

Phone: 608-266-2112 Web: http://dsps.wi.gov Email: dsps@wisconsin.gov

**Tony Evers, Governor Dan Hereth, Secretary** 

### VIRTUAL/TELECONFERENCE MEDICAL EXAMINING BOARD Virtual, 4822 Madison Yards Way, Madison Contact: Tom Ryan (608) 266-2112 February 21, 2024

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

### AGENDA

### 8:00 A.M.

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

A. Adoption of Agenda (1-5)

### B. Approval of Minutes of January 17, 2024 (6-13)

- C. Introductions, Announcements and Recognition
- D. Reminders: Conflicts of Interest, Scheduling Concerns

### E. Administrative Matters – Discussion and Consideration

- 1) Department, Staff and Board Updates
- 2) Board Members Term Expiration Dates
  - a. Bond, Jr., Milton 7/1/2027
  - b. Chou, Clarence P. -7/1/2027
  - c. Clarke, Callisia N. 7/1/2024
  - d. Ferguson, Kris 7/1/2025
  - e. Gerlach, Diane M. 7/1/2024
  - f. Goel, Sumeet K. 7/1/2027
  - g. Hilton, Stephanie -7/1/2024
  - h. Lerma, Carmen 7/1/2024
  - i. Leuthner, Steven R. 7/1/2027
  - j. Majeed-Haqqi, Lubna 7/1/2027
  - k. Schmeling, Gregory J. 7/1/2025
  - 1. Siebert, Derrick R. 7/1/2025
  - m. Yu, Emily S. 7/1/2024
- 3) Wis. Stat. § 15.085 (3)(b) Affiliated Credentialing Boards' Biannual Meeting with the Medical Examining Board to Consider Matters of Joint Interest
  - a. Physician Assistant Affiliated Credentialing Board Jennifer Jarrett, Chairperson

- F. Professional Assistance Procedure (PAP) Discussion of Expansion to Include Mental Health Disorders (14)
  - 1) **8:00 A.M. PRESENTATION:** Jim Lorence, WI Medical Society's Chief Value and Engagement Officer (15-26)
- G. Legislative and Policy Matters Discussion and Consideration
- H. Administrative Rule Matters Discussion and Consideration (27)
  - 1) Adoption Order: Med 26, Relating to Military Medical Personnel (28-35)
  - 2) Pending or Possible Rulemaking Projects (36)
- I. FDA Advisory Letter to FSMB Concerning Compounded Semaglutides Discussion and Consideration (37-40)
- J. Statement of Concern for Impact of Healthcare Dynamics on Wisconsin's Smaller Communities – Discussion and Consideration (41)
- K. Federation of State Medical Boards (FSMB) Matters Discussion and Consideration
- L. Newsletter Matters Discussion and Consideration
- M. Controlled Substances Board Report Discussion and Consideration
- N. Interstate Medical Licensure Compact Commission (IMLCC) Report from Wisconsin's Commissioners Discussion and Consideration
- O. Screening Panel Report
- P. Future Agenda Items
- Q. Discussion and Consideration of Items Added After Preparation of Agenda:
  - 1) Introductions, Announcements and Recognition
  - 2) Elections, Appointments, Reappointments, Confirmations, and Committee, Panel and Liaison 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) Public Health Emergencies
  - 11) Legislative and Policy Matters
  - 12) Administrative Rule Matters
  - 13) Liaison Reports
  - 14) Board Liaison Training and Appointment of Mentors
  - 15) Informational Items
  - 16) Division of Legal Services and Compliance (DLSC) Matters
  - 17) Presentations of Petitions for Summary Suspension
  - 18) Petitions for Designation of Hearing Examiner
  - 19) Presentation of Stipulations, Final Decisions and Orders
  - 20) Presentation of Proposed Final Decisions and Orders
  - 21) Presentation of Interim Orders

- 22) Petitions for Re-Hearing
- 23) Petitions for Assessments
- 24) Petitions to Vacate Orders
- 25) Requests for Disciplinary Proceeding Presentations
- 26) Motions
- 27) Petitions
- 28) Appearances from Requests Received or Renewed
- 29) Speaking Engagements, Travel, or Public Relation Requests, and Reports

### **R.** Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85(1)(b), and 448.02(8), Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).

### S. Deliberation on DLSC Matters

- 1) Proposed Stipulations, Final Decisions and Orders
  - a. 21 MED 532 Trinh G. Truong (**42-47**)
  - b. 22 MED 182 Lindsey A. Buswell Cleary (48-55)
  - c. 22 MED 301 & 23 MED 469 Richard W. Clasen (56-61)
  - d. 23 MED 019 Virendra K. Misra (62-68)
  - e. 23 MED 123 Rachel M. Gilbert (69-79)
  - f. 23 MED 354 Daniel A. Mackay (80-85)

### 2) Complaints

- a. 23 MED 072 S.A.A. (86-88)
- b. 23 MED 107 M.S. (89-91)
- 3) Administrative Warnings
  - a. 21 MED 342 P.D.K. (92-94)
  - b. 22 MED 307 R.R.L. (95-97)
- 4) Case Closings
  - a. 21 MED 502 P.G.C. (98-103)
  - b. 22 MED 532 O.G. (**104-121**)
  - c. 22 MED 553 U.K.V. (122-136)
  - d. 23 MED 009 B.R.R. (137-149)
  - e. 23 MED 107 M.S. (150-157)
  - f. 23 MED 285 B.G.M. (158-165)
  - g. 23 MED 390 A.K.C. (**166-170**)
  - h. 23 MED 395 N.R.K. (171-177)
  - i. 23 MED 501 M.R.M. (**178-182**)

### T. Credentialing Matters

- 1) Waiver of 24 Months of ACGME/AOA Accredited Post-Graduate Training a. Ayman Elnahry, M.D. (183-259)
- 2) Application Review
  - a. Hans Christian Diederich, M.D. Visiting Physician Applicant (260-291)
  - b. Adam Hall Medicine and Surgery Applicant (292-576)
  - c. Joseph Verzwyvelt, M.D. Medicine and Surgery Renewal Applicant (577-626)
- U. Deliberation of Items Added After Preparation of the Agenda

- 1) Education and Examination Matters
- 2) Credentialing Matters
- 3) DLSC Matters
- 4) Monitoring Matters
- 5) Professional Assistance Procedure (PAP) Matters
- 6) Petitions for Summary Suspensions
- 7) Petitions for Designation of Hearing Examiner
- 8) Proposed Stipulations, Final Decisions and Order
- 9) Proposed Interim Orders
- 10) Administrative Warnings
- 11) Review of Administrative Warnings
- 12) Proposed Final Decisions and Orders
- 13) Matters Relating to Costs/Orders Fixing Costs
- 14) Complaints
- 15) Case Closings
- 16) Board Liaison Training
- 17) Petitions for Extension of Time
- 18) Petitions for Assessments and Evaluations
- 19) Petitions to Vacate Orders
- 20) Remedial Education Cases
- 21) Motions
- 22) Petitions for Re-Hearing
- 23) Appearances from Requests Received or Renewed
- V. Open Cases
- 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
- Z. Delegation of Ratification of Examination Results and Ratification of Licenses and Certificates

### ADJOURNMENT

### ORAL INTERVIEWS OF CANDIDATES FOR LICENSURE VIRTUAL/TELECONFERENCE

### 10:00 A.M. OR IMMEDIATELY FOLLOWING THE FULL BOARD MEETING

**CLOSED SESSION** – Reviewing Applications and Conducting Oral Interview(s) of **seven (7)** (at time of agenda publication) Candidate(s) for Licensure – **Dr. Clarke** and **Dr. Goel** 

### NEXT MEETING: MARCH 20, 2024

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

### VIRTUAL/TELECONFERENCE MEDICAL EXAMINING BOARD MEETING MINUTES JANUARY 17, 2024

- PRESENT: Milton Bond, Jr. (excused at 9:35 a.m.); Clarence Chou, M.D.; Callisia Clarke, M.D. (excused at 11:16 a.m.); Kris Ferguson, M.D., Diane Gerlach, D.O.; Sumeet Goel, D.O. (arrived at 8:03 a.m.); Steven Leuthner, M.D.; Lubna Majeed-Haqqi, M.D.; Gregory Schmeling, M.D.; Derrick Siebert, M.D. (arrived at 8:27 a.m.) (excused at 10:15 a.m.) (arrived at 10:50 a.m.); Emily Yu, M.D.
- **EXCUSED:** Stephanie Hilton; Carmen Lerma
- **STAFF:** Tom Ryan, Executive Director; Jameson Whitney, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Dialah Azam, Board Administration Specialist; and other Department staff

### CALL TO ORDER

Clarence Chou, Chairperson, called the meeting to order at 8:02 a.m. A quorum was confirmed with nine (9) members present.

(Sumeet Goel arrived at 8:03 a.m.)

### **ADOPTION OF AGENDA**

### Amendment to the Agenda

- CHANGE 2-person oral examiner from Dr. Yu to Dr. Gerlach
- **CHANGE** 10:00 A.M. or Immediately Following the Full Board *Training* To 10 A.M. or Immediately Following the Full Board *Meeting*
- **CHANGE** agenda item I from Professional *Assistant* Procedure to Professional *Assistance* Procedure
  - **MOTION:** Callisia Clarke moved, seconded by Steven Leuthner, to adopt the Agenda as amended. Motion carried unanimously.

### APPROVAL OF MINUTES OF DECEMBER 20, 2023

**MOTION:** Gregory Schmeling moved, seconded by Diane Gerlach, to approve the Minutes of December 20, 2023 as published. Motion carried unanimously.

### **ADMINISTRATIVE MATTERS**

### Election of Officers, Appointments of Liaisons and Alternates, Delegation of Authorities

### **Election of Officers**

### Chairperson

### **NOMINATION:** Sumeet Goel nominated Clarence Chou for the Office of Chairperson. Clarence Chou accepted the nomination.

Tom Ryan, Executive Director, called for nominations three (3) times.

Clarence Chou was elected as Chairperson by unanimous voice vote.

### Vice Chairperson

**NOMINATION:** Clarence Chou nominated Sumeet Goel for the Office of Vice Chairperson. Sumeet Goel accepted the nomination.

Tom Ryan, Executive Director, called for nominations three (3) times.

Sumeet Goel was elected as Vice Chairperson by unanimous voice vote.

### Secretary

**NOMINATION:** Clarence Chou nominated Gregory Schmeling for the Office of Secretary. Gregory Schmeling accepted the nomination.

Tom Ryan, Executive Director, called for nominations three (3) times.

Gregory Schmeling was elected as Secretary by unanimous voice vote.

ELECTION RESULTS					
Chairperson	Clarence Chou				
Vice Chairperson	Sumeet Goel				
Secretary	Greogry Schmeling				

**Appointment of Liaisons and Alternates** 

LIAISON APPOINTMENTS				
Credentialing Liaison(s)	Callisia Clarke, Lubna Majeed-Haqqi, Emily Yu, Diane Gerlach, Kris Ferguson, Gregory Schmeling, Derrick Siebert, Steven Leuthner <i>Alternate:</i> Clarence Chou			
Education and Examinations Liaison(s)	Continuing Education: Diane Gerlach Alternate: Clarence Chou Examinations: Gregory Schmeling Alternate: Clarence Chou			
Monitoring Liaison(s)	Kris Ferguson Alternate: Clarence Chou			
Professional Assistance Procedure (PAP) Liaison(s)	Kris Ferguson Alternate: Clarence Chou			

Legislative Liaison(s)	Clarence Chou Alternate: Sumeet Goel			
Travel Authorization Liaison(s)	Sumeet Goel Alternate: Diane Gerlach			
Newsletter Liaison(s)	Clarence Chou Alternate: Sumeet Goel			
Website Liaison(s)	Sumeet Goel Alternate: Milton Bond Jr			
Opioid Abuse Report Liaison(s) per 440.035(2m)(c)	Kris Ferguson Alternate: Derrick Siebert			
Prescription Drug Monitoring Program Liaison(s)	Kris Ferguson Alternate: Lubna Majeed-Haqqi			
Appointed to Controlled Substances Board as per Wis. Stats. §15.405(5g) (MED)	Gregory Schmeling Alternate: Kris Ferguson			

OTHER APPOINTMENTS					
Council on Anesthesiologist Assistants Kris Ferguson					
Interstate Medical Licensure Compact Commission (IMLCC) Representatives	Clarence Chou, Sumeet Goel				

### **Delegation of Authorities**

### **Review and Approval of 2023 Delegations**

**MOTION:** Sumeet Goel moved, seconded by Lubna Majeed-Haqqi, to reaffirm all delegation motions from 2023 as reflected in the agenda materials. Motion carried unanimously.

### **Document Signature Delegations**

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

### **Delegation to Chief Legal Counsel for Stipulated Resolutions**

**MOTION:** Gregory Schmeling moved, seconded by Sumeet Goel, to delegate to DSPS Chief Legal Counsel the authority to act on behalf of the Board concerning stipulated resolutions providing for a surrender, suspension, or revocation of a credential, where the underlying merits involve serious and dangerous behavior, and where the signed stipulation is received between Board meetings. The Board further requests that CLC only act on such matters when the best interests of the Board, Department and the Public are best served by acting upon the stipulated resolution at the time the signed stipulation is received versus waiting for the next Board meeting. Any cases so resolved shall be presented to the Board for the Board's information at the next meeting. Motion carried unanimously.

### Monitoring Delegations

### **Delegation of Authorities for Monitoring**

**MOTION:** Kris Ferguson moved, seconded by Sumeet Goel, to adopt the "Roles and Authorities Delegated for Monitoring" document as presented in the January 17, 2024 agenda materials on pages 24-26. Motion carried unanimously.

### Delegation to DSPS When Applicant's Discipline History Has Been Previously Reviewed

**MOTION:** Gregory Schmeling moved, seconded by Steven Leuthner, to delegate authority to Department staff to approve applications where Applicant's prior discipline has been approved for a previous Wisconsin credential and there is no new discipline. Motion carried unanimously.

### **Delegation to Department Attorneys to Approve Duplicate Legal Issue**

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

### CONSIDERATION OF APPLICANT DR. JEFFREY LEE AS AN MEB APPOINTMENT TO THE COUNCIL ON ANESTHESIOLOGIST ASSISTANTS

**MOTION:** Lubna Majeed-Haqqi moved, seconded by Emily Yu, to approve Dr. Jeffrey Lee as a Medical Examining Board appointed member of the Council on Anesthesiologist Assistants. Motion carried unanimously.

### FEDERATION OF STATE MEDICAL BOARDS (FSMB) MATTERS

### FSMB Annual Meeting, April 18-20, 2024, Nashville, TN – Consider Attendance

- **MOTION:** Sumeet Goel moved, seconded by Gregory Schmeling, to designate Clarence Chou as the Board's delegate to attend the FSMB Annual Meeting from April 18-20 in Nashville, TN. Motion carried unanimously.
- **MOTION:** Steven Leuthner moved, seconded by Emily Yu, to designate Gregory Schmeling as the Board's alternate delegate to attend the FSMB Annual Meeting from April 18-20 in Nashville, TN. Motion carried unanimously.
- **MOTION:** Steven Leuthner moved, seconded by Lubna Majeed-Haqqi, to designate Sumeet Goel to attend the FSMB Annual Meeting from April 18-20 in Nashville, TN. Motion carried unanimously.

### **CLOSED SESSION**

**MOTION:** Callisia Clarke moved, seconded by Lubna Majeed-Haqqi, to convene to Closed Session to deliberate on cases following hearing (§ 19.85(1)(a), Stats.); to consider licensure or certification of individuals (§ 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (§ 19.85(1)(b), Stats. and § 448.02(8), Stats.); to consider individual histories or disciplinary data (§ 19.85(1)(f), Stats.); and to confer with legal counsel (§ 19.85(1)(g), Stats.). Clarence Chou, Chairperson, read the language of the motion aloud for the record. The vote of each member was ascertained by voice vote. Roll Call Vote: Milton Bond, Jr.-yes; Clarence Chou-yes; Callisia Clarke-yes; Kris Ferguson-yes; Diane Gerlach-yes; Sumeet Goel-yes; Steven Leuthner-yes; and Emily Yu-yes. Motion carried unanimously.

The Board convened into Closed Session at 9:31 a.m.

(Milton Bond Jr. excused at 9:35 a.m.)

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

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

### 22 MED 420 – Emily A. Olson

**MOTION:** Sumeet Goel moved, seconded by Steven Leuthner, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Emily A. Olson, DLSC Case Number 22 MED 420. Motion carried unanimously.

### Administrative Warnings

### 23 MED 150 - R.L.Z.

**MOTION:** Gregory Schmeling moved, seconded by Steven Leuthner, to issue an Administrative Warning in the matter of R.L.Z., DLSC Case Number 23 MED 150. Motion carried unanimously.

### **Case Closings**

- **MOTION:** Diane Gerlach moved, seconded by Emily Yu, to close the following DLSC Cases for the reasons outlined below:
  - a) 20 MED 406 L.K.S. Lack of Jurisdiction (L2)
  - b) 22 MED 259 S.W.L. No Violation
  - c) 22 MED 561 A.J.L. No Violation
  - d) 23 MED 046 S.J.N. No Violation
  - e) 23 MED 372 R.D.S. No Violation
  - f) 23 MED 496 R.H.T. Prosecutorial Discretion (P2)

Motion carried unanimously.

### 22 MED 457 – O.R.W.

MOTION: Sumeet Goel moved, seconded by Steven Leuthner, to close DLSC Case Number 22 MED 457, against O.R.W., for Prosecutorial Discretion (P2). Motion carried unanimously.

(*Emily Yu recused themself and left the room for deliberation and voting in the matter concerning O.R.W., DLSC Case Number 22 MED 457.*)

### 23 MED 428 – R.J.V.

MOTION: Lubna Majeed-Haqqi moved, seconded by Callisia Clarke, to close DLSC Case Number 23 MED 428, against R.J.V., for No Violation. Motion carried unanimously.

(Clarence Chou recused themself and left the room for deliberation and voting in the matter concerning R.J.V., DLSC Case Number 23 MED 428.)

### Petition for Authorization to Request Extension of Time

### 23 MED 015 – A.S.

**MOTION:** Lubna Majeed-Haqqi moved, seconded by Sumeet Goel, to grant the Petition for Authorization to Request an Extension of Time in the matter of DLSC Case Number 23 MED 015 against A.S. Motion carried unanimously.

### **CREDENTIALING MATTERS**

### Waiver of 24 Months of ACGME/AOA Accredited Post-Graduate Training

### Choon-Kee Lee, M.D.

**MOTION:** Callisia Clarke moved, seconded by Diane Gerlach, to approve the waiver of 24 Months of ACGME/AOA Accredited Post-Graduate Training application of Choon-Kee Lee, M.D. Motion carried unanimously.

### Erickson Torio, M.D.

**MOTION:** Steven Leuthner moved, seconded by Callisia Clarke, to approve the waiver of 24 Months of ACGME/AOA Accredited Post-Graduate Training application of Erickson Torio, M.D. Motion carried unanimously.

### Sherry Wang, M.D.

**MOTION:** Emily Yu moved, seconded by Callisia Clarke, to approve the waiver of 24 Months of ACGME/AOA Accredited Post-Graduate Training application of Sherry Wang, M.D. Motion carried unanimously.

(Derrick Siebert excused at 10:15 a.m.)

### **Application Review**

### Joseph Verzwyvelt, M.D. - Medicine and Surgery Renewal Applicant

- **MOTION:** Sumeet Goel moved, seconded by Steven Leuthner, to request the deferred prosecution agreement for Joseph Verzwyvelt's felony charge. Motion carried unanimously.
- **MOTION:** Sumeet Goel moved, seconded by Gregory Schmeling, to recommend Joseph Verzwyvelt voluntarily enter the Professional Assistance Procedure (PAP) program. Motion carried unanimously.

(Derrick Siebert arrived at 10:50 a.m.)

(Callisia Clarke excused at 11:16 a.m.)

### DELIBERATION ON REVIEW OF ADMINISTRATIVE WARNINGS

### <u>10:00 A.M. APPEARANCE: Julie Zimmer, DLSC Attorney; John R. Zwieg, Attorney for</u> <u>Respondent; C.B.S., Respondent: WARN00001686 – 22 MED 466 – C.B.S.</u>

MOTION: Sumeet Goel moved, seconded by Diane Gerlach, to rescind the issuance of the administrative warning in the matter of C.B.S., DLSC Case Number 22 med 466 and to close this matter for Prosecutorial Discretion (P2). Motion carried.

(Gregory Schmeling recused themself and left the room for deliberation and voting in the matter concerning C.B.S., DLSC Case Number 22 MED 466.)

### **RECONVENE TO OPEN SESSION**

**MOTION:** Diane Gerlach moved, seconded by Lubna Majeed-Haqqi, to reconvene to Open Session. Motion carried unanimously.

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

**MOTION:** Sumeet Goel moved, seconded by Steven Leuthner, 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.)

### DELEGATION OF RATIFICATION OF EXAMINATION RESULTS AND RATIFICATION OF LICENSES AND CERTIFICATES

**MOTION:** Gregory Schmeling moved, seconded by Sumeet Goel, to delegate ratification of examination results to DSPS staff and to ratify all licenses and certificates as issued. Motion carried unanimously.

### ADJOURNMENT

**MOTION:** Gregory Schmeling moved, seconded by Lubna Majeed-Haqqi, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 11:24 a.m.

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

1) Name and title of person submitting the request:		2) Date when request submitted:			
Clarence Chou, Board C	Chair				
					idered late if submitted after 12:00 p.m. on the
3) Name of Board, Com	mittaa Cr	ouncil Sections:		deadline date which	ch is 8 business days before the meeting
,	-	Junch, Sections.			
Medical Examining Boa		<b>.</b> .			
4) Meeting Date:	5) Attac	chments:	6) How	should the item be t	itled on the agenda page?
2/21/2024	🖾 Ye	es	Expand	ing the Professiona	I Assistance Program
		-			1
7) Place Item in:				e the Board being	9) Name of Case Advisor(s), if applicable:
Open Session		scheduled? (If ye Appearance Requ			N/A
□ Closed Session				,	
		Yes Jim Lor			
		Engagement Offi	cer, Wisc	onsin Medical	
		Society			
Image: 10 Describe the issue and action that should be addressed:					
Jim Lorence, Wisconsin Medical Society's Chief Value and Engagement Officer, will deliver a presentation to the Board about an initiative to create a program to assist physicians in seeking assistance for mental health and other challenges.					
11) Authorization					
				Date	
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					
<ul> <li>Directions for including supporting documents:</li> <li>1. This form should be saved with any other documents submitted to the <u>Agenda Items</u> folders.</li> <li>2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.</li> <li>3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.</li> </ul>					

### AGENDA REQUEST FORM

# WisMed Update Physician Health Program Status

## Dr. Jacqueline Landess – Chair Physician Wellness Advisory Committee

## Mike Flesher – Chief Executive Officer

Jim Lorence – Chief Value and Engagement Officer



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## 2023 – 2027 WisMed Strategic Plan

### **OUR MISSION**

To improve the health of the people of Wisconsin by supporting and strengthening physicians' ability to practice high-quality patient care in a changing environment.

### **OUR VISION**

To enable physicians to lead efforts with other health care partners to optimize health care delivery and ensure accessible, efficient, patient-centered quality care for all the people of Wisconsin.

### **OUR GOALS**



### **TRUSTED VOICE IN MEDICINE**

Position the Wisconsin Medical Society (WisMed) as the trusted authority, serve as the chief advocate and foster the physician voice to champion equitable and sound health care policy.

### HEALTHY WISCONSIN

Lead, partner and collaborate with the vast network of community-focused organizations to improve health outcomes, inequities and mental health in Wisconsin.

## 2 HEALTHY PHYSICIANS

Advance the workforce to meet diverse patient needs, address challenges and act as the catalyst for new physician performance models to support patient care and physician well-being.

## HEALTHY WISMED

Promote leadership opportunities for physicians and medical students, commit to being a great workplace and build a strong financial base for organizational sustainability and impact.

## Physician Health Program - Start

- Identifying Services that assist/help Wisconsin Physicians
- Wisconsin is one of three states that does not have a recognized program by the Federation of State Physician Health Programs (FSPHP)
- Formed Physician Wellness Advisory Committee
- Began search for funding



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## **Role of FSPHP**

- Partnering with FSPHP to learn about and create ideal model to start
- National guidelines to allow for best practices
- Attending national and regional conferences with representatives from US and Canadian PHPs, and expert evaluation and treatment professionals (expertise w/safety sensitive professional standards of care)
- Attend the FSPHP and FSMB annual Joint Education Session
- Support from FSPHP is and has been invaluable



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### Ideal Structure – FSPHP PHP Guidelines

- A 501c3 affiliated with State Medical Society
  - Allows for charitable donations
  - Separate from the licensing disciplinary process
  - Trust of State Medical Society incentivizes referral
- Authority to accept referrals when there is risk of a mental health illness including substance use disorder and there is no risk of patient safety
- A referral to a PHP is an exception to mandated reporting in licensing board rules



## **Model Consideration / Unique Characteristics**

- Voluntary
- Confidential "peer review legislation"
- Therapeutic
- Alternative to discipline via legislation and/or board regulation
- For concerns of risk of impairment
- Structurally separate but works in collaboration with the Medical Board when health professionals are known to the Medical Board



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### **Potential Funding Sources**

State Sources

- State Funding
  - Stable and predictable
- 501c3 application process for formation has commenced
  - Donations
- Applied for Grants Seed Money
- Medical Liability Insurance Companies
- If adequately funded, no fees to the participant



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### **Physician Wellness Advisory Committee – PHP Focus and Wellness Focus**

- PHP Focus
  - Create Operational Plan / PHP Model with FSPHP Support
    - Staffing model to start and build upon
  - Determine Services
    - Assessment and Consultation for Referent's and Referrals
    - Recommendations to therapy, coaching and peer support
    - Monitoring agreement
    - Elements of monitoring
    - Compliance reporting
    - Continuous education to the state on risk of illness, and how to refer
  - Develop Marketing Plan
    - Healthcare Organizations
    - System CEOs
  - Strategic Partners
    - Partner with MEB
  - Philanthropy



### **Physician Wellness Advisory Committee - Wellness Focus**

- WisMed Annual Event April 2024 Physician Wellness CME
- Wellness Programs
- Member offerings
- System Partnerships
- Supplement EAP



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## Wellness Programs

## wismed.org/wellness



# Marvin





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A staff of highly-trained therapists and psychologists vetted by the Wisconsin Medical Society Free to members in participating counties

Psychiatry focusing on complete wellness, with a holistic approach and advanced diagnostics Members receive 25% off a comprehensive assessment

# Physician Health Program – Next Steps

- Continue work of Advisory Committee
- Welcome MEB participation, collaboration and representation
  - Mutual goals and objectives
  - Communication and Information Sharing
  - Collaborative Decision-Making
  - Supportive Measures
  - Education and Prevention Initiatives
  - Confidentiality and Privacy
  - Continuous Improvement
- Commitment to promoting the well-being of physicians and protecting the public they serve
- Additional resource to MEB



# Physician Health Program – Summary

- Patient Safety
- Better performing physicians
- Protect the workforce and save patient access
- Save valued physician lives and careers
- Participation improves well-being
- Alternative to discipline, maintaining a duty to public safety
- Comprehensive long-term monitoring
- Documentation of compliance for employers, and the licensing board as needed for participants (with consent)
- Early detection to potentially impairing illness
- Program will benefit the entire state



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

1) Name and title of person submitting the request:		2) Date when request submitted:				
Nilajah Hardin, Administrative Rules Coordinator		02/9/24				
		Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting				
3) Name of Board, Committee, Council, Sections:						
Medical Examining Bo	ard					
4) Meeting Date:	5)	6) How should the	e item be title	d on the agenda page?		
02/21/24	Attachments:	Administrative	Rule Matter	rs – Discussion and Consideration		
	Yes	1. Adoption	on Order: M	led 26, Relating to Military Medical Personnel		
	L No		g or Possible le Projects C	e Rulemaking Projects		
		a. Ku	ie riojects (			
7) Place Item in:		ance before the Boa		9) Name of Case Advisor(s), if required:		
☑ Open Session		yes, please complete <mark>quest</mark> for Non-DSPS		N/A		
Closed Session			otany			
	☐ Yes ⊠ No					
10) Describe the issue a		ould be addressed:				
,						
Attachments: Med 26 Adoption Orde	. <b>r</b>					
Rule Project Chart						
(Board Rule projects can be Viewed Here if Needed: <u>https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx</u> )						
11)		Authoriza	tion			
maintal	Harlin			02/9/24		
Signature of person mal	king 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:						
<ol> <li>This form should be attached to any documents submitted to the agenda.</li> <li>Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.</li> </ol>						
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a						
meeting.	-	-		-		

### AGENDA REQUEST FORM

### STATE OF WISCONSIN MEDICAL EXAMINING BOARD

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#### PROPOSED ORDER

An order of the Medical Examining Board to **create** Med 26, relating to Military Medical Personnel.

Analysis prepared by the Department of Safety and Professional Services.

### ANALYSIS

Statutes interpreted: s. 440.077, Stats.

Statutory authority: ss. 15.08 (5) (b), 448.40 (1), and 448.40 (1m), 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 448.40 (1), Stats., provides that "[t]he board may promulgate rules to carry out the purposes of this subchapter, including rules requiring the completion of continuing education, professional development, and maintenance of certification or performance improvement or continuing medical education programs for renewal of a license to practice medicine and surgery."

Section 448.40 (1m), Stats., provides that "the board may promulgate rules to establish minimum standards for military medical personnel, as defined in s. 440.077 (1) (d), who preform skilled health services, as defined in s. 440.077 (1) (h), that are supervised under s. 440.077.

#### Related statute or rule: None

**Plain language analysis:** The objective of the proposed rules is to implement the statutory changes from 2021 Wisconsin Act 158. The Board achieved this objective by creating a new chapter in the Wisconsin Administrative Code, chapter Med 26, to cover the minimum practice standards required for participation in the military medical personal program that is administered by the Department of Safety and Professional Services.

### 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: $\rm N/A$

### Comparison with rules in adjacent states:

**Illinois**: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of the practice of medicine in Illinois, with input from the Illinois State Medical Board. The Illinois Department is also responsible for the promulgation of rules to implement certain sections of the Illinois Medical Practice Act of 1987. This Act contains requirements for applications, licensure, and discipline for physicians [225 Illinois Compiled Statutes ch. 60]. The rules in the Illinois Administrative Code include requirements for education programs, visiting physician permits, and disciplinary proceedings, among others. [Illinois Administrative Code Title 68, ch. 7, s. 1285]. Neither the Illinois statutes nor the administrative rules for medical practice include requirements for military medical personnel. The Illinois Service Member Employment and Reemployment Rights Acts includes general provisions for employment for all military personnel, but none are specific to medical or healthcare practice [330 Illinois Compiled Statutes ch. 61].

Iowa: The Iowa Board of Medicine is responsible for the licensure and regulation of medicine and surgery in Iowa. Chapter 148 of the Iowa Code includes statutory requirements for licensure, composition and powers of the Iowa Board, and discipline for physicians [Iowa Code ch. 148]. The Iowa Administrative Code includes rules relating to medical practice. These requirements also include rules on military service and veteran reciprocity. Military service members can apply to have their service and training counted for credit toward licensure as a medical physician or surgeon, osteopathic physician or surgeon, or licensed acupuncturist. Veterans can apply for provisional licensure to service members who are licensed in another jurisdiction with a credential that is not substantially equivalent to an Iowa license. This provisional license allows for that Veteran to obtain the additional experience or education needed for a regular Iowa license. Iowa also has rules for reciprocal licensure for veterans and their spouses that are licensed in other jurisdictions and that license is substantially equivalent to an Iowa license [653 Iowa Administrative Code ch. 18]. The Iowa statutes and rules for medicine and surgery do not include requirements specifically for military medical personnel supervision and practice.

**Michigan**: The Michigan Board of Medicine is responsible for the licensure and regulation of medical practice in Michigan. Act 368 Article 15 Part 170 of the Michigan Compiled Laws includes the regulations for medicine in Michigan, among several other occupations. Some of the requirements in this part include those for licensure, informed consent, and duties of the Michigan Board. This part of the Michigan rules also includes requirements for physician assistants and genetic counselors in addition to physicians. [Michigan Compiled Laws ss. 333.17001-333.17097]. The Michigan rules for medicine do not include requirements specifically for military medical personnel supervision and practice.

**Minnesota:** The Minnesota Board of Medical Practice is responsible for the licensure and regulation of medicine in Minnesota. Part 6800 of the Minnesota Administrative Code includes requirements for licensure, continuing education, and hearings before the Minnesota Board. [Minnesota Administrative Rules part 5600]. Chapter 147 of the Minnesota Statutes, or the Minnesota Medical Practice Act, also includes requirements for licensure, practice, and discipline for physicians [Minnesota Statutes ch. 147].

Chapter 197 of the Minnesota Statutes includes requirements for expedited licensing processing and temporary licensure for former and current military personnel. The expedited licensing process is for those service members who are otherwise qualified to obtain licensure in an efficient manner. The temporary license process allows certain qualified service members who are licensed in another state to practice while waiting for a regular license to be granted [Minnesota Statutes ch. 197]. The Minnesota statutes and rules for medicine do not include requirements specifically for military medical personnel supervision and practice.

### Summary of factual data and analytical methodologies:

The Board reviewed 2021 Wisconsin Act 158 and added to the Wisconsin Administrative Code accordingly. While promulgating these rules, the Board referenced material submitted by the Virginia Military Medic and Corpsman Program, Heroes for Healthcare, and the Wisconsin Hospital Association, among other sources.

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

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

### Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

### Effect on small business:

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

#### Agency contact person:

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

### TEXT OF RULE

SECTION 1. Chapter Med 26 is created to read:

### Chapter Med 26 MILITARY MEDICAL PERSONNEL

**Med 26.01 Authority and Purpose.** The rules in this chapter are adopted by the medical examining board pursuant to the authority delegated by ss. 15.08 (5) (b) and 448.40 (1m), Stats.

#### Med 26.02 Definitions. In this chapter:

(1) "Adequate supervision" means the licensed supervising practitioner is competent and authorized under his or her applicable license or certification to perform the delegated clinical act, and must have reasonable evidence that the supervised individual is minimally competent to perform the act under the circumstances.

(2) "Administering facility" means an inpatient health care facility defined in s. 50.135(1), Stats., an outpatient health care location, a community-based residential facility defined in s. 50.01(1g), Stats., or a residential care apartment complex defined in s. 50.01(6d), Stats., that is a party to the memorandum of understanding specified in s. Med 26.03(1) and maintains a written policy governing registered military medical personnel specified in s. Med 26.03 (1) (g).

(3) "Advanced practice nurse prescriber" means a certified advanced practice nurse prescriber authorized to issue prescription orders under s. 441.16 (2), Stats.

(4) "Basic patient care" means care that can be performed following a defined procedure with minimal modification in which the responses of the patient to the care are predictable.

(5) "Basic patient situation" as determined by a licensed supervising practitioner means the following 3 conditions prevail at the same time in a given situation:

- (a) The patient's clinical condition is predictable.
- (b) Medical or nursing orders are not changing frequently and do not contain complex modifications.
- (c) The patient's clinical condition requires only basic patient care.

(6) "Complex patient situation" as determined by a Licensed supervising practitioner means any one or more of the following conditions exist in a given situation:

- (a) The patient's clinical condition is not predictable.
- (b) Medical or nursing orders are likely to involve frequent changes or complex modifications.
- (c) The patient's clinical condition indicates care that is likely to require modification of procedures in which the responses of the patient to the care are not predictable.

(7) "Direct supervision" means immediate availability to continually coordinate, direct, and inspect in real time the practice of another.

(8) "General supervision" means to continually coordinate, direct, and inspect the practice of another.

(9) "Licensed supervising practitioner" means a physician licensed under s. 448.03 (1), Stats., a physician assistant licensed under s. 448.972 (1), Stats., a podiatrist licensed under s. 448.63 (1), Stats., a registered nurse licensed under s. 441.06 (1), Stats., and a certified advanced practice nurse prescriber defined in sub. (3).

(10) "Military medical personnel" means a person who served as an army medic, a navy or coast guard corpsman, or an air force aerospace medical technician in the U.S. armed forces.

(11) "Military medical personnel program participant" means a military medical personnel who qualifies to participate in the program created under s, 440.077 (2) (a), Stats.

**Med 26.03 Program participation.** A military medical program participant shall meet all of the requirements in s. SPS 11.03.

**Med 26.04 Delegated authority. (1)** Except as otherwise prohibited by any other rule or statute, a licensed supervising practitioner may delegate their licensed or certified professional practice authority to perform a clinical act to a person who is a military medical personnel program participant if all of the following are true:

- (a) The licensed supervising practitioner is competent and authorized under their applicable license or certification to perform the delegated clinical act.
- (b) The licensed supervising practitioner has reasonable evidence that the supervised military medical personnel program participant is minimally competent to perform the delegated clinical act under the circumstances based on the individual's level of training and experience. Such reasonable evidence may include the memorandum of understanding signed by the military medical personnel program participant and the administering facility specified in s. Med 26.05. Reasonable evidence may also include any other relevant information as determined by the licensed supervising practitioner.
- (c) The delegated clinical act is not a surgical procedure or the issuance of a prescription order.
- (d) The delegated clinical act is performed in an administering facility.

(2) The licensed supervising practitioner who delegates a clinical act for a patient to a registered military medical personnel pursuant to this section retains responsibility for the care of the patient.

(3) Subject to the limitation in s. 440.077 (2) (b), Stats. and except as provided in sub. (5), the scope in which a registered military medical personnel may practice is limited to the performance of acts in basic patient situations under the general supervision of a licensed supervising practitioner, which includes the following:

- (a) Accept only patient care assignments which the military medical personnel program participant is competent to perform.
- (b) Provide basic patient care.
- (c) Record patient care given and report changes in the condition of a patient to the appropriate person.
- (d) Consult with a provider in cases where the military medical personnel program participant knows or should know a delegated clinical act may harm a patient.
- (e) Perform the following other acts when applicable:
  - 1. Assist with the collection of data.
  - 2. Assist with the development and revision of a patient care plan.
  - 3. Reinforce the teaching provided by a licensed provider and provide basic health care instruction.
  - 4. Participate with other health team members in meeting basic patient needs.
- (f) Any other task authorized by the memorandum of understanding and delegated to the program participant by their supervising professional.

(4) In the performance of acts in complex patient situations the military medical personnel program participant shall perform delegated clinical acts beyond basic patient care only under the direct supervision of a licensed supervising provider. A military medical personnel program participant shall, upon request of the medical examining board, provide documentation of his or her education, training, or experience which prepares the military medical personnel program participant program participant to competently perform these assignments.

**Med 26.05 Documentation of training and experience. (1)** A military medical personnel who practices pursuant to this chapter shall sign a memorandum of understanding form published by the medical examining board that includes all of the following:

- (a) The name of the administering facility at which the military medical personnel will be providing delegated clinical care pursuant to this chapter.
- (b) An identification of the military medical personnel as either an army medic, a navy corpsman, a coastguard corpsman, or an air force aerospace medical technician, and the individual's dates of service in such role.
- (c) The date of the military medical personnel's date of honorable or regular discharge from military service. Such date must be within the 12 months prior to the date the memorandum of understanding is signed by the military medical personnel and the administering facility.

- (d) A description of the medical training and experience the individual received as an army medic, a navy corpsman, a coastguard corpsman, or an air force aerospace medical technician.
- (e) A reasonable timeline consistent with s. 440.077 (3) (c), Stats. that describes the actions the military medical personnel intends to take to acquire a license under ss. 441.06, 441.10, 448.04, 448.61, or 448.974, Stats., including the date by which the military medical personnel agrees to acquire the license. Except as provided in s. Med 26.06, the memorandum of understanding shall terminate one day after the date specified above or the date the military medical personnel acquires the license, whichever is earlier. A reasonable timeline shall be subject to approval by the Board or it's designee. Such approval may include consideration of any of the following factors:

1. The amount of time left in a military medical personnel's education program related to the license or certification they are applying for.

2. The dates and locations of examinations required for licensure or certification.

3. A military medical personnel's own serious medical condition diagnosed by a physician or that of an immediate family member.

4. Any other information that the Board deems necessary to approve a reasonable timeline.

- (f) An attestation by the military medical personnel that they will not accept a delegation of practice authority under this chapter to perform a clinical act if his or her training and experience as a military medical personnel did not include that clinical act.
- (g) An attestation by the administering facility that it has a written policy governing clinical practice by registered military medical personnel, and that policy is shared with the military medical personnel subject to the memorandum of understanding and those licensed supervising practitioners authorized to delegate clinical acts to the individual.
- (h) An attestation by the administering facility that the administering facility to the best of the administering facility's knowledge and with a reasonable degree of certainty, all of the information in the memorandum of understanding is true.
- (i) The memorandum of understanding is signed and dated by the military medical personnel and an authorized representative of the administering facility.

**Note:** The memorandum of understanding form can be located on the Department's website at <u>http://dsps.wi.gov</u>.

(2) The military medical personnel shall submit a completed memorandum of understanding that meets all of the requirements in sub. (1) to the military medical personnel's employer.

(3) The military medical personnel shall submit the completed timeline under sub. (1) (e) to the department in the manner specified by the medical examining board on its published timeline form.

**Med 26.06 Extension of Memorandum of Understanding Expiration Date.** The medical examining board may extend the termination date of a signed memorandum of understanding under s. Med 26.05 if it appears that, because of unforeseen circumstances, the applicant requires more time to receive a license under ss. 441.06, 441.10, 448.04, 448.61, or 448.974, Stats.

**Med 26.07 Complaints, investigations, suspension, and termination of authorization.** The medical examining board may receive and investigate complaints against a military medical personnel program participant performing delegated clinical acts pursuant to this chapter. The medical examining board may suspend or terminate a military medical personnel program participant's authority to perform delegated clinical acts pursuant to this chapter.

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

(END OF TEXT OF RULE)						
Dated	Agency	Chairperson Medical Examining Board				
		Medical Examining Board				

Page 8

### Medical Examining Board Rule Projects (updated 02/09/24)

Clearinghouse Rule Number	Scope #	Scope Expiration	Code Chapter Affected	Relating clause (description)	Current Stage	Next Step
Not Assigned Yet	117-23	06/26/2026	Med 24	Telemedicine and Telehealth	Drafting Rule	Board Review of Preliminary Rule Draft at a Future Meeting
23-037 (EmR 2308)	044-22	11/23/2024	Med 26	Military Medical Personnel	Adoption Order Reviewed at 2/21/24 Meeting (Emergency Rule 2308 was effective 6/1/23-12/1/23)	Submission for Publication; Anticipated Effective Date of 05/01/24

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

### AGENDA REQUEST FORM



Oct. 10, 2023

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

Dear Dr. Chaudhry:

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

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

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

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



### Compounded Drug Products Containing Semaglutide Salts

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

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

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

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

### Compounded Drug Products Containing Semaglutide

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

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



products.

We are also sending this letter to the National Association of Boards of Pharmacy to facilitate communication among associations with shared goals regarding these matters.

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

Sincerely,

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

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

1) Name and title of person submitting the request:		2) Date when request submitted:			
Dr. Sumeet Goel, MEB Vice Chair		1/26/24			
					dered late if submitted after 12:00 p.m. on the
3) Name of Board, Comr	mittaa Ca	unail Saatianau		deadline date whic	h is 8 business days before the meeting
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Medical Examining Boar					
4) Meeting Date:	5) Attac	hments:	6) How	should the item be titled on the agenda page?	
2/21/24	🗆 Ye	es	<click h<="" td=""><td>Here to Add Title&gt;</td><td></td></click>	Here to Add Title>	
	🖾 No				
7) Place Item in:				e the Board being	9) Name of Case Advisor(s), if applicable:
Open Session		scheduled? (If ye Appearance Requ			Board Consideration of Statement
□ Closed Session				11-D3F3 3(all)	Expressing Concern Regarding the Impact of
		□ Yes			Healthcare Dynamics on Patients with Special Concern for Wisconsin's Smaller
		🖾 No			Communities' Access to Appropriately
					Trained Physicians
10) Describe the issue a	nd action	that should be ad	dressed:		· · · · ·
Dr. Goel would like the Board to consider placing in the record a statement of concern regarding healthcare dynamics and their impact on patients and access to appropriately trained physicians.					
11) Authorization					
Sumeet Goel			1/26/24		
Signature of person mal	king this i	request			Date
Supervisor (Only required for post agenda deadline items)				Date	
Executive Director signature (Indicates approval for post agenda deadline items) Date				Date	
Directions for including supporting documents:					
<ol> <li>This form should be saved with any other documents submitted to the <u>Agenda Items</u> folders.</li> <li>Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.</li> </ol>					
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a					
meeting.					

### AGENDA REQUEST FORM