.2250].

Summary of factual data and analytical methodologies: The Pharmacy Examining Board completed a comprehensive review of Wisconsin Administrative Code Chapters Phar 1, 6, 7 and 10 and made changes as needed. The Board utilized references from Virginia's pharmacy rules and regulations, National Association of Boards of Pharmacy, and other sources.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The rule will be posted for 14 days on the Department of Safety and Professional Services' website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis will be attached upon completion.

Effect on small business:
These 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 a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 6.09 is created to read:

Phar 6.09 Workplace Conditions. A pharmacy shall provide a safe working environment by ensuring all of the following:

(1) Determine appropriate staffing levels to operate in a safe and effective manner in consultation with the managing pharmacist.
(2) Carry and utilize equipment as needed to meet the needs of the patients served that is maintained in accordance with manufacturer recommendations.
(3) That enough time is allotted for pharmacy staff to complete services safely and accurately.
(4) That staff are sufficiently trained and demonstrate competency in their assigned tasks as determined by the managing pharmacist.
(5) That the pharmacy shall not override the managing pharmacist when using their professional judgement regarding all aspects of pharmacy practice.

SECTION 2. Phar 10.03 (2), (13) and (17) are amended to read:

Phar 10.03 (2) Engaging in any pharmacy practice which constitutes a danger to the health, welfare, or safety of patient or public, including but not limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacy, pharmacist or pharmacy technician which harmed or could have harmed a patient.

(13) Exercising undue influence on or taking unfair advantage of a patient in the promotion or sale of services, drugs or other products for the financial gain of the pharmacy, pharmacist or a third party.

(17) Having a pharmacy license, pharmacist license or pharmacy technician registration revoked or suspended in another state or United States jurisdiction or having been subject to other disciplinary action by the licensing authority thereof.

SECTION 3. This emergency rule shall take effect upon publication in the official state newspaper.

(END OF TEXT OF RULE)

Pharmacy Examining Board
Rule Projects (updated 12/5/25)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet	Not Assigned Yet	TBD	Phar 1 and 7	Patient Drug Information Monographs	Scope Statement tabled at 10/16/25 Meeting	TBD
Not Assigned Yet	002-25	07/13/2027	Phar 1. 6, 7, and 10	Pharmacy Workplace Conditions	Emergency Rule Draft submitted to Governor on 11/21/15 Preliminary Permanent Rule Draft reviewed at 12/18/25 Meeting	Emergency Rule Draft approval by Governor and Publication; Permanent Rule Draft submission for EIA Comment and Clearinghouse Review
Not Assigned Yet	089-24	05/05/2027	Phar 7	Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check	Public Hearing held at 12/18/25 Meeting	Drafting Final Rule and Legislative Report

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:** 11/20/2025 **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: 12/18/2025	**5) Attachments:** ☐ Yes ☒ No	**6) How should the item be titled on the agenda page?** Speaking Engagements, Travel, or Public Relations Requests, and Reports – Discussion and Consideration 1) 122nd NABP Annual Meeting, May 12-15, 2026, Boston, MA	
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: Board discussion on travel opportunity to the 122nd Annual Meeting.			
11) Authorization **Signature of person making this request**			**Date** 11/20/2025
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.**

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	11/20/2025
	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?
12/18/2025	☒ Yes ☐ No	Implement 2021 Wisconsin Act 9 – Top 100 Most Prescribed Drugs – 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:

Review of updated Top 100 Prescribed Drug List for publication to DSPS website

11) Authorization

Signature of person making this request	Date
	11/20/2025
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.

PHARMACY EXAMINING BOARD

4822 Madison Yards Way
PO Box 8366
Madison WI 53708-8366

Email: dsps@wisconsin.gov
Voice: 608-266-2112
FAX: 608-251-3032

*** PUBLIC NOTICE *** Under Wis. Stats. s. 450.13 (5m) (a), the Pharmacist may substitute a less expensive drug product equivalent, unless the consumer or prescribing practitioner have indicated otherwise.

*** PUBLIC NOTICE *** Under Wis. Stats. s. 450.135 (8m), the Pharmacist may substitute a less expensive interchangeable biological product, unless the consumer or prescribing practitioner have indicated otherwise. The public may access a full list of interchangeable biological products that have been approved by the Food and Drug Administration (FDA) here: https://www.fda.gov/drugs/biosimilars/biosimilar-product-information

*** PUBLIC NOTICE *** Under Wis. Stats. s. 450.13 (5m) (b), each pharmacy must provide notice to the public on how it may access the Pharmacy Examining Board's list of the 100 most commonly prescribed generic drug product equivalents. The public may access this list here: https://dsps.wi.gov/Pages/BoardsCcouncils/Pharmacy/Default.aspx

TOP 100 DRUGS A TO Z BRAND NAME

BRAND NAME	DRUG GENERIC NAME	QUANTITY
ABILIFY	ARIPIPRAZOLE 10MG TABLET	30
ADVAIR DISKUS	FLUTICASONE PROPIONATE/SALMETEROL DISKUS	60
AMARYL	GLIMEPIRIDE 2MG TABLET	30
AMOXIL	AMOXICILLIN 500MG CAPSULE	30
ARICEPT	DONEPEZIL 10MG TABLET	30
AUGMENTIN	AMOX TR-K CLAV 875-125 MG TABLET	20
AVAPRO	IRBESARTAN 150MG	30
BACTRIM DS	SULFAMETH/TRIMETH DS TABLET	20
BACTROBAN	MUPIROCIN OINTMENT	22 GRAM
BENICAR	OLMESARTAN 20MG TABLET	30
CATAPRES	CLONIDINE 0.1MG TABLET	90
CELEBREX	CELECOXIB 200MG CAPSULE	30
CELEXA	CITALOPRAM 20MG TABLET	30
CIPRO	CIPROFLOXACIN 500MG TABLET	20
COREG	CARVEDILOL 6.25MG TABLET	60
COUMADIN	WARFARIN 5MG TABLET	30
COZAAR	LOSARTAN 50MG TABLET	30
CRESTOR	ROSUVASTATIN 10MG TABLET	30
CYMBALTA	DULOXETINE 30MG CAPSULE	30
DELTASONE	PREDNISONE 10MG TABLET	30
DELTASONE	PREDNISONE 20MG TABLET	30
DEPAKOTE	DIVALPROEX 500MG EC TABLET	90
DESYREL	TRAZODONE 50MG TABLET	30

DIFLUCAN	FLUCONAZOLE 150MG TABLET	1
DILANTIN	PHENYTOIN SOD EXT 100 MG CAPSULE	90
DIOVAN	VALSARTAN 80MG TABLET	30
EFFEXOR XR	VENLAFAXINE XR 75MG CAPSULE	30
ELIQUIS	APIXABAN 5MG TABLET	30
FLAGYL	METRONIDAZOLE 500MG TABLET	20
FLEXERIL	CYCLOBENZAPRINE 10MG TABLET	30
FLOMAX	TAMSULOSIN 0.4MG CAPSULE	30
FLONASE	FLUTICASONE 50MCG NASAL	16 GRAM
FLOVENT HFA	FLUTICASONE HFA 110MCG INHALER	12 GRAM
FOLVITE	FOLIC ACID 1MG TABLET	30
FOSAMAX	ALENDRONATE 70MG TABLET	4
GLUCOPHAGE	METFORMIN HCL 1,000 MG TABLETLET	60
GLUCOPHAGE	METFORMIN HCL 500 MG TABLETLET	60
GLUCOPHAGE XR	METFORMIN ER 500MG TABLET	60
GLUCOTROL XL	GLIPIZIDE ER 10MG TABLET	30
GLUCOTROL XL	GLIPIZIDE ER 5MG TABLET	30
HYDRODIURIL	HYDROCHLOROTHIAZIDE 12.5MG CAPSULE	30
HYDRODIURIL	HYDROCHLOROTHIAZIDE 25MG TABLET	30
IMITREX	SUMATRIPTAN 100MG TABLET	9
JANUVIA	SITAGLIPTAN 100MG TABLET	30
K-DUR	POTASSIUM 20MEQ TABLET	30
KEFLEX	CEPHALEXIN 500MG CAPSULE	28
LAMICTAL	LAMOTRIGINE 25MG TABLET	30
LAMISIL	TERBINAFINE 250MG TABLET	30
LASIX	FUROSEMIDE 20MG TABLET	30
LASIX	FUROSEMIDE 40MG TABLET	30
LEXAPRO	ESCITALOPRAM 10MG TABLET	30
LIPITOR	ATORVASTATIN 10MG TABLET	30
LIPITOR	ATORVASTATIN 20MG TABLET	30
LOPRESSOR	METOPROLOL 50MG TABLET	60
LYRICA	PREGABALIN 50MG CAPSULE	60
MACROBID	NITROFURANTOIN MONO 100MG CAPSULE	14
MAXZIDE	TRIAMTERENE/HCTZ 37.5MG TABLET	30
MOBIC	MELOXICAM 15MG TABLET	30
MOTRIN	IBUPROFEN 600MG TABLET	90
MOTRIN	IBUPROFEN 800MG TABLET	90
NAPROSYN	NAPROXEN 500MG TABLET	60
NEURONTIN	GABAPENTIN 300MG CAPSULE	90
NEXIUM	ESOMEPRAZOLE 40MG CAPSULE	30
NORVASC	AMLODIPINE 10MG TABLET	30
PAXIL	PAROXETINE 20MG TABLET	30
PLAVIX	CLOPIDOGREL 75MG TABLET	30
PRAVACHOL	PRAVASTATIN 20MG TABLET	30
PRILOSEC	OMEPRAZOLE 20MG CAPSULE	30
PROCARDIA XL	NIFEDIPINE ER 30MG TABLET	30
PROSCAR	FINASTERIDE 5MG TABLET	30
PROTONIX	PANTOPRAZOLE 40MG TABLET	30
PROZAC	FLUOXETINE 20MG CAPSULE	30
RISPERDAL	RISPERIDONE 1MG TABLET	30
SEROQUEL	QUETIAPINE 100MG TABLET	30

SINGULAIR	MONTELUKAST SOD 10 MG TABLET	30
SYNTHROID	LEVOTHYROXINE 100MCG	30
SYNTHROID	LEVOTHYROXINE 50MCG	30
TENORMIN	ATENOLOL 25MG TABLET	30
TENORMIN	ATENOLOL 50MG TABLET	30
TOPAMAX	TOPIRAMATE 50MG TABLET	30
TOPROL XL	METOPROLOL XL 50MG TABLET	30
TRICOR	FENOFIBRATE 145MG TABLET	30
V-CILLIN-K	PENICILLIN -VK 500MG TABLET	40
VALTREX	VALACYCLOIVIR 500MG TABLET	30
VASOTEC	ENALAPRIL 10MG TABLET	30
VENTOLIN INHALER	ALBUTEROL HFA INHALER	18 GRAM
VIBRAMYCIN	DOXYCYCLINE 100MG CAPSULE	30
WELLBUTRIN SR	BUPROPION SR 150MG TABLET	60
XALATAN	LATANOPROST 0.005% DROPS	2.5 ML
XARELTO	RIVAROXABAN 20MG TABLET	30
ZESTORETIC	LISINOPRIL/HCTZ 20/12.5MG	30
ZESTRIL	LISINOPRIL 10MG TABLET	30
ZESTRIL	LISINOPRIL 20MG TABLET	30
ZETIA	EZETIMIBE 10MG TABLET	30
ZITHROMAX	AZITHROMYCIN 250MG TABLET	6
ZOCOR	SIMVASTATIN 20MG TABLET	30
ZOCOR	SIMVASTATIN 40MG TABLET	30
ZOLOFT	SERTRALINE 100MG TABLET	30
ZOLOFT	SERTRALINE 50MG TABLET	30
ZYLOPRIM	ALLOPURINOL 100MG TABLET	30
ZYPREXA	OLANZAPINE 5MG TABLET	30

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:** 11/20/2025 **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: 12/18/2025	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Guidance on Compounding Pharmacies, Phar 15, and Semaglutide/Tirzepatide production – Discussion and Consideration
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:

During the October 22, 2025 Interdisciplinary Advisory Committee meeting, the committee voted on a motion to have the Board of Pharmacy consider drafting a guidance document relating to semaglutide/tirzepatide compounding.

11) Authorization

Signature of person making this request	**Date** 11/20/2025
Supervisor (Only required for post agenda deadline items)	**Date**
Executive Director signature (Indicates approval for post agenda deadline items)	**Date**

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DECLARATORY RULING OF

THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

On July 18, 2024, the Alabama State Board of Medical Examiners ("the Board") considered a request submitted on behalf of the Alabama Board of Pharmacy ("Petitioner") for a declaratory ruling pursuant to Ala. Code § 41-22-11 and Ala. Admin. Code r. 540-X-1-.10, concerning the purchasing and compounding of Glucagon-like peptide-1 agonist (GLP-1) products by physicians.

FACTS PRESENTED

Petitioner presents the following factual background[1]:

Purchasing

Semaglutide powder is being advertised to physician offices and the public for purchase from innumerable sources. Much of this semaglutide is NOT prescription quality. The outlets are selling semaglutide salt forms and research grade powder. These salt forms and research grade powders are NOT approved by the FDA nor are they evaluated for safety. As such, the only powder that should be used in compounding is the prescription quality powder.

Pharmacists are required to purchase and use only prescription quality active pharmaceutical ingredients when compounding a drug for human consumption. Outlets attempting to sell GLP-1 powder or products to practitioners in Alabama must have the appropriate permit from the ALBOP. Physicians can validate a supplier has an active permit with ALBOP by utilizing the License Verification feature on the ALBOP website, www.albop.com.

Compounding

[1] A complete copy of Petitioner's petition is attached as Attachment A.

The Federal Food, Drug and Cosmetic Act (FDCA) expressly recognizes the United States Pharmacopeia (USP) quality standards for medicines. USP has extensive standards outlining the proper and safe processes for compounding sterile injectable products. USP explicitly states that the standards apply to all places where compounded sterile preparations (CSPs) are prepared, including physician offices, and enforcement falls on state regulatory bodies.

These standards expressly lay out requirements for sterility, stability, and beyond use dating as the industry standard to protect public safety in compounding products for prescription use. An abbreviated outline [appears in Attachment A].

The Board of Pharmacy is charged with regulating the safe and effective compounding of medications (§34-23-162). As such Rule 680-X-2-.43 states:

> 680-X-2-.43 Requirements For Compounding.
>
> All pharmacies that engage in the compounding of drugs or drug products shall comply with all applicable and current regulations of United States Pharmacopeia–National Formulary (USP)-NF. Section 34-23-11 applies.

While Rule 680-X-2-.43 specifically references 34-23-11 which exempts physicians from Chapter 23, Pharmacists and Pharmacies, of the Code of Alabama, it seems counterintuitive that exemption was intended to take away all the requirements for compounding from physicians that would ensure such compounding is done in a manner that is safe and effective for their patients.

We are aware some physicians may not consider themselves compounding because they are simply drawing unit dose syringes from a bulk vial to send home with the patient. However, this practice is regulated as a compounding action.

QUESTIONS PRESENTED

(1) Does the exemption of physicians under Ala. Code § 34-23-11 permit a physician to compound and dispense a drug using non-prescription quality ingredients?

(2) Are physicians required to ensure any prescription product or ingredient is purchased from an entity permitted by the Alabama State Board of Pharmacy?

(3) Are physicians required to comply with USP standards when compounding GLP-1 products?

ANSWER

(1) Alabama-licensed physicians are not permitted to compound or dispense a drug using non-prescription quality ingredients.

(2) Alabama-licensed physicians are required to purchase prescription products and ingredients only from an entity permitted by the Alabama State Board of Pharmacy.

(3) Alabama-licensed physicians are required to comply with USP standards when compounding GLP-1 products.

DISCUSSION

The Alabama State Board of Pharmacy ("ALBOP") regulates the practice of pharmacy, the importation of drugs, and the compounding and dispensing of drugs "in such a manner as to protect the public." Ala. Code § 34-23-2. Generally, no "person, firm, or corporation" can practice pharmacy, compound drugs, or dispense medications unless he or she possesses a license issued by ALBOP. Ala. Code § 34-23-50(a). However, Alabama-licensed physicians may compound, dispense, administer, or supply drugs to their patients for the patient's personal use without a license issued by ALBOP. Ala. Code § 34-23-11.

This exemption is referenced in Ala. Code § 34-23-70, which sets forth certain requirements and restrictions attaching to the operation of a pharmacy. In the midst of a list of requirements ALBOP is empowered to enforce, the Legislature clarified that ALBOP is not authorized to "promulgate or enforce any rule which governs, regulates, or restricts the professional practice of a physician licensed to practice medicine in this state." Ala. Code § 34-23-70(g)(3). It appears to the Board that the Legislature's intent is that ALBOP not impair an Alabama-licensed physician's medical practice or subject physicians to regulation by ALBOP. This accords with the broad definition of the practice of medicine and the exclusive authority of the Board and Medical Licensure Commission to license and regulate the practice of medicine in this state. *See* Ala. Code § 34-24-50; § 34-24-53; and § 34-24-311.

However, it is the opinion of the Board that this statute is <u>not</u> intended to exempt physicians from the public welfare and safety purposes accomplished by the licensing and regulation of pharmacists and pharmacies. Indeed, a primary goal of the regulation of the practice of medicine by the Board is "prioritize patient safety and wellness" and to "determine the medical practices" that achieve this goal. Ala. Code § 34-24-53.1(a)(2)-(3). Patient safety and wellness is not prioritized if physicians disregard the safety measures put in place and enforced by ALBOP. Instead, Alabama-licensed physicians should participate in and bolster ALBOP's efforts to combat unscrupulous actors who seek to introduce dangerous drugs to Alabama's citizens.

While it is true that nothing in the Alabama Pharmacy Act "shall prevent any licensed practitioner of the healing arts from personally compounding, dispensing, administering or supplying to his or patients drugs and medicines for their use," it is also true that "[n]o manufacturer . . . wholesale drug distributor . . . or [any other person or entity] identified in the supply chain of any legend drug or device shall ship, or cause to be shipped, into the state any

legend drug or device without a valid permit issued by [ALBOP]." Ala. Code §§ 34-23-11 and 34-23-32(g). It is the unambiguous intent of the Legislature that all drugs come into the state through licensed sources. Accordingly, it is the opinion of the Board that physicians must purchase prescription products and ingredients only from an entity permitted by ALBOP.[2]

Furthermore, ALBOP has determined that patient safety requires "[a]ll pharmacies that engage in the compounding of drugs or drug products" to comply with "all applicable and current regulations of the United States Pharmacopeia-National Formulary (USP)-NF." Ala. Admin. Code r. 680-X-2-.43. This directive requires pharmacists to adhere to USP 797, which sets the standards for compounding sterile preparations. USP 797 is a national standard utilized by the FDA, as well as many states.[3] It is intended to apply to "all persons who prepare [compounded sterile preparations] and all places where [these preparations] are prepared. . . . [including] physicians." USP 797 1.1.3. The Board agrees with ALBOP that these sterile practices promote the health and safety of Alabama patients. Indeed, many of the practices promoted in USP 797 accord with existing medical standards, including limitations on the use of bulk vials, garbing and cleanliness, sterilization, and prohibitions on reusing components. There is no evidence before the Board justifying any departure from these standards when a physician is compounding a GLP-1 product. In fact, the evidence before the Board overwhelmingly favors adherence to the USP 797 standards. Consequently, it is the opinion of the Board that Alabama-licensed physicians are required to comply with USP standards when compounding GLP-1 products.

Finally, it is the opinion of the Board that physicians must use prescription quality ingredients when compounding and dispensing a drug to their patients. Patient health and wellness

[2] ALBOP does not keep a list of 503-B permitted pharmacies on their website; however, physicians are invited to contact ALBOP for more information and to verify any source for prescription products and ingredients.
[3] https://www.usp.org/compounding/general-chapter-797

is best served when a physician uses quality ingredients intended for human use. In light of recent warnings by the United States Food and Drug Administration ("FDA"), the publication of adverse event data, the warnings of relevant drug manufacturers, and other state boards, it appears to the Board that a physician's patients are put at unjustifiable risk by non-prescription grade GLP-1 products.[4] Therefore, physicians are not permitted to compound or dispense a drug using non-prescription quality ingredients.

This ruling is based upon the precise facts presented and upon statutes and rules currently in existence. The Board specially notes that this decision accords with the actions of other medical boards as well as the FDA. Should any relevant statutes or rules be amended or repealed, this ruling may no longer be valid.

DONE this 8th day of August, 2024.

C.M.A. "Max" Rogers, IV, M.D.
Chairman
Alabama State Board of Medical Examiners

[4] See Attachment B

Attachment A

ALABAMA BOARD OF PHARMACY

Donna C. Yeatman, R.Ph., CISCI
Executive Secretary

Location:
111 Village Street
Birmingham, AL 35242

(205) 981-2280
www.albop.com

June 7, 2024

Mr. E. Wilson Hunter
General Counsel
Alabama Board of Medical Examiners
848 Washington Avenue (36104)
PO Box 946
Montgomery, AL 36101-0946

Mr. William M. Perkins
Executive Director
Alabama Board of Medical Examiners
Montgomery, Alabama 36104

Dear Mr. Hunter and Mr. Perkins,

As Executive Secretary of the Alabama Board of Pharmacy (ALBOP), I am requesting a Declaratory Ruling regarding Glucagon-like peptide-1 agonists (GLP-1) products. Numerous calls and complaints have been fielded by this office relative to GLP-1 physician compounding and dispensing. Please see attached complaint as one example. These calls and complaints are surrounded by two issues: purchasing and compounding.

Purchasing

Semaglutide powder is being advertised to physician offices and the public for purchase from innumerable sources. Much of this semaglutide is NOT prescription quality. The outlets are selling semaglutide salt forms and research grade powder. These salt forms and research grade powders are NOT approved by the FDA nor are they evaluated for safety. As such, the only powder that should be used in compounding is the prescription quality powder.

Pharmacists are required to purchase and use only prescription quality active pharmaceutical ingredients when compounding a drug for human consumption. Outlets attempting to sell GLP-1 powder or products to practitioners in Alabama must have the appropriate permit from the ALBOP. Physicians can validate a supplier has an active permit with ALBOP by utilizing the License Verification feature on the ALBOP website, www.albop.com.

Attachment A

Compounding

The Federal Food, Drug and Cosmetic Act (FDCA) expressly recognizes the United States Pharmacopeia (USP) quality standards for medicines. USP has extensive standards outlining the proper and safe processes for compounding sterile injectable products. USP explicitly states that the standards apply to all places where compounded sterile preparations (CSPs) are prepared, including physician offices, and enforcement falls on state regulatory bodies.

These standards expressly lay out requirements for sterility, stability, and beyond use dating as the industry standard to protect public safety in compounding products for prescription use. An abbreviated outline is attached for your reference.

The Board of Pharmacy is charged with regulating the safe and effective compounding of medications (§34-23-162). As such Rule 680-X-2-.43 states:

> 680-X-2-.43 Requirements For Compounding.
> All pharmacies that engage in the compounding of drugs or drug products shall comply with all applicable and current regulations of United States Pharmacopeia–National Formulary (USP)-NF. Section 34-23-11 applies.

While Rule 680-X-2-.43 specifically references 34-23-11 which exempts physicians from Chapter 23, Pharmacists and Pharmacies, of the Code of Alabama, it seems counterintuitive that exemption was intended to take away all the requirements for compounding from physicians that would ensure such compounding is done in a manner that is safe and effective for their patients.

We are aware some physicians may not consider themselves compounding because they are simply drawing unit dose syringes from a bulk vial to send home with the patient. However, this practice is regulated as a compounding action.

Considering the above, the Alabama Board of Pharmacy requests a Declaratory Ruling on the following:

1) Does the exemption of physicians under Ala. Code 34-23-11 permit a physician to compound and dispense a drug using non-prescription quality ingredients?
2) Are physicians required to ensure any prescription product or ingredient is purchased from an entity permitted by the Alabama State Board of Pharmacy?
3) Are physicians required to comply with USP standards when compounding GLP-1 products?

Thank you for your consideration and advisement on these issues.

Sincerely,

Donna C. Yeatman

Donna C. Yeatman
Executive Secretary

Attachment A

Submission Date :02/26/2024 **Status :**Processed

COMPLAINT DETAILS1

PHARMACY NAME [redacted]

PHARMACIST/TECHNICIAN COMPLAINT IS AGAINST: [redacted]

Address [redacted]

City [redacted] State [redacted] Zip [redacted] Phone [redacted]

Explain the incident in your own words

[redacted] conducted a virtual visit with me on Tues Feb 20,2024 for the purpose of prescribing Trizepatide for weight loss. On Wed Feb 21 my Rx was shipped over night. On Thursday, Feb 22 I receivd my shipment via UPS. It was a cardboard box without insulation. My Rx was wrapped in white paper and the small ice pack in the cardboard box was warm to the touch and completely thawed (not even cool). The package had a strong odor of cigarette smoke. I immediately administered the first injection which i now regret. After further inspection of the packaging, I became aware that the labels on the shipping box and the little plastic box the pre-drawn syringes were in had no information about the compound pharmacy and was not labeled by the pharmacy at all. All labels referred to [redacted]. there was no expiration date on the label. Thursday night, Feb 22nd after becoming concerned about the possible adulteration of the medication I took, I contacted the clinic. I left voice mails and sent messages through their Website and sent email with my concerns. Finally, on Monday, Feb 26th I spoke with [redacted], the office manager. She informed that the clinic obtains meds from a compound pharmacy and draws the meds into syringes and then re-distributes them to patients. She would not give me any information about the compound pharmacy where the medication originated from. She further denied that anyone at their clinic smokes so the package could not have been exposed to smoke. she further stated that they are not responsible for how the package is handled by UPS. She stated that the syringe was packed with an ice pack so being warm upon arrival should not have a negative impact on the meds even though it was not insulated for shipping. Although I regretfully injected the first syringe before realizing all the red flags, I now have concerns about what product I put in my body and the conditions it was drawn under. Please help

Complaint Filed By

First Name [redacted] Middle Name [redacted] Last Name [redacted]

Phone Type [redacted] Phone [redacted]

Alternate Phone Type Select Alternate Phone Phone

Business Name

Business Name

Email [redacted]

Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Attachment A

Office: 111 Village Street Birmingham, AL 35242 **Voice:** 205-981-2280 **OFFICE HOURS:** 8:00AM - 4:00PM CST **Privacy Policy**

ashp
pharmacists advancing healthcare®

USP <797>

KEY CHANGES

The following represents key changes from the currently enforceable version of USP Chapter <797> (last major revision in 2008) to the revised USP Chapter <797> (official as of November 1, 2023). The following are the major changes and are not meant to be an exhaustive list of the entirety of all changes made. Some changes will be reported as direct text excerpts from the respective chapter (notated by quotation marks), while others will be reported as a general comment describing the text or change. *Note: Bolding has been added to the text below for emphasis.*

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
01. INTRODUCTION AND SCOPE		
"The use of technologies, techniques, materials, and procedures other than those described in this chapter … "	" … not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein."	" … not prohibited as long as they are **noninferior** to those described herein **and validated for the intended purpose" (e.g., USP <1223>, <1225>)**
Compounded sterile preparations (CSPs) affected	" … irrigations for wounds and body cavities … " " … aqueous bronchial and nasal inhalations … "	" … Irrigations for **internal** body cavities … [NOTE—irrigations for the mouth, rectal cavity, and sinus cavity **are not required to be sterile**.]" "Nasal dosage forms intended for local application are **not required to be sterile**."
Hazardous drugs	Covered within the chapter under section Hazardous Drugs as CSPs Allows preparation of a "low volume of hazardous drugs" outside of a negative pressure space as long as two tiers of containment are used (closed-system transfer device with containment primary engineering control)	Removed from chapter and references to follow USP <800> No longer allows preparation of a low volume of hazardous drugs outside of a negative pressure space.
Radiopharmaceuticals	Covered within the chapter under section Radiopharmaceuticals as CSPs	Removed from chapter and references to follow USP <825>
Personnel and settings affected	Largely refers to and addresses only compounding personnel	**"Any person entering a sterile compounding area**, *whether preparing a CSP or not*, must meet the requirements in **3. Personal Hygiene and Garbing."**
The designated person(s)	Not addressed	"The compounding facility must designate one or more individuals (i.e., **the designated person(s)) to be responsible and accountable** for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions as described in this chapter." A complete list of the designated person responsibilities has been provided as a separate resource.

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
Administration	Standards do not pertain to the clinical administration of CSPs to patients (e.g., implantation, infusion, inhalation)	"For the purposes of this chapter, 'administration' means the direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form."
Immediate-use CSPs	"Administration begins not later than 1 hour following the start of the preparation … " Does not involve > 3 commercially manufactured packages of sterile nonhazardous products	"Administration begins **within 4 h following the start of preparation.**" "The preparation involves **not more than 3 different sterile products.**" "Personnel are trained and demonstrate competency in aseptic processes as they related to assigned tasks and the facility's SOPs."
Preparation per approved labeling	Strictly following the manufacturers' approved labeling (product package inserts) is considered a CSP and the requirements of the chapter apply	"**Compounding does not include** mixing, reconstituting, or other such acts that are **performed in accordance with directions contained in approved labeling or supplemental materials** provided by the product's manufacturer." "The product is prepared as a **single dose** for an **individual patient** … " "Approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time."
Proprietary bag and vial system	Does not mention BUDs other than following the manufacturer's instructions for handling and storing	Docking of the proprietary bag and vial system for **future activation** • This is **considered compounding** and must be performed in accordance with this chapter (ISO Class 5 environment) • BUDs must not be longer than the manufacturer's labeling
CSP microbial categories	CSP Categories • Low Risk • Low Risk with 12-h BUD • Medium Risk • High Risk Factors that determine CSP Category • Type of manipulation • Complexity and length of preparation • If any nonsterile ingredient, component, or equipment is used • Number of sterile products and packages • Number of transfers into any single container • Number of doses being prepared • Following proper garbing • Exposure to lower than ISO class 5 air and duration	CSP Categories • Category 1 • Category 2 • Category 3 Factors that determine CSP Category • Primarily based on environment/conditions of where the CSP is compounded • Level of garbing • Environmental testing and monitoring • Frequency of application of a sporicidal • Based on BUD assignment "Category 1, Category 2, and Category 3 CSPs can be compounded by using only sterile starting ingredients, or by using some or all nonsterile starting ingredients." One (or more) component is non-sterile: sterility of the compound must be achieved through a sterilization process (e.g., terminal sterilization) and must be maintained if it is subsequently manipulated

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
02. PERSONNEL TRAINING AND EVALUATION		
Who needs to be trained and how often	"Personnel who prepare CSPs shall be trained … " How often: • Low- and medium-risk level: at least annually • High-risk level: semi-annually	Compounders and those who have direct oversight of compounders • Initially and at least every 6 or 12 months (depends on the individual) Personnel who do not compound nor have direct oversight of compounders, but are associated with other tasks **(e.g., restock or clean/disinfect the SCA, only compound immediate-use CSPs)**: • Defined by facility SOPs
Initial garbing competency evaluations	Compounders need to pass garbing competency evaluations before beginning to prepare CSPs	Garbing competency evaluations include: • Visual observation • Gloved fingertip and thumb sampling (GFT) of both hands Compounders and those who have direct oversight of compounders • " … must complete an initial garbing competency evaluation **no fewer than 3 separate times. The 3 successful completions must be in succession** … " Remediation of failed competency • " … failure of any of the 3 initial garbing competency evaluations r**equires repeat testing until personnel successfully completes 3 evaluations in a row.**"
Ongoing garbing competency evaluations	Visual observation of hand hygiene and garbing • At least annually Gloved fingertip and thumb sampling • Low/medium risk – at least annually • High-risk – at least semiannually	Compounders • Category 1 and 2: **at least every 6 months** • Category 3: **at least every 3 month**s Those who have direct oversight of compounders • At least every 12 months
Initial aseptic manipulation competency evaluations	Compounders need to pass media-fill testing of aseptic manipulation skills before beginning to prepare CSPs	Aseptic manipulation evaluations include: • Visual observation • Media-fill testing with post-GFT • Surface sampling Compounders and those who have direct oversight of compounders • Must complete 1 successful aseptic manipulation competency evaluation Remediation of failed competency • "A failure in the media fill, gloved fingertip and thumb sampling, or surface sample constitutes an overall failure of the aseptic manipulation competency."

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Category	USP <797>, 2008[1]	USP <797>, 2023[2]
Ongoing aseptic manipulation competency evaluations	Each person authorized to compound in a low-risk or medium-risk level environment: At least annually Each person authorized to compound in a high-risk level environment: At least semiannually	Compounders Category 1 and 2: **at least every 6 months** Category 3: **at least every 3 months** Those who have direct oversight of compounders: At least every 12 months
Gloved fingertip and thumb sampling incubation standards	Incubate sample at 30-35 C for 2-3 days	"Incubate the media device at 30-35 C for no less than 48 h **and** then at 20-25 C for no less than 5 additional days."
Media-fill testing incubation standards	Incubate sample at 20-25 C or 30-35 C for 14 days	"Incubate the final containers at 20-25 C **and** 30-35 C for a minimum of 7 days at each temperature band … " "The order of the incubation temperatures must be described in the facility's SOPs"
Action levels for gloved fingertip and thumb sampling	0 cfu	After garbing: >0 cfu After media-fill testing: >3 cfu Action levels based on total cfu count **from both hands**
03. PERSONAL HYGIENE AND GARBING		
Order of handwashing and garbing	Gave a specific order for garbing and handwashing Sterile gloves could be donned in the buffer room	Order of handwashing and garbing is determined by the placement of the sink Order of garbing must be described by facility's SOPs "Donning and doffing garb should not occur in the same area at the same time" "Sterile gloves must be donned in a classified room or SCA"
Hand hygiene	Allows use of hand dryers Does not mention soap containers	Hand dryers **must not** be used Disposable soap containers **must not** be refilled or topped off – need to be replaced
Sanitizing hands	" … perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity."	Do not need an agent with persistent killing
Reusing garb	Allows gown to be reused if used on the same work day	Category 1 and Category 2 • " … gowns may be reused within the **same shift by the same person** if the gown is **maintained in a classified area or adjacent to, or within, the SCA in a manner that prevents contamination.**" • Other garb cannot be reused and should be discarded or laundered before reuse Category 3 • "Disposable garbing items **must not be reused**, and laundered garb **must not be reused without being laundered and resterilized with a validated cycle.**" • "The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment."

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
Garbing for category 3	Not applicable	"If the facility compounds Category 3 CSPs, **additional garbing requirements must be continuously met in the buffer room in which Category 3 CSPs are prepared."** • No exposed skin (I.e., face and neck must be covered) • All low-lint outer garb must be sterile • Disposable garb cannot be reused • Laundered garb cannot be reused until it is laundered and re-sterilized • Facility's SOPs describe disinfection procedures for reusing goggles, respirators, and other reusable equipment
04. FACILITIES AND ENGINEERING CONTROLS		
ISO classification of particulate matter	Particle count listed as m^3 and ft^3	Particle count is only listed as **m^3**
Use of isolators	PECs shall be located within a restricted access ISO Class 7 buffer area, with exceptions for CAI/CACI which would allow for BUD's equivalent to a full cleanroom suite in a segregated compounding area when certain conditions are met	The exception for CAI/CACI's has been removed; to obtain Category 2 CSP BUD's, the CAI/CACI must be placed in an ISO Class 7 buffer room located within a cleanroom suite Alternatively, a pharmaceutical isolator (different type of engineering control than a CAI/CACI) can be placed in an ISO Class 8 environment without the need for an anteroom
Air exchange requirements	Does not address ISO Class 8 ACPH requirements	ISO Class 8 room: >20 ACPH
Cleanroom	Not addressed	Term to describe ISO-classified anteroom and buffer room
Cleanroom suites: access doors and seals	Not addressed	Seals should not be installed at doors between buffer rooms and anterooms Access doors should be hands-free
Precision and accuracy of pressure differentials	Listed as 0.02 (two decimal places), broad	Listed as 0.020 (three decimal places), narrow
Humidity requirements	Does not mention humidity	"… should be maintained at … a relative humidity of 60% or below … "
05. CERTIFICATION AND RECERTIFICATION		
Certification of PEC and SEC	"Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities shall be used."	All professional organizations have been removed: " … independently certified using the requirements in this chapter and when applicable, manufacturer specifications."
06. MICROBIOLOGICAL AIR AND SURFACE MONITORING		
Viable air sampling – timing and locations	At least every 6 months for all compounds	Category 1 and Category 2: • At least every 6 months Category 3 • Within 30 days before the start of any Category 3 compounding • At least monthly

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Category	USP <797>, 2008[1]	USP <797>, 2023[2]
Viable air sampling – incubation standards	TSA: • 30-35 C for 48 to 72 h Fungal media: • 26-30 C for 5 to 7 days	Incubate at 30-35 C for no less than 48 h then incubate at 20-25 C for no less than 5 additional days **"To shorten overall incubation period, two sampling media devices may be collected for each sample location and incubated concurrently"** • Incubate one at 30-35 C for no less than 48 h and the other at 20-25 C for no less than 5 days
Surface sampling – timing and locations	"Surface sampling shall be performed in all ISO classified areas on a **periodic** basis"	Locations: • Equipment contained within the PEC • Staging or work area(s) near the PEC • Frequently touched surfaces Category 1 and 2 • At least monthly Category 3 • At least weekly • Prior to assigning a BUD longer than the limits established for Category 2 CSPs
Surface sampling – action levels	Action levels • ISO Class 5: >3 • ISO Class 7: >5 • ISO Class 8 or worse: >100	Action levels • ISO Class 5: >3 • ISO Class 7: >5 • ISO Class 8: **>50**
Identifying microorganisms and Corrective Actions	Identification of microorganisms (at least the genus level) is required regardless of cfu count Mention of **highly pathogenic microorganisms** (e.g., gram-negative rods, coagulase *Staphylococcus*, molds and yeasts) must be immediately remedied regardless of cfu count	If action levels specified for air and surface sampling are exceeded, **" … an attempt must be made to identify any microorganism recovered to the genus level … "** Does not mention highly pathogenic microorganisms "The extent of the investigation should be consistent with the deviation and should include an evaluation of trends" "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective." "The corrective action plan must be dependent on the cfu count and the microorganism recovered."
07. CLEANING, DISINFECTING, AND APPLYING SPORICIDAL DISINFECTANTS AND STERILE 70% IPA		
Minimum frequency for cleaning and disinfecting surfaces	Does not split up minimum frequency based on method (e.g., cleaning, disinfecting)	Minimum frequency for cleaning is broken down by cleaning, disinfecting, and applying sporicidal disinfectant

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
Cleaning/disinfecting supplies	Does not specify the type of material	Cleaning and disinfecting supplies (e.g., wipers, sponges, pads, mop heads) • Must be low-lint • Should be disposable • Reusable cleaning tools must be dedicated for use and not be removed from classified areas or SCA and be made of cleanable materials (e.g., not wood or any other porous material) "Cleaning, disinfecting and sporicidal agents used within the PEC **must be sterile**." Sterile water must be used when diluting concentrated agents for use in the PEC.
08. INTRODUCING ITEMS INTO THE SEC AND PEC		
No major changes	--	--
09. EQUIPMENT, SUPPLIES, AND COMPONENTS		
No major changes	--	--
10. STERILIZATION AND DEPYROGENATION		
Biological indicators	Steam Heat – *Bacillus stearothermophilus* Dry Heat – *Bacillus subtilis*	Steam Heat – *Geobacillus stearothermophilus* Dry Heat – *Bacillus atrophaeus*
11. MASTER FORMULATION AND COMPOUNDING RECORDS		
Master formulation records (MFR)	Specific requirements not listed	• Must be created for all CSPs prepared for more than one patient or when using non-sterile components • Any changes or alterations must be approved and documented based on facility's SOPs • Requirements for MFR are listed out in section
Compounding records (CR)	Specific requirements not listed	• Must be created for all Category 1, Category 2, and Category 3 CSPs and for immediate-use CSPs when prepared for more than one patient • Requirements for CR are listed out in section
12. RELEASE INSPECTIONS AND TESTING		
Maximum batch size	Not addressed	"The maximum batch size for all CSPs **requiring sterility testing** must be limited to **250 final yield units.**"
Sterility testing	"A method not described in the *USP* may be used if verification results demonstrate that the alternative is at least as effective and reliable ... "	Specifies a *USP* chapter "... or a **validated alternative method (see <1223>) that is noninferior to <71> testing."**
Number of CSPs needed to send for sterility testing	Does not specify number of CSPs needed to be sent for sterility testing	Number of CSPs sent for sterility testing depends on **number of CSPs to be compounded in a single batch** • 1-39 CSPs – must send 10% of the number of CSPs prepared, rounded up to the next whole number • >40 CSPs – must use sample sizes specified in *<71>*, Table 3

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Category	USP <797>, 2008[1]	USP <797>, 2023[2]
Sterility testing requirements	Required for high-risk level CSPs under certain circumstances: • >25 identical individual single-dose packages • Multiple-dose vials for administration to multiple patients • Exposed longer than 12 h at 2-8 C and longer than 6 h at warmer than 8 C before they are sterilized	Category 1 – not required Category 2 – based on BUD Category 3 – required
13. LABELING		
Compounding notification on label	Not addressed	**"The labeling on the CSP should indicate that the preparation is compounded."**
14. ESTABLISHING BEYOND-USE DATES		
Establishing a BUD for a CSP	Factors that determine a BUD for risk categories • Storage conditions • Information gathered from professional sources (e.g., sterility studies)	Factors that determine Category 1 BUDs • Storage conditions (e.g., controlled room temperature, refrigerator) Factors that determine Category 2 BUDs • Compounding method (e.g., aseptic process, terminally sterilized) • If sterility testing is performed • Starting component of compound (e.g., sterile, nonsterile) • Storage conditions Additional requirements needed for longer BUDs in Category 3 CSPs for: • Increase use of sporicidal disinfectants • Increase of environmental monitoring • Use of sterile garb • Stability determination • Personnel qualification
Non-preserved topical ophthalmic CSPs	Not addressed	"The beyond-use-date of a multiple-dose, aqueous, non-preserved CSP intended for topical, including **topical ophthalmic**, administration may be **assigned in accordance with *14.5 Multiple-Dose CSPs.***" Requirement for passing antimicrobial effectiveness testing in accordance with <51> is not required only if the preparation is: • Prepared as a Category 2 or Category 3 CSP • For use by a single patient • Labeled to indicate that once opened, it must be discarded after 24 h stored at controlled room temp or 72 h stored under refrigeration

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Category	USP <797>, 2008[1]	USP <797>, 2023[2]
15. USE OF CONVENTIONALLY MANUFACTURED PRODUCTS AS COMPONENTS		
Use of conventionally manufactured single-dose containers	"Single-dose vials exposed to ISO Class 5 or cleaner may be used up to **6 h** after initial needle puncture."	"If a single-dose vial is entered or punctured only in an ISO Class 5 or cleaner air, **it may be used up to 12 h after initial entry or puncture as long as the labeled storage requirements during that 12-h period are maintained**."
Use of conventionally manufactured pharmacy bulk package	Not addressed	"The pharmacy bulk package must be used according to the manufacturer's labeling (see *<659>, General Definitions, Injection Packaging Systems*). The pharmacy bulk package must be entered or punctured only in an ISO Class 5 PEC."
16. USE OF CSPS AS COMPONENTS		
Use of compounded multiple-dose CSPs	Not addressed	When used as a component to compound additional CSPs • Required to meet criteria for antimicrobial effectiveness testing and requirements in *14.5* • Must be stored in conditions the BUD is based (e.g., refrigerator) • After punctured, must not be used longer than assigned BUD or 28 days, whichever is shorter. Remainder must be discarded
Use of compounded single-dose CSPs and CSP stock solutions	Not addressed	When used as a component to compound additional CSPs • Must be entered or punctured in ISO Class 5 or cleaner air • Must be stored in conditions the BUD is based (e.g., refrigerator) • May be used for sterile compounding up to **12 h** or its assigned BUD, whichever is shorter. Remainder must be discarded
17. SOPS		
Who needs training based on facilities SOPs	Not addressed	"All personnel who perform or oversee compounding or support activities must be trained in the SOPs"
18. QUALITY ASSURANCE AND QUALITY CONTROL		
Notification and recall of CSPs with out-of-specification limits	Not addressed except for notifying the patient and physician of potential risk	SOP for recall of out-of-specification limits must contain procedures • To determine severity of problem and urgency for implementation and completion of the recall • To determine distribution of any affected CSP • To identify patients who received the CSP • For disposal and documentation of recalled CSP • To investigate and document reason for failure
Redispensed CSPs	Unopened, unused, returned CSPs may be redispensed when certain conditions are met to ensure the CSP is sterile, pure, and stable	Not specifically addressed; however does not prohibit this practice. Would need to refer to state board of pharmacy for guidance.
19. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, AND TRANSPORT		
No major changes	--	--

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
20. DOCUMENTATION		
No major changes	--	--
21. COMPOUNDING ALLERGENIC EXTRACTS		
Compounding allergenic extract prescription sets	No mention of training or competency evaluation needed for compounders making allergenic extracts	Requirements for personnel who prepare allergenic extracts • Training must be done initially prior to compounding independently and annually • Gloved fingertip and thumb sampling on both hands no fewer than 3 separate times needs to be done prior to compounding independently and at least every 12 months • Sterile technique of compounders needs to be evaluated at least every 12 months • Personnel that have not compounded in 6 months need to be evaluated in all core competencies before resuming their duties

References

1. United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—nonsterile preparations. USP43-NF38. Rockville, MD: U.S. Pharmacopeial Convention; 2019.
2. United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—sterile preparations. USP-NF 2023, Issue 1, November 1, 2022, official as of November 1, 2023.

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

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

Attachment B

GUIDANCE REGARDING SEMAGLUTIDE-BASED MEDICATIONS FROM THE MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

The Board recognizes that Type 2 Diabetes and obesity are two of the most serious public health problems facing our state. The potential benefits for many Mississippi patients of new semaglutide-based medications like Ozempic® and Wegovy® are obvious.[1] However, because these drugs are in high demand and short supply, some providers have turned to the use of compounded versions that are represented to be safe substitutes for the patented drugs, but which are unproven. Public safety requires that the Board emphasize three points concerning this issue:

1. The off-label use of semaglutide-based legend drugs is prohibited by Board regulation;[2]

2. Compounded semaglutide products likely use as Active Pharmaceutical Ingredients (APIs) salt forms of semaglutide, chemically synthesized versions, or research-grade ingredients not intended for human use. Such APIs have not been proven to be safe and effective substitutes or equivalents for the patented drugs;

3. The Board strongly advises medical licensees to refrain from prescribing, dispensing, or administering any compounded semaglutide until further notice.

Ozempic® and Wegovy® are currently listed on the Food and Drug Administration (FDA) "shortage list." Generally, when a drug appears on the shortage list, compounded drugs can be made and distributed with fewer restrictions. However, the listing of Ozempic® and Wegovy® does not change the high standards for quality of ingredients and sanitary manufacturing conditions with which compounders must comply.

Board regulations prohibit off-label use of any non-FDA-approved medication solely for the purpose of weight loss. On March 22, 2023, the Board passed an emergency rule to permit waivers to be granted for the off-label use of diet medications on a per-medication or class of medications basis. The Board then granted an emergency waiver or exemption for Semaglutide-based legend drugs until July 1, 2023.[3] However, since that time the Board has received additional information on this issue from various sources, including the Food and Drug Administration (FDA) and the Mississippi Board of Pharmacy. Therefore, on July 27, 2023 the Board RESCINDED the exemption permitting off-label use

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[1] Saxenda® (liraglutide) is also FDA-approved for weight loss. Other non-semaglutide based medications showing promise for these conditions are also becoming available, such as Mounjaro™ (tirzepatide).

[2] *See* Part 2640, Chapter 1, Rule 1.5(F). "Off-label use of any medication that does not have Food and Drug Administration approval for use in the treatment of weight loss is prohibited if administered solely for the purpose of weight loss."

[3] On April 18, 2023, after the Board received information from the Mississippi Board of Pharmacy expressing concerns about the safety of compounded semaglutide based on FDA publications, the Executive Director emailed to all Board licensees a memorandum prepared by the Pharmacy Board and distributed to Mississippi pharmacists. That memo outlined problems with the use of semaglutide salt forms as APIs for compounding purposes.

of semaglutide-based medications, and REJECTED a new request for a waiver specifically authorizing the use of compounded semaglutide.[4]

Ozempic®, Wegovy®, Mounjaro™ and similar medications are already becoming important tools for treating and managing Type 2 Diabetes and obesity. However, the use of unproven and potentially unsafe compounded versions of these patented medications cannot be condoned by the Board under current circumstances.

CONCLUSION

1. Currently Wegovy® (semaglutide) and Saxenda® (liraglutide) are the only peptides approved by the FDA for weight loss. The off-label use of peptide-based legend drugs solely for weight loss is prohibited;

2. Compounded semaglutide products have not been proven to be safe and effective substitutes or equivalents for the patented drugs;

3. Licensees are advised to refrain from prescribing, dispensing, or administering compounded semaglutide at this time.

Kenneth E. Cleveland, M.D.
Executive Director
MISSISSIPPI STATE BOARD
OF MEDICAL LICENSURE

CC: All Board Licensees

[4] On July 27, 2023, the Board was asked to grant a waiver for compounded semaglutide. Susan McCoy, the Executive Director of the Mississippi Board of Pharmacy, appeared and provided current information concerning compounded semaglutides. The available compounded versions are likely being made with salt forms of semaglutide, chemically synthesized versions, or research-grade ingredients not intended for use in humans. Research-grade materials are not subject to the same strict manufacturing regulations as pharmaceutical-grade APIs, nor are they intended for human use. Director McCoy advised that the substitute ingredients, manufactured in China, have not been proven to be legitimate, effective, or manufactured under sanitary conditions. At least some such products appear to have been originally labeled as research-grade drugs and then relabeled as pharmaceutical grade after they were imported into the United States. Further, some compounding pharmacies appear to be using misleading or inaccurate information in their advertising. At least one out-of-state pharmacy actively marketing compounded semaglutide to Mississippi physicians has ever had a Mississippi compounding certificate, and therefore cannot legally sell any compounded products in this state. The video from July 27 Board meeting is available at: https://www.youtube.com/live/PaXqYWd2In0?si=G0LwcbzHHr3W1ve4&t=1976 The waiver request, comments, and discussion of this issue begin at the 21:20 mark.

July 16, 2024

Humayun J. Chaudhry, DO, MS, FACP, FACOI
President and Chief Executive Officer
Federation of State Medical Boards
400 Fuller Wiser Road, Suite 300
Euless, TX 76309
hchaudhry@fsmb.org

Dear Dr. Chaudhry:

The purpose of this letter is to bring to the attention of the Federation of State Medical Boards (FSMB) information related to injectable compounded drug products containing semaglutide or tirzepatide. We encourage you to share the information in this letter with your members for their awareness and consideration.

FDA is aware of increased interest in compounded semaglutide and tirzepatide products. Compounded drug products can serve an important medical need for certain patients. However, compounded drug products, including compounded semaglutide and tirzepatide products, are not FDA-approved. They do not undergo premarket review by FDA for safety, effectiveness, or quality.

FDA has received reports describing patients who experienced adverse events following the administration of compounded semaglutide or tirzepatide products in doses exceeding the recommended dosing or titration schedule for FDA-approved semaglutide and tirzepatide products. The adverse events described in the reports included nausea, vomiting, fatigue, stomach pain, shortness of breath, headache, heartburn, weakness, intestinal blockage, hypoglycemia, impacted bowels, electrolyte imbalances, bowel infection, ketoacidosis, pancreatitis, and rhabdomyolysis. Some of these are serious adverse events and some of the patients reported seeking medical attention for their symptoms.

FDA's ability to derive conclusions about safety concerns from these reports is limited because, for example, compounding pharmacies that are not registered with the FDA as outsourcing facilities generally do not submit adverse event reports to the FDA, and among the reports submitted, reported information varies. However, certain factors noted in the reports that may have contributed to the adverse events include the following:

- Prescribers started patients on doses that were approximately two to four times higher than the recommended starting doses of FDA-approved semaglutide and

tirzepatide products.
- Compounded semaglutide products were prescribed to be administered twice a week instead of once weekly, which is the recommended frequency of administration for FDA-approved semaglutide and tirzepatide products.
- Prescribers titrated the patients' doses every one to two weeks instead of every four weeks, which is the recommended titration schedule of FDA-approved semaglutide and tirzepatide products.

Health care providers and your members may consider information about the potential for adverse events when doses, dose frequencies, or titration schedules vary from those of the FDA-approved products, and when weighing the risks versus benefits and determining appropriate doses and titration and dosing schedules for patients.

FDA encourages health care professionals and compounders to report adverse events or quality problems experienced with the use of compounded drugs to FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at MedWatch: The FDA Safety Information and Adverse Event Reporting Program or

- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

We are also sending this letter to the Alliance for Pharmacy Compounding, the National Association of Boards of Pharmacy, the National Council of State Boards of Nursing and the Outsourcing Facility Association, for your awareness.

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

Sincerely,

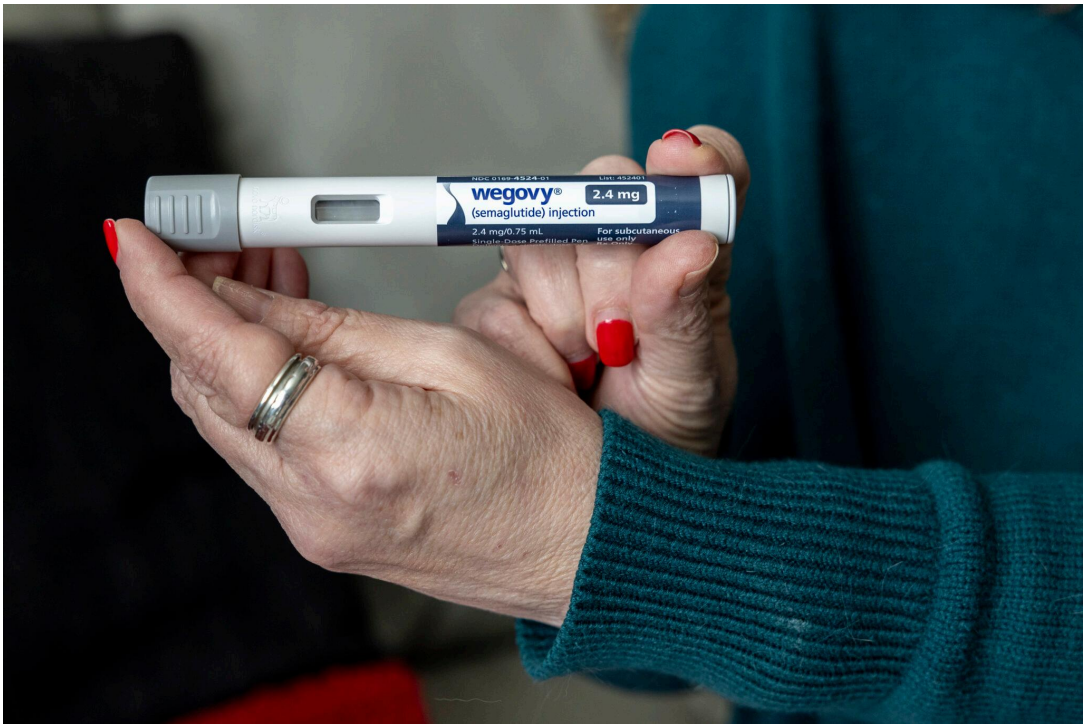
Shannon Glueck, Pharm.D.
Branch Chief, Compounding Branch 4
Division of Compounding II
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food & Drug Administration

HEALTH CARE

‘Compounded’ weight-loss drugs are a growing problem for state regulators

Some pharmacies and clinics are skirting rules meant to keep consumers safe.

BY: **ANNA CLAIRE VOLLERS** - JULY 8, 2024 5:00 AM



Wegovy and other injectable weight-loss medications have soared in popularity in the past two years. Supply issues and spotty insurance coverage have driven some patients to seek out compounded versions of the drug, which tend to be less expensive. Amanda Andrade-Rhoades/The Associated Press

Anna Wysock’s “aha” moment arrived in an Ohio amusement park, as she got ready to ride a roller coaster with her 7-year-old son: The safety bar across her lap would only click into place once. The attendant told her it had to click twice, or she couldn’t ride. She was mortified.

"I had to do the walk of shame and get off the roller coaster and let my 7-year-old ride it with his cousin," Wysock, an elementary school teacher and married mother of two, said of the 2022 incident. "I thought, 'Anna, you've got to get yourself together.'"

Three months after the roller coaster incident, Wysock got a prescription for Mounjaro, an injectable diabetes drug that can be used for weight loss. Her insurance didn't cover it, but a manufacturer's coupon cut the cost to $25 per month. In six months, combined with diet and exercise changes, it helped her shed nearly 60 pounds.

Then the discount ended, raising the price to about $1,000 per month. Friends told her about a local clinic that offered cheaper, compounded versions of weight-loss drugs, and she got a prescription costing $150 per month. She began losing weight again.

To create a compounded drug, pharmacists reformulate the active ingredients in a commercial drug to customize it for an individual patient. Wysock was concerned about making the switch, fearing that the compounded version would cause unfamiliar side effects, "but it was worth it to me to try."

> It's not a normal situation that a blockbuster drug immediately goes on shortage and meets criteria for compounding pharmacies to compound it. I don't think we've ever seen anything like this.
>
> *– Tenille Davis, chief advocacy officer for the Alliance of Pharmacy Compounding*

Drugs prescribed for weight loss such as Mounjaro, Ozempic, Wegovy and Zepbound are popular, expensive, and in short supply. To meet the demand, many physicians, medical spas, IV infusion clinics, telehealth entrepreneurs and pharmacies are jumping on the opportunity to provide compounded versions of the weight-loss medications, which haven't been on the market long enough to have generic equivalents.

State regulators are having trouble keeping up.

The U.S. Food and Drug Administration regulates commercial drugs, but the licensing and oversight of compounding pharmacies falls to states. States including Idaho and Tennessee have announced investigations into illegal dispensing by medical spas and other providers, while states such as California are looking to beef up their oversight.

"It's not a normal situation that a blockbuster drug immediately goes on shortage and meets criteria for compounding pharmacies to compound it," said Tenille Davis, an Arizona pharmacist and the chief advocacy officer for the Alliance of Pharmacy Compounding, an industry group representing compounding pharmacists.

"I don't think we've ever seen anything like this."

A cheaper alternative

Compounding pharmacies are allowed to make a medication that's essentially a copy of a commercially available drug if its active ingredients are listed on the FDA's drug shortage list. The active ingredient in weight-loss drugs such as Wegovy and Zepbound is either semaglutide or tirzepatide, and both are on the list.

"As the demand continues to grow, there continues to be a shortage of conventionally manufactured product, and compounding pharmacies are filling that need," said Davis. "Compounding pharmacies have been able to step in and fill some of those gaps in the marketplace."

Most states have similar compounding rules, though some states — including California and Texas — are stricter than others. Enforcement also varies.

In Mississippi, regulators have told doctors and other providers to stop prescribing compounded medications for weight loss — period. The state medical board has a rule that only medications that have been FDA-approved for weight loss can be prescribed for weight loss — meaning compounded drugs don't qualify.

But many states and compounding pharmacies aren't sure where the lines are. States including Kansas and New Jersey have had to issue statements clarifying their regulations. Last spring, North Carolina and West Virginia issued warnings that compounding weight-loss drugs wasn't allowed — only to amend their statements after determining they had misinterpreted FDA guidance.

Pandemic Health Inequities Expose Need for Greater Obesity Prevention

The pandemic has thrust longstanding racial and economic health disparities into bold relief. Americans of color have died from COVID-19 at two to three times the rate of the rest of the population. A primary underlying cause is obesity. "The fact that obesity has proven to be such a significant risk factor for severe COVID-19 ... Continue reading

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Federal law requires most U.S. compounding pharmacies to make medications for specific patients. They aren't supposed to bulk manufacture medications unless they're registered with the FDA as "outsourcing facilities," which follow a stricter set of federal regulations.

But some states have found compounders breaking those rules.

In May, for example, Idaho's licensing agency announced that regulators had discovered videos of health professionals filling syringes of weight-loss medications that weren't compounded for specific patients, and then sending those syringes to patients, which is illegal under state law.

A compounding pharmacy in Nashville, Tennessee, that was producing tens of thousands of doses of compounded weight-loss medications shut down last year. It had been shipping its drugs nationwide. After state regulators inspected the facility and issued a disciplinary order requiring the company to make several changes

before it could resume compounding, an executive died by suicide and the pharmacy's owner chose to close.

And in Florida, a physician told the state pharmacy board he'd been approached by representatives from a multistate compounding pharmacy that wanted him to write prescriptions for their specific compounded semaglutide product — a form of prescription solicitation that's likely illegal, Carter said.

Compounders generally don't have to register with the FDA, and they aren't required to report which drugs they're compounding. That means there's no way to know exactly how much semaglutide or tirzepatide they are dispensing, said Davis.

'Like Whac-A-Mole'

To protect patients, the FDA enforces strict safety and quality requirements for drug manufacturers and for the small subset of compounding pharmacies registered as outsourcing facilities. The idea is that companies that are bulk manufacturing drugs need closer oversight than smaller compounding pharmacies that are merely customizing drugs for individual patients.

Compound pharmacies that bulk produce weight-loss drugs without FDA approval are doing so without that oversight. And because compounding pharmacies aren't required to report instances of patient harm involving their medications, problems may go undetected.

"It's kind of like 'Whac-A-Mole,'" said Al Carter, a pharmacist and executive director at the National Association of Boards of Pharmacy. He said state boards will only investigate when they receive a complaint.

"There are bad actors out there, purporting to be compounding pharmacies that are licensed in specific states or have the credentials to be able to compound when in actuality they don't," said Carter. "My understanding is most licensed, legitimate pharmacies aren't compounding" weight-loss medications.

Citing Cost to Taxpayers, Cities and States Tackle Obesity

© The Associated Press Kevin Durant of the Oklahoma City Thunder is greeted by students at the Oklahoma Capitol as part of an initiative to battle childhood obesity in Oklahoma City, one of a number of cities and states with plans to tackle obesity. More than 35 percent of Arkansas adults are obese, making it … Continue reading

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Most of the complaints that state regulators are hearing, he said, come from patients who tried to purchase their medications online. The National Association of Boards of Pharmacy recently released a report that found illegal online pharmacies – many operating outside the United States – sell substandard or fake weight-loss medications, or misrepresent the products they sell.

But even some domestic, legally operating clinics misrepresent the products they offer. Some clinics and online pharmacies advertise a "generic" form of semaglutide, even though the FDA hasn't approved a generic form of semaglutide or tirzepatide.

Meanwhile, pharmaceutical giants Novo Nordisk and Eli Lilly have gone on the offensive, filing dozens of lawsuits in multiple states against medical spas, weight-loss clinics and pharmacies. Many of the suits allege the companies falsely marketed their compounded products as commercial medications.

An Eli Lilly spokesperson told Stateline in a statement that "Lilly will continue to pursue legal remedies against those who falsely claim their products are Mounjaro, Zepbound, or 'FDA-approved' tirzepatide, including certain med-spas, wellness centers, online retailers, and compounding pharmacies."

Some states are focusing their investigations specifically on medical spas and IV infusion clinics that offer compounded weight-loss medications. The California State Board of Pharmacy recently discussed expanding its oversight of IV hydration clinics, noting that even when their drug products are from licensed compounding

pharmacies, clinic staff may not be giving them to consumers legally.

And in Texas, some physicians are pushing for legislation to tighten state oversight of medical spas following the death last July of a woman who died after receiving an IV infusion treatment.

But ultimately the burden rests on patients to figure out whether the medications they're taking were made by a licensed and reputable compounder.

For patients like Wysock, compounded versions of weight-loss medications have been life- changing. Wysock said her compounded tirzepatide has enabled her to continue to lose weight, to maintain a healthier lifestyle and to be present for her family and students.

"As a teacher you're on your feet all day long, and then coming home to two kids, I was exhausted by the weekend," she said. "I used to take naps every weekend. That was a 'nonnegotiable.' Now it's not a necessity anymore."

CALIFORNIA IDAHO MISSISSIPPI NORTH CAROLINA TEXAS

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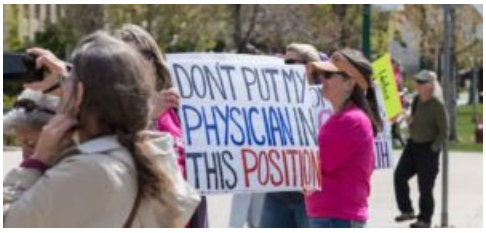

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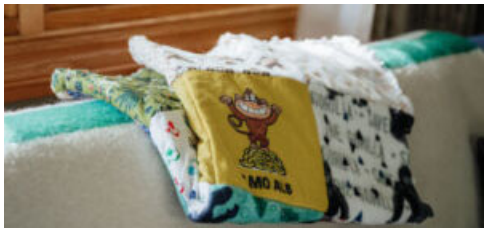

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STATES NEWSROOM

Via Email June 28, 2024

Donna Yeatman
Executive Director
111 Village St
Birmingham, AL 35242

Re: Request to Take Actions Regarding Compounded "Semaglutide" To Support Patient and Prescription Drug Safety

Dear Executive Director Yeatman,

I write on behalf of Novo Nordisk Inc. ("Novo Nordisk") regarding a serious concern for the public health and patient safety relating to compounded products claiming to contain semaglutide. To date, nine Boards of Pharmacy and Medicine, Food and Drug Administration ("FDA" or "Agency"), international regulators, and obesity advocacy groups have issued warnings about compounded "semaglutide." One key global regulator has taken steps to fully ban the compounding of "semaglutide" given the "clear risk to human health," posed by these "potentially unsafe and dangerous" compounded products.[28] We are respectfully urging your Board of Pharmacy to issue a statement warning patients and providers about the risks of compounded "semaglutide" and investigate and take enforcement action against pharmacies unlawfully and unsafely compounding "semaglutide," as appropriate.

Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases, like diabetes and obesity, and 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 Novo Nordisk's well-known, prescription-only medicines: Rybelsus® (semaglutide) tablets as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes; Ozempic® (semaglutide) injection as an adjunct to diet and exercise 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 and established cardiovascular disease; and Wegovy® (semaglutide) injection to reduce excess body weight and maintain weight reduction long term in patients 12 years or older with obesity or adults with overweight and at least one weight-related comorbidity and to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight.

[28] Honorable Mark Butler MP, Ministers: Department of Health and Aged Care, *Protecting Australians from unsafe compounding of replica weight loss products* (May 22, 2024), https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products?language=en.

Driven by core values that prioritize patient safety, we have been taking actions to protect patients from unlawful sales and marketing of potentially dangerous compounded "semaglutide." Compounded products do not have the same assurances of safety, effectiveness, or quality as our FDA-approved products. We have seen several concerning safety, effectiveness, and quality issues with compounded drugs claiming to contain semaglutide, including peptide-related impurities, unknown impurities, inconsistent strengths compared to the labeled strength, and, in one case, no semaglutide at all in the product. As a company, Novo Nordisk shares the Board of Pharmacy's desire to support patient and prescription drug safety. In this regard, we are reaching out to you for your support in addressing unlawful and potentially dangerous compounded drugs purporting to contain semaglutide.

I. Actions Taken by Regulators and Advocacy Groups Concerning Compounded "Semaglutide"

At least nine state regulators have issued statements concerning compounding of products that claim to contain semaglutide.[29] For instance, the Executive Director of the Mississippi Board of Pharmacy advised the Mississippi State Board of Medical Licensure that "substitute ingredients" manufactured in foreign jurisdictions "have not been proven to be legitimate, effective, or manufactured under sanitary conditions."[30] The Mississippi State Board of Examiners "strongly advise[d] medical licensees to refrain from prescribing, dispensing, or administering compounded semaglutide until further notice," because such drugs are "unproven and potentially unsafe."[31] In addition, the

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[29] *See* N.J. Bd. Pharmacy, *Statement Concerning Semaglutide Compounding* (Nov. 6, 2023), https://www.njconsumeraffairs.gov/phar/Documents/Semaglutide-Compounding-Statement-04282023.pdf; N.C. Bd. Pharmacy, *Statement Concerning Semaglutide Compounding* (Apr. 2023), https://www.ncbop.org/downloads/SemaglutideCompounding.pdf; Miss. Bd. Pharmacy, *Compounded Products Due to Shortage or Due to Special Patient Needs*, https://www.mbp.ms.gov/sites/default/files/inline-images/Semaglutide.compoundguidance%20%28002%29.pdf; Ala. Bd. Pharmacy, *Compounding Semaglutide* (Nov. 2023), https:/nabp.pharmacy/wp-content/uploads/2023/11/November-2023-Alabama-State-Newsletter.pdf; Ky. Bd. Pharmacy, Newsletter (June 2023), https://pharmacy.ky.gov/Newsletters/June%202023.pdf; W. Va. Bd. Pharmacy, *Statement Concerning Semaglutide Compounding* (Apr. 2023), https://www.wvbop.com/admin/attachment/FINALSemaglutideCompoundingStatement21APR2023WVBoPdatedFV.pdf; Meg Farris, *Low-cost weight loss drug banned in La.*, 4WWL (Apr. 27, 2023), https://www.wwltv.com/article/news/health/weight-loss-wednesday/low-costweight-loss-drug-banned/289-d2608b63-f8c2-4eb4-9982-0530331d50ea (reflecting ban by Louisiana Board of Pharmacy); Ala. Bd. Med. Exam'rs & Med. Licensure Comm'n, *Concerns with Semaglutide and Other GLP-1 Receptor Agonists*, https://www.albme.gov/press-release/concerns-with-semaglutide-and-other-glp-1-receptor-agonists; Miss. State Bd. Med. Licensure, *Guidance Regarding Semaglutide-Based Medications From the Mississippi State Board of Medical Licensure* (Aug. 29, 2023), https://www.msbml.ms.gov/sites/default/files/news/Semaglutide%20Guidance%2008-29-23.pdf.

[30] Miss. State Bd. Med. Licensure, *Guidance Regarding Semaglutide-Based Medications From the Mississippi State Board of Medical Licensure*, 2 n.4 (Aug. 29, 2023), https://www.msbml.ms.gov/sites/default/files/news/Semaglutide%20Guidance%2008-29-23.pdf.

[31] *Id.* at 1-2.

Alabama Board of Medical Examiners has cautioned that semaglutide products other than those manufactured by Novo Nordisk "may be contaminated, improperly stored and transported, or adulterated."[32]

FDA also has issued statements and published a website related to the compounding of "semaglutide." On April 11, 2023, FDA Commissioner Califf cautioned the public about the use of unapproved compounded drugs for weight loss purposes.[33] In May 2023, FDA published a notice on its website warning patients and providers about the potential safety risks posed by compounded "semaglutide" products.[34] In October 2023, FDA sent a letter to the National Association of Boards of Pharmacy ("NABP") and the Federation of State Medical Boards ("FSMB") highlighting that it had received an increased number of adverse event reports and complaints concerning compounded drug products containing "semaglutide."[35] FDA is also actively monitoring the internet for fraudulent or unapproved products and has issued warning letters to stop the distribution of illegally marketed semaglutide.[36] The Agency warns that such unapproved products may be counterfeit; contain too little, too much, or no active ingredient at all; or contain other harmful ingredients.

The Australian government and Therapeutic Goods Administration ("TGA") recently took broad action to protect patients in Australia from potentially unsafe and dangerous compounded drugs purporting to contain semaglutide. On May 22, 2024, the government announced that to "protect Australians from the clear risk to human health

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[32] Ala. Bd. Med. Exam'rs & Med. Licensure Comm'n, *Concerns with Semaglutide and Other GLP-1 Receptor Agonists*, https://www.albme.gov/press-release/concerns-with-semaglutide-and-other-glp-1-receptor-agonists.

[33] *See* Meg Tirrell, *Health misinformation is lowering U.S. life expectancy, FDA Commissioner Robert Califf says*, CNBC (Apr. 11, 2023), https://www.cnbc.com/2023/04/11/us-life-expectancy-hurt-by-misinformation-fda-commissioner-robert-califf.html.

[34] FDA, *Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss* (current as of Oct. 31, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss.

[35] *See* Letter from F. Gail Bormel to Lemrey "Al" Carter (Oct. 10, 2023), https://www.fda.gov/media/173456/download.

[36] FDA, Warning Letter to www.semaspace.com (Oct. 2, 2023), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/wwwsemaspacecom-665848-10022023; FDA, Warning Letter to www.gorillahealing.com (Oct. 2, 2023), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/wwwgorillahealingcom-664245-10022023; FDA, Warning Letter to US Chem Labs (Feb. 7, 2024), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/us-chem-labs-669074-02072024; FDA, Warning Letter to Synthetix Inc. DBA Helix Chemical Supply (Feb. 7, 2024), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/synthetix-inc-dba-helix-chemical-supply-668918-02072024; FDA, Warning Letter to *www.dashpct.com* (Apr. 24, 2024), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/wwwdashpctcom-679727-04242024.

posed by the large-scale manufacture of compounded injections," they will issue new regulations that will remove GLP-1 RAs from the pharmacy compounding exemption.[37] While acknowledging the valid place for compounding in certain circumstances and recognizing the ongoing shortage of OZEMPIC® and WEGOVY® in Australia, the government determined that the "risk of not acting is far greater [than the consequences of banning GLP-1 RAs from compounding] . . . . You only have to look at the recent reports of individuals impacted by large scale compounding to realize the dangers posed."[38]

Other international regulators also have warned about the risks associated with compounded "semaglutide." The South African Health Products Regulatory Authority ("SAHPRA") has warned that "products claiming to contain semaglutide may not contain the active ingredient, semaglutide, as the SAHPRA registered product, which has been reviewed for quality, safety, and efficacy." The body further recommends that patients should use an SAHPRA-approved product if available over a compounded medicine claiming to contain semaglutide.[39] Relatedly, the Ontario College of Pharmacists explained that pharmacies should contact the prescribing physician to confirm that compounded "semaglutide" is appropriate because "differences may exist in the pharmacokinetics or pharmacodynamics of the compounded preparation" of semaglutide compared to Novo Nordisk's approved products that "could affect its efficacy."[40]

Organizations representing practitioners and patients, such as The Obesity Society, Obesity Medicine Association, and Obesity Action Coalition, echoed these warnings and issued a statement recommending that patients avoid compounded GLP-1 drugs. The groups warn that compounded drugs "are not the same as the drug provided by the manufacturers," and "may pose serious health risks because of impurities or other non-pharmaceutical additives."[41]

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[37] Honorable Mark Butler MP, Ministers: Department of Health and Aged Care, *Protecting Australians from unsafe compounding of replica weight loss products* (May 22, 2024), https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products?language=en.

[38] *Id.*

[39] *See* South African Health Products Regulatory Authority, *SAHPRA's Position On Semaglutide Compounded Products* (Dec. 13, 2023), https://www.sahpra.org.za/news-and-updates/sahpras-position-on-semaglutide-compounded-products/.

[40] Ontario College of Pharmacists, *Important guidance to pharmacists during the current Ozempic® shortage: Expectations when compounding semaglutide preparations to ensure quality and safe patient care* (Dec. 21, 2023), https://www.ocpinfo.com/important-guidance-pharmacists-ozempic-shortage/.

[41] *See* Obesity Medicine Association, *Leading Obesity Expert Organizations Release Statement to Patients on Compounded GLP-1 Alternatives* (Jan. 8, 2024), https://obesitymedicine.org/blog/leading-obesity-expert-organizations-release-statement-to-patients-on-glp-1-compounded-alternatives/.

II. Safety and Effectiveness Risks Posed by Compounded and Online "Semaglutide" Drugs

FDA has received adverse event reports related to compounded products purporting to contain "semaglutide." As of March 31, 2024, FDA's Adverse Event Reporting System ("FAERS") reports 442 cases of adverse events associated with compounded "semaglutide." Of those cases, 319 were classified as "serious" adverse events, 99 reported hospitalization, and seven involved deaths. The FAERS database also includes several reports on product quality issues, dosing issues, and lack of efficacy associated with these compounded drugs. Besides the reports in the FAERS database, there are recent reports highlighting administration errors associated with compounded "semaglutide," where patients self-administered doses up to 10 times greater than the correct amount.[42] Given the historic underreporting of the adverse events associated with compounded drugs,[43] Novo Nordisk is concerned that these 442 cases are just the tip of the iceberg and many more patients are experiencing adverse events from compounded "semaglutide" drugs.

Further heightening the potential risks to patients, Novo Nordisk has seen several entities sell compounded "semaglutide" in combination with other ingredients or in other dosage forms. For example, some entities sell compounded "semaglutide" with the peptide BPC-157, which FDA has placed on a list of bulk drug substances that raise significant safety risks in compounding.[44] Specifically, FDA has determined that BPC-157 "pose[s] risk for immunogenicity" and has "complexities with regard to peptide-related impurities and API characterization."[45] Additionally, a growing number of entities sell sublingual solutions, sublingual tablets, transmucosal films, or oral troches claiming to contain semaglutide. None of these dosage forms with these routes of administration has been studied in clinical trials or reviewed by FDA. Novo Nordisk has also observed that some entities now compound sublingual "semaglutide" products that are liposomal drug products, which FDA has proposed to include on a list of drug products that cannot be compounded because they are demonstrably difficult to compound and therefore present risks to patients that outweigh the benefits.[46]

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[42] Joseph E. Lambson et al., *Administration errors of compounded semaglutide reported to a poison control center – Case series*, 63 J. OF THE AM. PHARMACISTS ASS'N. 1643 (Sep. 25, 2023).

[43] *See* Janet Woodcock and Julie Dohm, *Toward Better-Quality Compounded Drugs — An Update from the FDA*, 377 NEW ENG. J. MED. 2509, 2510 (2017).

[44] *See* FDA, *Safety Risks Associated with Certain Bulk Drug Substances Nominated for Use in Compounding*, https://www.fda.gov/drugs/human-drug-compounding/safety-risks-associated-certain-bulk-drug-substances-nominated-use-compounding (last updated Dec. 12, 2023).

[45] *Id.*

[46] FDA, *Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act*, 89 Fed. Reg. 19,776, 19,780 (Mar. 20, 2024), https://www.regulations.gov/document/FDA-2023-N-0061-0001; Comment from Novo Nordisk, No. FDA-2023-N-0061-0021 (Jun. 18, 2024), https://www.regulations.gov/comment/FDA-2023-N-0061-0021.

Novo Nordisk surveillance and testing offer a snapshot of the types of risks to patients associated with compounded "semaglutide." Testing results have revealed that some compounded "semaglutide" samples contain peptide-related impurities, including 24% total impurities in a sample from WellHealth Inc., 33% unknown impurities in a sample from Wells Pharmacy Network, amino acid additions and deletions, and dimers.[47] When these types of peptide-related impurities are present in compounded drugs administered to patients, they have the potential to stimulate an immune reaction upon repeated injections, which can lead to serious and life-threatening reactions like anaphylaxis for patients.[48]

In addition, testing results have shown that certain compounded "semaglutide" samples have substantially lower strengths than labeled (e.g., 12% reduction in strength in a sample from TruLife Pharmacy, 19% reduction in strength in a sample from Brooksville Pharmacy, and 20% reduction in strength in a sample from Medi-Oak Pharmacy),[49] rendering them potentially less effective than expected. To protect patients from compounded "semaglutide" products with these types of safety and efficacy issues, Novo Nordisk has filed several lawsuits against compounding pharmacies alleging that their drug products are adulterated and misbranded.

Novo Nordisk has also uncovered that some compounded products claiming to contain semaglutide do not have any semaglutide at all. Testing results for a sublingual "semaglutide" liquid solution sold by Midtown Express Pharmacy in Tennessee showed that the sample contained no semaglutide whatsoever.[50] The pharmacy also advertises that its product is comparable to Novo Nordisk's FDA-approved drug products and has better semaglutide absorption in the body than RYBELSUS® and that patients experience less nausea than those taking Novo Nordisk's injectable semaglutide products.[51] Novo Nordisk has filed a lawsuit against Midtown Express Pharmacy, alleging that its drug products are adulterated and misbranded and that the pharmacy has engaged in false advertising.

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[47] *See* Complaint, *Novo Nordisk Inc. v. Wells Pharmacy Network, LLC*, No. 5:23-cv-689 (M.D. Fla. Nov. 2023).

[48] Arne Staby et al., *Influence of Production Process and Scale on Quality of Polypeptide Drugs: A Case Study on GLP-1 Analogs*, 37 PHARM. RES. 120, 123 (2020); FDA, *Immunogenicity Assessment for Therapeutic Protein Products* 2 (Aug. 2014), https://www.fda.gov/media/85017/download.

[49] *See, e.g.*, First Amended Complaint, *Novo Nordisk Inc. v. Brooksville Pharm. Inc.*, No. 8:23-cv-01503-WFJ-TGW (M.D. Fla. Nov. 2023); Amended Complaint, *Novo Nordisk Inc. v. Live Well Drugstore LLC*, No. 3:23-cv-808 (M.D. Fla. May 2024); Complaint, *Novo Nordisk Inc. v. MediOAK Pharmacy LLC*, No. 4:24-cv-02032 (Dist. Ct. S.D. Tex. May 2024).

[50] *See* Complaint, *Novo Nordisk Inc. v. Dunklau Pharmacy Holdings LLC et al.,* No. 3:24-CV-00667 (M.D. Tenn. May 2024).

[51] *Id.*

In addition to the actions taken with respect to compounded "semaglutide," Novo Nordisk has initiated action against an unlawful, online retailer of "semaglutide" named Aesthetic Maison. The online-only site sold "semaglutide" powder intended for reconstitution and injection directly to patients without any prescription from a medical professional, claiming that it was for "research use only."[52] Aesthetic Maison also makes claims on its website about the safety and efficacy of its unapproved "semaglutide" powder and products based on research of Novo Nordisk's FDA-approved medicines containing semaglutide.[53] Novo Nordisk's lawsuit against Aesthetic Maison alleges that its sales of "semaglutide" drugs violate state unfair competition laws and that the entity has engaged in false advertising. This lawsuit is born out of patient safety concerns similar to the ones raised by NABP in its RogueRx report about online entities selling GLP-1 agonists for "research purposes only" to patients without holding required pharmacy licensure and without requiring a valid prescription.[54]

III. Requests for Action

We believe that your state's support is critical to protect patients and address unlawful and potentially dangerous compounding of "semaglutide" products. We urge your Board of Pharmacy to release a statement describing the potential safety concerns associated with compounded drugs purporting to contain semaglutide. We ask that the statement cover:

- Quality issues Novo Nordisk's testing has revealed about several compounded samples, including peptide-related impurities and inaccurately labeled "semaglutide" strength;
- Adverse events associated with compounded "semaglutide" drugs listed in FDA's FAERS database;
- Evidence that some entities sell compounded "semaglutide" in combination with other ingredients, such as the peptide BPC-157, or in dosage forms and with routes of administration that have not been studied in clinical trials or reviewed by FDA, such as dissolvable tablets and liposomal drug products for the sublingual route of administration;
- State regulator statements identifying concerns with compounding of products that claim to contain semaglutide, including concerns about "substitute ingredients"; manufacture in foreign jurisdictions; the lack of proof that the drugs are legitimate, effective, or manufactured under sanitary conditions; and the potential for contamination, improper storage and transportation, and adulteration;

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[52] Complaint, *Novo Nordisk Inc. v. Aesthetic Maison LLC*, No. 4:24-cv-2036 (S.D. Tex. May 2024).

[53] Complaint, *Novo Nordisk Inc. v. Aesthetic Maison LLC*, No. 4:24-cv-2036 (S.D. Tex. May 2024).

[54] *See* National Association of Boards of Pharmacy, *RogueRx Activity Report: Injectable Weight Loss Drugs: How Illegal Online Drug Sellers Are Taking Advantage of Patients* (2024), https://nabp.pharmacy/wp-content/uploads/2024/04/RogueRx-Activity-Report-Injectable-Weight-Loss-Drugs-2024.pdf.

- FDA's statements on compounded "semaglutide," including its concern that "illegally marketed semaglutide" could "contain too little, too much, or no active ingredient at all, or contain other harmful ingredients";
- Foreign regulator statements describing the concerns associated with compounded "semaglutide" drugs and the actions they have or intend to take, including Australia's plan to protect Australian patients from the clear risk to human health posed by the large-scale manufacture of compounded injections; and
- Statements from organizations like The Obesity Society, Obesity Medicine Association, and Obesity Action Coalition, which recommend that patients avoid compounded GLP-1 drugs like compounded "semaglutide."

We encourage the Board to remind pharmacists and practitioners that compounding with the active pharmaceutical ingredient ("API") semaglutide must comply with the Federal Food, Drug, and Cosmetic Act, including section 503A, and any applicable state laws and regulations. Federal law prohibits compounding using any non-pharmaceutical grade API, using API unaccompanied by a valid certificate of analysis, or using API produced by an establishment that is not registered with FDA.

Novo Nordisk will be reaching out soon to set up a meeting or call with your Board of Pharmacy to discuss patient safety, including the compounding of drug products purporting to contain "semaglutide" and associated risks. We look forward to hearing from you.

Sincerely,

Robert B. Clark
Vice President, Regulatory Affairs
Novo Nordisk Inc.

Kentucky Board of Pharmacy

Important Update- Compounding Semaglutide and Tirzepatide

The Kentucky Board of Pharmacy (Board) staff has received inquiries concerning the compounding of GLP-1 medications such as semaglutide and tirzepatide. Semaglutide is available as a commercially available drug product marketed as Ozempic™ and Rybelsus™ for treating diabetes and as Wegovy™ for weight loss. Tirzepatide is available as a commercially available drug product marketed as Mounjaro™ for treating diabetes and as Zepbound™ for weight loss.

The federal Food Drug & Cosmetic Act prohibits pharmacies from compounding "drug products that are essentially copies of a commercially available drug product."1 In general, compounding pharmacies may not compound semaglutide or tirzepatide, a commercially available drug product.

Further, 201 KAR 2:076 also prohibits the compounding of essential copies of a commercially available drug product unless authorized by 21 U.S.C. 353(a). This is enforceable by the Kentucky Board of Pharmacy for individuals or entities licensed or permitted by the Commonwealth.

On March 10, the FDA provided the following timeline updates for compounders:

Tirzepatide: On March 5, 2025, the district court denied the plaintiffs' preliminary injunction motion in Outsourcing Facilities Association v. FDA, 4:24-cv-00953 (N.D. Tex.). Therefore, consistent with FDA's February 11, 2025 update:

- For a state-licensed pharmacy or physician compounding under section 503A of the FD&C Act, the period of enforcement discretion described below has ended.
- For outsourcing facilities under section 503B, FDA does not intend to take action against compounders for violations of the FD&C Act arising from conditions that depend on tirzepatide injection products' inclusion on FDA's drug shortage list until March 19, 2025.

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Semaglutide: On April 24, 2025, the district court denied the plaintiffs' preliminary injunction motion in Outsourcing Facilities Association v. FDA, 4:25-cv-00174 (N.D. Tex.) regarding compounded semaglutide. Therefore, consistent with FDA's March 10, 2025, update:

- For a state-licensed pharmacy or physician compounding, dispensing or distributing semaglutide injection products under section 503A of the FD&C Act, the period of enforcement discretion (described below) has ended.
- For outsourcing facilities compounding, distributing or dispensing semaglutide injection products under section 503B, FDA does not intend to take action for violations of the FD&C Act arising from conditions that depend on semaglutide injection products' inclusion on FDA's drug shortage list until May 22, 2025.

https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize

When Is Compounding of Semaglutide or Tirzepatide Permissible?

FDA does not consider a drug to be "commercially available" if it appears on the FDA's shortage list.2 As is true of all drug products, pharmacists and pharmacies should regularly monitor FDA's shortage list at the link provided below.2

Also, the federal FD&C Act states that a compounded drug product is not "essentially a copy" of a commercially available drug product if a change is made for an identified individual patient and the prescribing practitioner has determined that the change will produce a significant difference for that patient.3 FDA has explained:

However, 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.4

Is adding another commercially available drug, such as B12, still considered compounding a commercially available drug product?

The FDA has explained:

FDA intends to consider 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 section III.B.2 (see above reference to compounding for an individualized patient*).*

The Bottom Line

Compounding a commercially available product is allowable only in certain narrow circumstances, as described above.

The Board is charged with protecting the public. Therefore, compounding semaglutide or tirzepatide drug products in a way that fails to conform with governing law may lead to enforcement action by the Food and Drug Administration and the Kentucky Board of Pharmacy.

Pharmacies should also be aware that pharmaceutical manufacturers may initiate legal proceedings against prescribers and compounders to combat illegal semaglutide or tirzepatide drug product compounding.

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1. FD&C Act § 503A(b)(1)(D).

2. The FDA's shortage list may be found at https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

3. FD&C Act § 503A(b)(2).

4. Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act at pp. 8-9.

5. FD&C Act § 503A(b)(1)(A)(i).

GUIDANCE REGARDING SEMAGLUTIDE-BASED MEDICATIONS FROM THE MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

The Board recognizes that Type 2 Diabetes and obesity are two of the most serious public health problems facing our state. The potential benefits for many Mississippi patients of new semaglutide-based medications like Ozempic® and Wegovy® are obvious.[1] However, because these drugs are in high demand and short supply, some providers have turned to the use of compounded versions that are represented to be safe substitutes for the patented drugs, but which are unproven. Public safety requires that the Board emphasize three points concerning this issue:

1. The off-label use of semaglutide-based legend drugs is prohibited by Board regulation;[2]

2. Compounded semaglutide products likely use as Active Pharmaceutical Ingredients (APIs) salt forms of semaglutide, chemically synthesized versions, or research-grade ingredients not intended for human use. Such APIs have not been proven to be safe and effective substitutes or equivalents for the patented drugs;

3. The Board strongly advises medical licensees to refrain from prescribing, dispensing, or administering any compounded semaglutide until further notice.

Ozempic® and Wegovy® are currently listed on the Food and Drug Administration (FDA) "shortage list." Generally, when a drug appears on the shortage list, compounded drugs can be made and distributed with fewer restrictions. However, the listing of Ozempic® and Wegovy® does not change the high standards for quality of ingredients and sanitary manufacturing conditions with which compounders must comply.

Board regulations prohibit off-label use of any non-FDA-approved medication solely for the purpose of weight loss. On March 22, 2023, the Board passed an emergency rule to permit waivers to be granted for the off-label use of diet medications on a per-medication or class of medications basis. The Board then granted an emergency waiver or exemption for Semaglutide-based legend drugs until July 1, 2023.[3] However, since that time the Board has received additional information on this issue from various sources, including the Food and Drug Administration (FDA) and the Mississippi Board of Pharmacy. Therefore, on July 27, 2023 the Board RESCINDED the exemption permitting off-label use

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[1] Saxenda® (liraglutide) is also FDA-approved for weight loss. Other non-semaglutide based medications showing promise for these conditions are also becoming available, such as Mounjaro™ (tirzepatide).

[2] *See* Part 2640, Chapter 1, Rule 1.5(F). "Off-label use of any medication that does not have Food and Drug Administration approval for use in the treatment of weight loss is prohibited if administered solely for the purpose of weight loss."

[3] On April 18, 2023, after the Board received information from the Mississippi Board of Pharmacy expressing concerns about the safety of compounded semaglutide based on FDA publications, the Executive Director emailed to all Board licensees a memorandum prepared by the Pharmacy Board and distributed to Mississippi pharmacists. That memo outlined problems with the use of semaglutide salt forms as APIs for compounding purposes.

of semaglutide-based medications, and REJECTED a new request for a waiver specifically authorizing the use of compounded semaglutide.[4]

Ozempic®, Wegovy®, Mounjaro™ and similar medications are already becoming important tools for treating and managing Type 2 Diabetes and obesity. However, the use of unproven and potentially unsafe compounded versions of these patented medications cannot be condoned by the Board under current circumstances.

CONCLUSION

1. Currently Wegovy® (semaglutide) and Saxenda® (liraglutide) are the only peptides approved by the FDA for weight loss. The off-label use of peptide-based legend drugs solely for weight loss is prohibited;

2. Compounded semaglutide products have not been proven to be safe and effective substitutes or equivalents for the patented drugs;

3. Licensees are advised to refrain from prescribing, dispensing, or administering compounded semaglutide at this time.

Kenneth E. Cleveland, M.D.
Executive Director
MISSISSIPPI STATE BOARD
OF MEDICAL LICENSURE

CC: All Board Licensees

[4] On July 27, 2023, the Board was asked to grant a waiver for compounded semaglutide. Susan McCoy, the Executive Director of the Mississippi Board of Pharmacy, appeared and provided current information concerning compounded semaglutides. The available compounded versions are likely being made with salt forms of semaglutide, chemically synthesized versions, or research-grade ingredients not intended for use in humans. Research-grade materials are not subject to the same strict manufacturing regulations as pharmaceutical-grade APIs, nor are they intended for human use. Director McCoy advised that the substitute ingredients, manufactured in China, have not been proven to be legitimate, effective, or manufactured under sanitary conditions. At least some such products appear to have been originally labeled as research-grade drugs and then relabeled as pharmaceutical grade after they were imported into the United States. Further, some compounding pharmacies appear to be using misleading or inaccurate information in their advertising. At least one out-of-state pharmacy actively marketing compounded semaglutide to Mississippi physicians has ever had a Mississippi compounding certificate, and therefore cannot legally sell any compounded products in this state. The video from July 27 Board meeting is available at: https://www.youtube.com/live/PaXqYWd2In0?si=G0LwcbzHHr3W1ve4&t=1976 The waiver request, comments, and discussion of this issue begin at the 21:20 mark.

SUPPLEMENTAL GUIDANCE REGARDING
GLP-1 and GIP MEDICATIONS

FROM THE MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE, ISSUED AUGUST 6, 2024

APPLICABILITY

This Supplemental Guidance Regarding GLP-1- And GIP Medications updates the previous Guidance Regarding Semaglutide-Based Medications, issued by the Mississippi State Board of Medical Licensure on August 28, 2023, and supersedes the previous Guidance to the extent any conflict exists.

EXEMPTION FOR CERTAIN COMPOUNDED GLP-1 AND GIP MEDICATIONS APPROVED

Based on updated information, at its meeting on July 17, 2024, the Mississippi State Board of Medical Licensure unanimously voted to grant a request for a limited waiver or exemption from the FDA requirements contained in Part 2640, Chapter 1, Rule 1.5(F) for certain compounded versions of GLP-1 and GIP medications. **The exemption applies only if the following terms and conditions are met:**

1. The FDA approval requirements in Rule 1.5(F) shall not apply to compounded versions of GLP-1 and GIP drug classes in two situations: (1) a patient has a specific clinical need that is not met by a commercially available product or (2) the specific medication is currently on the FDA's Drug Shortages List, AND

2. If ANY compounded GLP-1 or GIP drugs are administered or dispensed, the licensee has a duty to confirm that the pharmacy supplying the compounded medications has either obtained the active pharmaceutical ingredient (API) from a US based re-packager or wholesaler that has performed API verification testing to confirm the supplied certificate of analysis (COA), or the supplying pharmacy has independently performed API verification testing to confirm the supplier's COA

A copy of the Board Order approving the exemption is attached hereto.

The first condition may be met by documenting in the patient's medical records that one of the two circumstances under which a compounded version of a legend drug may be produced (specific clinic need or appearance on the FDA Drug Shortages List) exists. The second condition may be met by a licensee obtaining documentation from the wholesaler or supplying pharmacy confirming that proper chemical analysis and API verification testing has been performed. The Board strongly advises that licensees maintain copies of the COA and verification documentation in their records.

The FDA does not approve any compounded drug products. Therefore, the restriction on off-label use for the purpose of weight loss does not apply to compounded versions of GLP-1 and GIP based medications that qualify for the exemption.

Despite the creation of this exemption, Licensees must remain vigilant, as untested and unsafe APIs will undoubtedly remain available on the black or gray markets. This includes both unconfirmed and untested versions of base APIs as well as salt-forms which are not equivalent to base APIs. The Board cannot and does not condone the use of unproven and potentially unsafe versions of any compounded GLP-1 or GIP medications obtained from a source that cannot provide the requisite verification and documentation.

CONCLUSION

1. Compounded versions of GLP-1 and GIP medications may be used without violating Board regulations if a specific clinical need exists or if the medication appears on the FDA Drug Shortages List; and

2. Licensees obtain and maintain COA and API verification testing documentation for any such compounded medications prescribed, administered, or dispensed;

3. Prescribing, dispensing, or administering any compounded GLP-1 or GIP medication **that does not qualify for the exemption** would violate Board regulations, specifically Part 2640, Chapter 1, Rule 1.5(F).

KENNETH E. CLEVELAND, MD
EXECUTIVE DIRECTOR

MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

BEFORE THE MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

ORDER

THIS MATTER comes before the Mississippi Board of Medical Licensure Board (Board) as a request for a waiver exempting Glucagon-like Peptide-1 (GLP-1) Receptor Agonist and Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Drug Classes from the requirements of Part 2640 Chapter 1: Rules Pertaining to Prescribing, Administering and Dispensing of Medication Rule 1.5(f) under certain circumstances. Board Rule 1.5(f) states:

> A licensee must not utilize a schedule III, IV or V controlled substance or legend drug for purposes of weight loss unless it has an FDA approved indication for this purpose and then only in accordance with all of the above enumerated conditions. The purpose of this rule is to prohibit the use of such drugs as diuretics and thyroid medications for the sole purpose of weight loss.
>
> Off-label use of any medication that does not have Food and Drug Administration approval for use in the treatment of weight loss is prohibited if administered solely for the purpose of weight loss. Thyroid hormone, diuretics, vitamin B12, B1, B2, B6, methionine, choline, inositol, chromium picolate and human chorionic gonadotropin are examples of medications that may not be used in this manner. This prohibition does not apply to FDA categories of nutritional supplements sold without prescription.
>
> Licensees may request the Board waive the FDA requirements set forth in Rule 1.5(F) on a per-medication or class of medications basis, for good cause. Temporary waiver may be approved by the Executive Director until the request can be heard before the Board
>
> .

Edra S. Kimmel, MD (License #15452) personally appeared before the Board and presented the request. Todd Dear, Associate Director of the Mississippi Board of

Pharmacy, also personally appeared and provided information to the Board concerning the use of compounded versions of GLP-1 and GIP medications.

After consideration and discussion, the Board unanimously voted to approve the waiver request and issues the following **FINDINGS OF FACT AND CONCLUSIONS OF LAW:**

Good cause exists for the Board to grant a limited waiver of the FDA requirements set forth in Rule 1.5(F), specifically exempting compounded versions of Glucagon-like Peptide-1 (GLP-1) Receptor Agonist and Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Drug Classes under the following terms and conditions:

1. The FDA approval requirements in Rule 1.5(F) shall not apply to compounded versions of GLP-1 and GIP drug classes in two situations: (1) a patient has a specific clinical need that is not met by a commercially available product or (2) the specific medication is currently on the FDA's Drug Shortages List.

2. If ANY compounded GLP-1 or GIP drugs are administered or dispensed, the licensee has a duty to confirm that the pharmacy supplying the compounded medications has either obtained the active pharmaceutical ingredient (API) from a US based re-packager or wholesaler that has performed API verification testing to confirm the supplied certificate of analysis (COA), or the supplying pharmacy has independently performed API verification testing to confirm the supplier's COA.

SO ORDERED, this the 17th day of July 2024.

MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

BY: Michelle Y. Owens
MICHELLE Y. OWENS, M.D.
PRESIDENT

Compounded Products Due to Shortage or Due to Special Patient Needs

The FDA does not typically allow compounding of commercially available drugs unless the drug is not readily available and is listed on the FDA drug shortage list OR there is a specific change for an identified patient whose medical needs cannot be met by the commercially available product. While correctly applying either of the above exceptions prevents FDA action on compounding drugs that are essentially copies of a commercially available drug product, compounders must ensure that compounded bulk drug substance complies with FDA Bulk Drug Substance Requirements.

Semaglutide compounding: The compounding of semaglutide salts by pharmacies and outsourcers has risen due to the FDA shortage status of Wegovy® and Ozempic®. Below is an explanation of how semaglutide compounding does not meet FDA requirements:

1. Comply with the standards of applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding: **Semaglutide does not have a USP or NF monograph.**
2. If such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary: **Semaglutide base is in the approved FDA products list but not semaglutide sodium, semaglutide acetate or other salt forms. The FDA has verbally stated that compounding with semaglutide salts does not meet this requirement.**
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 section 503A or section 503b: **Semaglutide does not meet the bulk substance requirements and is not included in the categories of nominated substances.**

Mississippi Board of Pharmacy staff are utilizing this communication to inform all licensees involved in compounding that semaglutide compounding does not meet the requirements as set by FDA; therefore, compounding in this manner may result in enforcement action being taken by FDA and/or the Mississippi Board of Pharmacy. We would also like to make licensees aware of the need to read the fine print on any invoices received for bulk drug substances as there may be instances where these substances are actually research grade product and not pharmaceutical grade product. Lastly, drug manufacturers have become aware of the practice of using semaglutide salts for compounding and may choose to initiate legal proceedings to combat this practice.

References:

- Compounded Drug Products that Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
- Compounded Drug Products that Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act.
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.

PHILIP D. MURPHY
Governor

TAHSHA WAY
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
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November 6, 2023

STATEMENT CONCERNING SEMAGLUTIDE COMPOUNDING

New Jersey Board of Pharmacy (the Board) staff have received inquiries concerning compounding of semaglutide. Semaglutide is, of course, a commercially available drug product marketed as Ozempic™ for treatment of diabetes and as Wegovy™ for weight loss.

The federal Food Drug & Cosmetic Act prohibits pharmacies from compounding "drug products that are essentially copies of a commercially available drug product." FD&C Act § 503A(b)(1)(D). In general, then, compounding pharmacies may not compound semaglutide, a commercially available drug product.

Board regulations address this topic in N.J.A.C.13:39-11.25 PROHIBITED COMPOUNDING:

a) A pharmacist shall not compound preparations that contain drug products that appear on the Federal Food and Drug Administration's List of Drug Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness, codified at 21 CFR 216.24.

b) A pharmacist shall not compound any commercially available drug products unless:

1) The commercially available product is modified to produce a significant difference, in the professional judgment of the prescriber, between the compounded product for the patient and the comparable commercially available product; or

2) The commercially available product is not available from normal distribution channels in a timely manner to meet the patient's needs, and the dispensing of the compounded product has been approved by the prescriber and the patient.

c) A pharmacist who compounds a commercially available product consistent with the requirements of (b) above shall maintain documentation of the reason for such compounding.

When Is Compounding of Semaglutide Permissible?

FDA does not consider a drug to be "commercially available" if it appears on the FDA's shortage list – https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm Ozempic™ and Wegovy™ have, at times, appeared on the shortage list. On April 27, 2023, FDA officials clarified that a drug is considered in shortage by the FDA if it is listed at the above site and its "status" is described as "currently in shortage." As is true of all drug products, pharmacists and pharmacies should regularly monitor FDA's shortage list at the link above to determine semaglutide's shortage status.

The federal FD&C Act also states that a compounded drug product is not "essentially a copy" of a commercially available drug product if a change is made for an identified individual patient and the prescribing practitioner has determined that the change will produce a significant difference for that patient. FD&C Act § 503A(b)(2). FDA has explained:

> However, 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.

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act at pp. 8-9.

Adding additional substances to a compounded product that is otherwise an essential copy of a commercially available drug product is not included in FDA's list of circumstances meeting Section 503A(b)(2)'s requirements.

If/When Compounding of Semaglutide Is Permissible, How Must It Be Performed?

If and when compounding of a semaglutide drug product is allowed under the terms of the FD&C Act, pharmacists should be aware that substances used to compound must: (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, be components of drugs approved by the Secretary [of HHS]; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary [of HHS], appear on a list developed by the Secretary through regulation. FD&C Act § 503A(b)(1)(A)(i).

With respect to semaglutide:

(1) There is no USP or NF monograph for semaglutide.

(2) Ozempic™ and Wegovy™ contain semaglutide base. Hence, only the base is a component of an FDA-approved drug. No salt form of semaglutide is contained in an FDA-approved drug.

(3) Semaglutide does not – in any form – appear on the FDA's "bulks list" for compounding. Section 503A Bulks List Final Rule Questions and Answers So, for this separate and independent reason, no salt form of semaglutide may be used in a compounded drug product.

Even if a pharmacy obtained semaglutide base for potential compounding use, the pharmacy must ensure that the API received is a pharmaceutical grade product, accompanied by a valid certificate of analysis, and is sourced from an establishment registered with FDA under Section 510 of the FD&C Act. FD&C Act § 503A(b)(1)(A)(ii) – (iii). Board staff are aware that some "wholesalers" are offering "research use only" products and/or products produced by establishments not registered with FDA. These may not be used for compounding in any circumstance.

The Bottom Line

Compounding of a commercially-available product is allowable only in certain narrow circumstances described above. Even when compounding of a semaglutide drug product is allowable under the FD&C Act, the use of semaglutide salts, the use of any non-pharmaceutical grade API, or one not produced by an FDA-registered establishment, is prohibited.

Compounding semaglutide drug product in a way that fails to conform with governing law may lead to enforcement action by the Food and Drug Administration and/or the New Jersey Board of Pharmacy.

Pharmacies should be aware that pharmaceutical manufacturers may choose to initiate their own legal proceedings against prescribers and compounders to combat illegal semaglutide drug product compounding.

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STATEMENT CONCERNING SEMAGLUTIDE COMPOUNDING

The West Virginia Board of Pharmacy (Board) staff has received inquiries concerning the compounding of semaglutide. This topic has become very prominent across the nation[1], as the medication has gained notoriety for various reasons. Semaglutide is, of course, a commercially available drug product marketed as Ozempic™ for treating diabetes and as Wegovy™ for weight loss. The Board of Pharmacy in both Mississippi[2] and North Carolina[3] have already issued statements, and the Boards of Pharmacy in other states appear ready to make similar statements.

The federal Food Drug & Cosmetic Act prohibits pharmacies from compounding "drug products that are essentially copies of a commercially available drug product."[4] In general, compounding pharmacies may not compound semaglutide, a commercially available drug product.

When Is Compounding of Semaglutide Permissible?

FDA does not consider a drug to be "commercially available" if it appears on the FDA's shortage list.[5] Ozempic™ and Wegovy™ have, at times, appeared on the shortage list, but as of April 18, 2023, the FDA's shortage list indicates that all strengths of Ozempic™ and Wegovy™ are "available." Accordingly, there is no shortage list justification to copy commercially available semaglutide products. As is true of all drug products, pharmacists and pharmacies should regularly monitor FDA's shortage list at the link provided below.[5]

Also, the federal FD&C Act states that a compounded drug product is not "essentially a copy" of a commercially available drug product if a change is made for an identified individual patient and the prescribing practitioner has determined that the change will produce a significant difference for that patient.[6] FDA has explained:

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[1] We are aware that at least Mississippi and North Carolina have taken action. See FNs 2 & 3.
[2] https://www.mbp.ms.gov/news/semaglutide-compounding
[3] http://www.ncbop.org/PDF/SemaglutideCompounding.pdf
[4] FD&C Act § 503A(b)(1)(D).
[5] The FDA's shortage list may be found at https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
[6] FD&C Act § 503A(b)(2).

However, 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.[7]

Further, the FDA's list of circumstances that meet the requirements of Section 503A(b)(2) does not include adding additional substances to a compounded product that is otherwise "essentially a copy" of a commercially available drug product.

When Compounding of Semaglutide Is Permissible, How Must It Be Performed?

When compounding of a semaglutide drug product is allowed under the FD&C Act, pharmacists should be aware that substances used to compound must: (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, be components of drugs approved by the Secretary [of HHS]; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary [of HHS], appear on a list developed by the Secretary through regulation.[8]

With respect to semaglutide:

(1) There is no USP or NF monograph for semaglutide.

(2) Ozempic™ and Wegovy™ contain semaglutide base. Hence, only the base is a component of an FDA-approved human drug product. No salt form of semaglutide is contained in an FDA-approved drug.

(3) Semaglutide does not – in any form – appear on the FDA's "bulks list" for compounding.[9] So, for this separate and independent reason, no salt form of semaglutide may be used in a compounded drug product.

Even if a pharmacy obtained semaglutide base for potential compounding use, the pharmacy must ensure that the API received is a pharmaceutical-grade product, accompanied by a valid certificate of analysis, and is sourced from an establishment registered with the FDA under Section 510 of the FD&C Act.[10] Board staff is aware that some "wholesalers" offer "research use only" products and products produced by establishments which are not registered with the FDA. These products may not be used for compounding in any circumstance.

[7] Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act at pp. 8-9.
[8] FD&C Act § 503A(b)(1)(A)(i).
[9] Section 503A Bulks List Final Rule Questions and Answers
[10] FD&C Act § 503A(b)(1)(A)(ii) – (iii).

The Bottom Line

Compounding a commercially available product is allowable only in certain narrow circumstances, as described above. Even when the compounding of a semaglutide drug product is allowed under the FD&C Act, the use of semaglutide salts, the use of any non-pharmaceutical grade API, or one not produced by an FDA-registered establishment, is prohibited.

The Board is charged with protecting the public.[11] Therefore, compounding semaglutide drug products in a way that fails to conform with governing law may lead to enforcement action by the Food and Drug Administration and the West Virginia Board of Pharmacy.

Pharmacies should also be aware that pharmaceutical manufacturers may initiate legal proceedings against prescribers and compounders to combat illegal semaglutide drug product compounding.

[11] W. Va. Code § 30-1-1a.

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:** 12/11/2025 **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: 12/18/2025	**5) Attachments:** ☐ Yes ☒ No	**6) How should the item be titled on the agenda page?** Credentialing Matters – Discussion and Consideration 1) Remote Dispensing Site Application Update	
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 12/11/2025 **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.