WASHINGTON

Medical Commission

Licensing. Accountability. Leadership.

Regular Meeting & Rules Hearing May 8-9, 2025

Meeting Agenda
May 8-9, 2025 – 1st Revised

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

In accordance with the Open Public Meetings Act, this meeting notice was sent to individuals requesting notification of the Department of Health, Washington Medical Commission (WMC) meetings. This agenda is subject to change. The WMC will accept public comments at the Business Meeting. To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

These meetings will be hybrid. Participants can attend either in person or virtually.
In-person location: Capital Event Center, 6005 Tyee Drive SW, Tumwater, WA
Virtual via Teams: Meeting and registration links can be found below.

Time	Thursday – May 8, 2025		Room
Open Sessions			
Personal Appearances			
8:30 am	Panel A – Meeting Link: 5/8/2025 Panel A	Page 16	Lewis
8:30 am	Panel B – Meeting Link: 5/8/2025 Panel B	Page 17	Mason
Closed Sessions			
Case Disposition			
9:15 am	Panel A		Lewis
9:45 am	Panel B		Mason
Noon	Lunch Break		Thurston
Case Disposition			
12:30 pm	Panel A		Lewis
12:30 pm	Panel B		Mason

Time	Friday – May 9, 2025	
Closed Session		
8:30 am	Finance Workgroup	Pacific
Open Session		
Rules Hearing		
9:30 am	**Anesthesiologist Assistants**	**Thurston**

To attend virtually, please register for this meeting at: WMC Rules Hearing

Hearing Notice

Agenda	Presented By:	Page(s)
Housekeeping	Amelia Boyd	
Hearing opened by Presiding Officer • Introduction • Call for questions regarding the rule or hearing process	Karen Domino, MD	

PO Box 47866 | Olympia, Washington 98504-7866 | Medical.Commission@wmc.wa.gov | **WMC.wa.gov**

Agenda continued	Presented By:	Page(s)
• Call for testimony from the public and interested parties regarding proposed language • Call for written comments • Commissioners discuss comments and proposed language • Vote	Karen Domino, MD	29-90
Hearing closed by Presiding Officer		
CR-102, Proposed Rules, document	CR-102	19-28

Break The Chair will announce the designated time to reconvene.

Open Session

Business Meeting

To attend virtually, please **register** for this meeting at: WMC Business Meeting

1.0 Chair Calls the Meeting to Order

2.0 Public Comment

The public will have the opportunity to provide comments. If you wish to speak, please use the Raise Hand function, and you will be called upon. Keep your comments brief, and when the Chair opens the floor, state your name and, if applicable, the organization you represent. If you would prefer to submit written comments, send them to amelia.boyd@wmc.wa.gov by **May 5, 2025**. ***Please do not use this public comment period to address disciplinary cases or issues that the WMC is currently covering in its rulemaking or policy efforts. If you wish to comment on rules currently under development, to ensure your comments are considered as part of rulemaking, visit our "Rules in Progress" page and select the specific rule from the "Current Rules in Progress" table. We also welcome you to attend and comment at our rulemaking workshops and hearings. The schedule for these meetings can be found on our "Rules in Progress page. For feedback on WMC policies, guidelines, or interpretive statements, you may email medical.policy@wmc.wa.gov or provide verbal comments at one of the upcoming Policy: Interested Parties or Policy Committee meetings. You can find the schedule for these meetings on the Policy Meetings page.***

Disclaimer: The WMC accepts written comment into the record as a normal course of the Business Meeting. On a case-by-case basis, the WMC will, at its sole discretion, grant a request to verbally read a comment into the record. Comments containing profanity, discriminatory language, ad hominem attacks on Commissioners or staff, threats of violence, or discussion of active cases or litigation before or involving the WMC will not be read. The comment will still be included in the packet for consideration and awareness.

2.1 The Chair will call for comments from the public.

3.0 Chair Report

PO Box 47866 | Olympia, Washington 98504-7866 | Medical.Commission@wmc.wa.gov | **WMC.wa.gov**

4.0 Consent Agenda

Items listed here are considered routine agency matters and are approved by a single motion without separate discussion. If separate discussion is desired, that item will be removed from the Consent Agenda and placed on the regular Business Agenda. **Action**

4.1 Agenda – Approval of the May 9, 2025, Business Meeting agenda. Pages 2-6

4.2 Minutes – Approval of the March 14, 2025, Business Meeting minutes. Pages 90-95

5.0 New Business

5.1 **Petition for Declaratory Order** **Action**

On March 11, 2025, the WMC received a petition requesting clarification of licensing requirements for independent medical examinations. Commissioners must now consider whether to issue a declaratory order in response and vote accordingly. Petition on pages 96-99 Memo on pages 100-102

5.2 **Letter from Eli Lilly and Company** Discussion & **Possible Action**

Kyle Karinen, Executive Director, will present this letter titled *"Mounjaro® and Zepbound® and Continued Patient Safety Concerns"* for discussion and possible vote. Pages 103-137

6.0 Old Business

6.1 **Committee/Workgroup Reports** Update

The written reports are on page 138. The Chair will call for additional reports. See pages 139-140 for a list of committees and workgroups. Pages 138-140

6.2 **Rulemaking Activities** Report

Rules Progress Report provided on pages 141-142.

The Preproposal Statement of Inquiry, or CR-101, for Opioid Prescribing General Provisions for MDs and PAs, was filed on April 30, 2025, as WSR #25-10-039. Update & Request

Amelia Boyd, Program Manager, will request volunteers from the Commission to serve as panelists for this rulemaking effort. At least three Commissioners are needed to participate in the upcoming workshops, which will be scheduled soon.

6.3 **Interpretive Statement: "Qualified Physician" Under Optometry Law** **Action**

This document has completed the DOH Secretary review and minimal changes were made. Commissioners need to review and consider approving for adoption. Pages 143-144

6.4 **Interpretive Statement: Opioid Prescribing & Monitoring for Allopathic Physicians and Physician Assistants** **Action**

This document has completed the DOH Secretary review. Commissioners need to review and either approve or deny the suggested edits. If the suggested edits are approved, Commissioners will need to consider approving for adoption. Pages 145-152

PO Box 47866 | Olympia, Washington 98504-7866 | Medical.Commission@wmc.wa.gov | **WMC.wa.gov**

6.5	**Interpretive Statement: Opioid Prescribing & Monitoring for Patients** This document has completed the DOH Secretary review. Commissioners need to review and either approve or deny the suggested edits. If the suggested edits are approved, Commissioners will need to consider approving for adoption.	**Action** Pages 153-158
6.6	**Policy: Visiting Student Learning Opportunity License Exemptions** This document has completed the DOH Secretary review. Commissioners need to review and either approve or deny the suggested edits. If the suggested edits are approved, Commissioners will need to consider approving for adoption.	**Action** Pages 159-160

7.0 Policy Committee Report

Christine Blake, Public Member, Chair, will report on items discussed at the Policy Committee meeting held on May 1, 2025. The agenda was as follows: Report/Action

7.1	**Request for WMC Commissioner Volunteers for Small Workgroup on Medical Marijuana Authorization Guidelines** Members of this workgroup will work with the Department of Health to review and update the Medical Marijuana Authorization Guidelines. They will identify needed changes, ensure clarity and consistency, and recommend updates based on current best practices and regulations. Commissioners who would like to volunteer for this workgroup should contact Ms. Boyd at amelia.boyd@wmc.wa.gov.	Pages 161-166
7.2	**Policy: Practitioners Exhibiting Disruptive Behavior (MD2021-01)** This document was reviewed as part of its scheduled four-year review process. The Committee recommended reaffirming this document.	Pages 167-170
	Comments from Washington State Medical Association	Page 171
7.3	**Procedure: Interactive and Transparent Development of Evidence-based Policies and Guidelines (PRO2018-02)** This document was reviewed as part of its scheduled four-year review process. Micah Matthews, Deputy Executive Director, asked the Committee to defer this document so that the incoming Policy Manager can review and provide feedback on this procedure at a future policy meeting. The Committee granted this request and recommended deferring the document.	Pages 172-174
7.4	**Guidance Document: Medical Professionalism** This document was reviewed as part of its scheduled four-year review process. The Committee recommended deferring this document for additional work based on comments received.	Pages 175-179
	Comments from the P3 Alliance	Pages 180-181
7.5	**Proposed: Joint Guidance for Retail Intravenous Therapy Clinics** The Committee reviewed this document and provided suggested edits and feedback to Mike Farrell, Supervising Staff Attorney. The	Pages 182-185

PO Box 47866 | Olympia, Washington 98504-7866 | Medical.Commission@wmc.wa.gov | **WMC.wa.gov**

version included in this packet reflects those suggested edits. Ms. Blake will ask that Commissioners provide feedback on this document.

8.0 Member Reports

The Chair will call for reports from Commission members.

9.0 Staff Member Reports

The Chair will call for further reports from staff.

Written reports on pages 186-192

10.0 AAG Report

Heather Carter, AAG, may provide a report.

11.0 Leadership Elections

11.1 Restatement of Nominating Committee Report — Report

Previously announced nominations for the following positions:

- Chair – Terry Murphy, MD
- Vice Chair – Ed Lopez, PA-C
- Officer-at-Large – Elisha Mvundura, MD

11.2 Nominations from the floor — Nominations

The Chair will call for other nominations for all positions from the panel of Commissioners.

11.3 Election of Leadership — **Action**

For any position where there is more than one nominee, the panel of Commissioners will need to vote by roll call.

12.0 Adjournment of Business Meeting

Informational

Hearing Schedule	Page 7
2025 Meeting Schedule	Pages 8-11
2026 Meeting Schedule	Pages 12-15

Correspondence

Letter from The Opioid Analgesic REMS Program Companies	Pages 193-196
Letter from Tom Green, MD regarding Commissioner Lopez	Pages 197-198
WMC letter to HSQA regarding Proposed Expansion of Pharmacist Prescribing Authority Sunrise Review 2025	Pages 199-203

Open Session

Noon **Lunch & Learn** **Thurston**

Register to attend this virtual meeting here: https://tinyurl.com/y8yu8zz5

2025 Legislative Session: Post Mortem

Micah Matthews, Deputy Executive Director, will provide a recap of the 2025 legislative session. He'll highlight the bills that passed and explain how they affect the WMC, as well as the way care is delivered by allopathic physicians (MDs), physician assistants (PAs), and anesthesiologist assistants (AAs) in Washington State.

PO Box 47866 | Olympia, Washington 98504-7866 | Medical.Commission@wmc.wa.gov | **WMC.wa.gov**

FORMAL HEARING SCHEDULE

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

DISCLAIMER: THE BELOW HEARING SCHEDULE IS SUBJECT TO CHANGE.

Hearing Date	Respondent	Case No.	Location
May 2025			
NO HEARINGS SCHEDULED THIS MONTH			
June 2025			
NO HEARINGS SCHEDULED THIS MONTH			
July 2025			
July 11	Bunin, Alan, MD	M2024-631	TBD
July 16-18	Siler, Thomas T., MD	M2022-366	TBD
July 21-24	Jackson, Ricky, MD	M2022-491	TBD
August 2025			
August 5-7	Hammel, James F., MD	M2023-493	TBD
August 13-15	Steneker, Sjardo, MD	M2024-204	TBD

Information on how to observe a hearing can be obtained from the Adjudicative Clerk Office, (206) 391-5193.

2025 Meeting Schedule

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

January

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

1	New Years Day	Holiday – Offices Closed	
2	Policy Committee	4 pm	Virtual
9	Personal Appearances	8:30 am	Virtual
9	Case Disposition	10:45 am	Virtual
10	Committees/Workgroups	8:30 am	Virtual
10	Business	9:30 am	Virtual
10	Lunch & Learn	Noon	Virtual
20	Martin Luther King Day	Holiday – Offices Closed	
30	Policy: Interested Parties	10 am	Virtual

February

S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	

17	President's Day	Holiday – Offices Closed	
27	Policy Committee	4 pm	Virtual

March

S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

13	Personal Appearances	8:30 am	Hybrid Capital Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater
13	Case Disposition	10:45 am	
14	Committees/Workgroups	8:30 am	
14	Business	9:30 am	
14	Lunch & Learn	Noon	
27	Policy: Interested Parties	10 am	Virtual

2025 Meeting Schedule

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

April

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

18	SMART Training	8:30 am	Hilton Seattle Airport 17620 Intl. Blvd.

May

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

1	Policy Committee	4 pm	Virtual
8	Personal Appearances	8:30 am	Hybrid Capital Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater
8	Case Disposition	10:45 am	
9	Committees/Workgroups	8:30 am	
9	Business	9:30 am	
9	Lunch & Learn	Noon	
26	Memorial Day	Holiday – Offices Closed	

June

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

19	Juneteenth	Holiday – Offices Closed	
26	Policy: Interested Parties	10 am	Virtual

July

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

4	Independence Day	Holiday – Offices Closed	
10	Personal Appearances	8:30 am	Virtual
10	Case Disposition	10:45 am	Virtual
24	Policy Committee	4 pm	Virtual

2025 Meeting Schedule

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

August

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

21	Personal Appearances	8:30 am	Hybrid DOH TC2 Rm 166/167 111 Israel Rd SE Tumwater
21	Case Disposition	10:45 am	
22	Committees/Workgroups	8:30 am	
22	Business	9:30 am	
22	Lunch & Learn	Noon	

September

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

1	Labor Day	Holiday – Offices Closed	
25	Policy: Interested Parties	10 am	Virtual

October

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

2	Personal Appearances	8:30 am	Virtual
2	Case Disposition	10:45 am	Virtual
30	Policy Committee	4 pm	Virtual

2025 Meeting Schedule

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

November

S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

11	Veterans Day	Holiday – Offices Closed	
20	Personal Appearances	8:30 am	Hybrid DOH TC2 Rm 166/167 111 Israel Rd SE Tumwater
20	Case Disposition	10:30 am	
21	Committees/Workgroups	8:30 am	
21	Business	9:30 am	
21	Lunch & Learn	Noon	
27	Thanksgiving Day	Holiday – Offices Closed	
28	Native American Heritage Day	Holiday – Offices Closed	

December

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

25	Christmas	Holiday – Offices Closed

Association Meetings

Association	Date(s)	Location
Washington Academy of Physician Assistants (WAPA) & Oregon Society of Physician Associates (OSPA) Joint Spring Conference	March 9-11, 2025	Portland, OR
Washington State Medical Association (WSMA) Annual Meeting	September 20-21, 2025	Bellevue, WA
WAPA Fall Conference	TBA (Usually October)	TBA

Other Meetings

Entity	Date(s)	Location
Council on Licensure, Enforcement and Regulation (CLEAR) Winter Symposium	January 15, 2025	Savannah, GA
Federation of State Medical Boards (FSMB) Annual Conference	April 25-26, 2025	Seattle, WA
FSMB International Conference	September 3-6, 2025	Dublin, Ireland
CLEAR Annual Conference	September 15-18, 2025	Chicago, IL
FSMB Board Attorneys Workshop	Tentative: November 6-7	TBA

2026 Meeting Schedule

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

January

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

1	New Years Day	Holiday – Offices Closed	
8	Policy Committee	4 pm	Virtual
15	Personal Appearances	8:30 am	Virtual
15	Case Disposition	10:45 am	Virtual
16	Committees/Workgroups	8:30 am	Virtual
16	Business	9:30 am	Virtual
16	Lunch & Learn	Noon	Virtual
19	Martin Luther King Day	Holiday – Offices Closed	
29	Policy: Interested Parties	10 am	Virtual

February

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

16	President's Day	Holiday – Offices Closed	
26	Policy Committee	4 pm	Virtual

March

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

12	Personal Appearances	8:30 am	Hybrid Location: TBD
12	Case Disposition	10:45 am	
13	Committees/Workgroups	8:30 am	
13	Business	9:30 am	
13	Lunch & Learn	Noon	
26	Policy: Interested Parties	10 am	Virtual

2026 Meeting Schedule

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

April

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

17	SMART Training	8:30 am	In person Location: TBD
23	Policy Committee	4 pm	Virtual

May

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

7	Personal Appearances	8:30 am	Hybrid Location: TBD
7	Case Disposition	10:45 am	
8	Committees/Workgroups	8:30 am	
8	Business	9:30 am	
8	Lunch & Learn	Noon	
25	Memorial Day	Holiday – Offices Closed	

June

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

19	Juneteenth	Holiday – Offices Closed	
25	Policy: Interested Parties	10 am	Virtual

July

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

3	Independence Day (observed)	Holiday – Offices Closed	
9	Personal Appearances	8:30 am	Virtual
9	Case Disposition	10:45 am	Virtual
23	Policy Committee	4 pm	Virtual

2026 Meeting Schedule

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

August

S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

20	Personal Appearances	8:30 am	Hybrid Location: TBD
20	Case Disposition	10:45 am	
21	Committees/Workgroups	8:30 am	
21	Business	9:30 am	
21	Lunch & Learn	Noon	

September

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

7	Labor Day	Holiday – Offices Closed	
24	Policy: Interested Parties	10 am	Virtual

October

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

8	Personal Appearances	8:30 am	Virtual
8	Case Disposition	10:45 am	Virtual
29	Policy Committee	4 pm	Virtual

2026 Meeting Schedule

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

November

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

11	Veterans Day	Holiday – Offices Closed	
19	Personal Appearances	8:30 am	Hybrid Location: TBD
19	Case Disposition	10:30 am	
20	Committees/Workgroups	8:30 am	
20	Business	9:30 am	
20	Lunch & Learn	Noon	
26	Thanksgiving Day	Holiday – Offices Closed	
27	Native American Heritage Day	Holiday – Offices Closed	

December

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

3	Policy: Interested Parties	10 am	Virtual
25	Christmas	Holiday – Offices Closed	

Association Meetings

Association	Date(s)	Location
Washington Academy of Physician Assistants (WAPA) & Oregon Society of Physician Associates (OSPA) Joint Spring Conference	TBA	TBA
Washington State Medical Association (WSMA) Annual Meeting	TBA	TBA
WAPA Fall Conference	TBA	TBA

Other Meetings

Entity	Date(s)	Location
Council on Licensure, Enforcement and Regulation (CLEAR) Winter Symposium	TBA	TBA
Federation of State Medical Boards (FSMB) Annual Conference	TBA	TBA
FSMB International Conference	TBA	TBA
CLEAR Annual Conference	TBA	TBA
FSMB Board Attorneys Workshop	TBA	TBA

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Panel A
Personal Appearance Agenda

Thursday, May 8, 2025

Meeting Link: Personal Appearances - Panel A

Panel Members:	Harlan Gallinger, MD, Panel Chair	Daniel Cabrera, MD	Jimmy Chung, MD	Arlene Dorrough, PA-C
	Anjali D'Souza, MD	Jamie Koop, Public Member	Sarah Lyle, MD	Elisha Mvundura, MD
	Douglas Pullen, Public Member	Scott Rodgers, Public Member		
	Penny Reck, MD, Pro-Tem	Robert Bernstein, MD, Pro-Tem	Charlie Browne, MD, Pro-Tem	Peter Casterella, MD, Pro-Tem
	Peggy Hutchison, MD, Pro-Tem			

Compliance Officer: Anthony Elders

8:30 a.m.	**Basil M. Griffin, III, MD** Attorney: Eric Byrd	M2023-999 (2023-10478) RCM: Anjali D'Souza, MD SA: Joel Defazio

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Panel B

Personal Appearance Agenda

Thursday, May 8, 2025

Meeting Link: Personal Appearances - Panel B

Panel Members:

Chair: Terry Murphy, MD	Michael Bailey, Public Member	Christine Blake, Public Member	Toni Borlas, Public Member
Po-Shen Chang, MD	Diana Currie, MD	Karen Domino, MD	April Jaeger, MD
Ed Lopez, PA-C	Claire Trescott, MD	Richard Wohns, MD	
Hal Goldberg, MD, Pro-Tem	John Maldon, Public Member, Pro-Tem		

Compliance Officer: Mike Kramer

8:30 a.m.	**Stanley R. Schiff, MD** Attorney: Jennifer Smitrovich	M2023-350 (2022-9586) RCMs: Po-Shen Chang, MD SA: Mike Farrell
9:00 a.m.	**Anthony E. Harris, MD** Attorney: Deanna R. Bui	M2020-711 (2019-18383) RCM: Richard Wohns, MD SA: Lisa Krynicki

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.

Rules Hearing

Anesthesiologist Assistants

WSR 25-08-028
PROPOSED RULES
DEPARTMENT OF HEALTH
(Washington Medical Commission)
[Filed March 25, 2025, 3:44 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 24-18-057.

Title of Rule and Other Identifying Information: Anesthesiologist assistants; the Washington medical commission (commission) is proposing new chapter 246-921 WAC, Anesthesiologist assistants, to implement SB 5184 (chapter 362, Laws of 2024), codified under chapter 18.71D RCW, which created the new anesthesiologist assistant (AA) license. The commission is proposing this new chapter to establish licensing regulations for AAs.

Hearing Location(s): On May 9, 2025, at 9:30 a.m., via Teams at https://tinyurl.com/j7kc38pr; or in person at Capital Event Center, ESD 113, 6005 Tyee Drive S.W., Tumwater, WA 98512. To join the commission's rules interested parties email list, please visit https://public.govdelivery.com/accounts/WADOH/subscriber/new?topic_id=WADOH_153.

Date of Intended Adoption: May 9, 2025.

Submit Written Comments to: Amelia Boyd, Program Manager, P.O. Box 47866, Olympia, WA 98504-7866, email medical.rules@wmc.wa.gov, https://fortress.wa.gov/doh/policyreview/, beginning the date and time of this filing, by May 2, 2025, at 5:00 p.m.

Assistance for Persons with Disabilities: Contact Amelia Boyd, program manager, phone 1-800-525-0127, TTY 711, email medical.rules@wmc.wa.gov, by May 2, 2025.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: SB 5184 (chapter 362, Laws of 2024) mandates the commission to establish and implement a regulatory framework for the new profession of AA, ensuring appropriate qualifications, safe practice standards, and effective supervision.

The proposed rules establish clear licensure requirements that ensure AAs have met high educational and competency standards before they are allowed to practice. The proposed rules define and clarify the scope of practice, establish proper supervision regulations, and implement disciplinary measures and enforcement for licensed AAs. The proposed rules are clear, concise, and flexible for the health workforce that clarify the AA's role in anesthesia care that promotes the public trust in anesthesia.

Reasons Supporting Proposal: Chapter 18.71D RCW directs the commission to undertake several specific actions regarding the licensure, regulation, and supervision of anesthesiologist assistants. Below is a breakdown of the commission's responsibilities required by chapter 18.71D RCW:

(1) Adoption of Rules for Licensure:

- Set Qualifications and Training Standards:
  - The commission must establish the qualifications, educational, and training requirements for anesthesiologist assistant licensure.
- Application Process:
  - Create an application form with required details, including education, training, experience, and other commission-defined information.
  - Require applicants to provide proof of completing an accredited program and eligibility to take the required exam.
  - Assess physical and mental fitness of applicants to practice safely, with the ability to mandate examinations to verify fitness if necessary.

(2) Authority Over Licenses:

- Approve, deny, or take disciplinary action on license applications based on the Uniform Disciplinary Act.
- Set requirements for license renewal, including requesting professional practice information from licensees at the time of renewal.

(3) Regulating Practice:

- Prohibit unlicensed practice.
- Establish rules governing the scope of practice and supervision requirements for anesthesiologist assistants. These rules must:
  - Define how many anesthesiologist assistants a single anesthesiologist may supervise concurrently, with a default maximum of four unless otherwise approved by the commission.
  - Develop rules for backup or on-call supervisory arrangements for anesthesiologists overseeing multiple assistants.

Statutory Authority for Adoption: RCW 18.71.017, 18.130.050, 18.71D.020, and 18.71D.030.
Statute Being Implemented: Chapter 18.71D RCW.
Rule is not necessitated by federal law, federal or state court decision.
Name of Proponent: Washington medical commission, governmental.
Name of Agency Personnel Responsible for Drafting: Amelia Boyd, 111 Israel Road S.E., Tumwater, WA 98501, 360-918-6336; Implementation and Enforcement: Kyle Karinen, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-4810.
A school district fiscal impact statement is not required under RCW 28A.305.135.
A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Amelia Boyd, Program Manager, P.O. Box 47866, Olympia, WA 98504-7866, phone 360-918-6336, TTY 711, email medical.rules@wmc.wa.gov.
This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:
Is exempt under RCW 19.85.025(4).
Explanation of exemptions: The proposed new chapter establishes regulations and impacts an individual professional license, not small businesses.
Scope of exemption for rule proposal:
Is fully exempt.

March 24, 2025
Kyle S. Karinen
Executive Director
Washington Medical Commission

RDS-6060.4

Chapter 246-921 WAC
ANESTHESIOLOGIST ASSISTANTS—WASHINGTON MEDICAL COMMISSION

NEW SECTION

WAC 246-921-005 Definitions.

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise:
(1) "Anesthesiologist" means an actively practicing, board-eligible physician licensed under chapter 18.71, 18.71B, or 18.57 RCW who has completed a residency or equivalent training in anesthesiology.
(2) "Anesthesiologist assistant" or "certified anesthesiologist assistant" means a person who has successfully completed an accredited anesthesiologist assistant program approved by the commission and has successfully passed the certification exam offered by the National Commission for Certification of Anesthesiologist Assistants (NCCAA), or other exam approved by the commission. These individuals, who may be known as "AA" or "CAA," are licensed by the commission under chapter 18.71D RCW and this chapter to assist in developing and implementing anesthesia care plans for patients under the supervision of an anesthesiologist or group of anesthesiologists approved by the commission to supervise such assistant.
(3) "Assist" means the anesthesiologist assistant personally performs those duties and responsibilities delegated by the anesthesiologist. Delegated services must be consistent with the delegating anesthesiologist's

education, training, experience, and active practice. Delegated services must be of the type that a reasonable and prudent anesthesiologist would find within the scope of sound medical judgment to delegate.

(4) "Commission" means the Washington medical commission.

(5) "Commission approved program" means a Commission on Accreditation of Allied Health Education Programs (CAAHEP) accredited education program specifically designed for training anesthesiologist assistants or other substantially equivalent organization(s) approved by the commission.

(6) "Practice medicine" has the same meaning defined in RCW 18.71.011.

(7) "Supervise" means the immediate availability of the medically directing anesthesiologist for consultation and direction of the activities of the anesthesiologist assistant. A medically directing anesthesiologist is immediately available if they are in physical proximity that allows the anesthesiologist to reestablish direct contact with the patient to meet medical needs and any urgent or emergent clinical problems, and personally participating in the most demanding procedures of the anesthesia plan including, if applicable, induction and emergence. These responsibilities may also be met through coordination among anesthesiologists of the same group or department. Supervision through remote or telecommunications methods are not permitted under this definition and rule.

NEW SECTION

WAC 246-921-100 Application withdrawals.

An application for a license may not be withdrawn after the commission determines that grounds exist for denial of the license or for the issuance of a conditional license under chapter 18.130 RCW. Applications that are subject to investigation of unprofessional conduct or impaired practice may not be withdrawn.

NEW SECTION

WAC 246-921-105 Anesthesiologist assistant—Requirements for licensure.

(1) An applicant for licensure as an anesthesiologist assistant must submit to the commission:

(a) A completed application on forms provided by the commission;

(b) Proof the applicant has completed a CAAHEP accredited commission-approved anesthesiologist assistant program and successfully passed the NCCAA examination;

(c) All applicable fees as specified in WAC 246-921-990; and

(d) Other information required by the commission.

(2) The commission will only consider complete applications with all supporting documents for licensure.

(3) Internationally trained individuals do not currently have a pathway to licensure as an anesthesiologist assistant due to ineligibility for the certifying exam offered by NCCAA. Should an exam become available the internationally trained individual may petition the commission for licensure.

NEW SECTION

WAC 246-921-110 Background check—Temporary practice permit.

The commission may issue a temporary practice permit when the applicant has met all other licensure requirements, except the national criminal background check requirement. The applicant must not be subject to denial of a license or issuance of a conditional license under this chapter.

(1) If there are no violations identified in the Washington criminal background check and the applicant meets all other licensure conditions, including receipt by the department of health of a completed Federal Bureau of Investigation (FBI) fingerprint card, the commission may issue a temporary practice permit allowing time to complete the national criminal background check requirements.

(2) A temporary practice permit that is issued by the commission is valid for six months. A one-time extension of six months may be granted if the national background check report has not been received by the commission.

(3) The temporary practice permit allows the applicant to work in the state of Washington as an anesthesiologist assistant during the time period specified on the permit. The temporary practice permit is a license to practice medicine as an anesthesiologist assistant, provided that a supervision arrangement exists with an anesthesiologist or anesthesiologists of the same group or department as provided in this rule.

(4) The commission issues a license once it receives the national background check report, as long as the report is not negative, and the applicant meets all other licensing requirements.

(5) The temporary practice permit is no longer valid after the license is issued or the application for a full license is denied.

NEW SECTION

WAC 246-921-115 Expedited temporary license—Military spouse.

A military spouse may receive an expedited temporary license while completing any specific additional requirements that are not related to training or practice standards for anesthesiologist assistants under the following conditions.

(1) An expedited temporary license may be issued to an applicant who is a military spouse and:

(a) Is moving to Washington as a result of the military person's transfer to the state of Washington;

(b) Holds an unrestricted, active license in another state or United States territory that the commission currently deems to have substantially equivalent licensing standards for an anesthesiologist assistant to those in the state of Washington; and

(c) Is not subject to any pending investigation, charges, or disciplinary action by the regulatory body in any other state or United States territory in which the applicant holds a license.

(2) An expedited temporary license grants the applicant the full scope of practice for the anesthesiologist assistant.

(3) An expedited temporary license expires when any one of the following occurs:

(a) A full or limited license is issued to the applicant;

(b) A notice of decision on the application is mailed to the applicant, unless the notice of decision on the application specifically extends the duration of the expedited temporary license; or

(c) One hundred eighty days after the expedited temporary license is issued.

(4) To receive an expedited temporary license, the applicant must:

(a) Meet all requirements and qualifications for the license that are specific to the training, education, and practice standards for anesthesiologist assistants;

(b) Submit a written request for an expedited temporary license; and

(c) Submit a copy of the military service member's orders and a copy of one of the following:

(i) The military-issued identification card showing the military service member's information and the applicant's relationship to the military service member;

(ii) A marriage license; or

(iii) A state registered domestic partnership.

(5) For the purposes of this section the following definitions shall apply:

(a) "Military spouse" is someone married to or in a registered domestic partnership with a military person who is serving in the United States Armed Forces, the United States Public Health Service Commissioned Corps, or the Merchant Marine of the United States; and

(b) "Military person" means a person serving in the United States Armed Forces, the United States Public Health Service Commissioned Corps, or the Merchant Marine of the United States.

NEW SECTION

WAC 246-921-120 Exemption from licensure—Qualified physician assistant pathway.

(1) A physician assistant may practice medicine within the full scope of an anesthesiologist assistant without requiring a separate license under chapter 18.71D RCW if the physician assistant:

(a) Fulfills of the practice, education, training, and licensure requirements specified in WAC 246-918-080;

(b) Has graduated from a commission-approved program accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) that is specifically designed to train anesthesiologist assistants as required in WAC 246-918-055;

(c) Has successfully passed and maintains certification through the National Council on Certification of Anesthesiologist Assistants; and

(d) Is supervised according to the requirements in this chapter and chapter 18.71D RCW by an anesthesiologist licensed under chapter 18.71, 18.71B, or 18.57 RCW.

NEW SECTION

WAC 246-921-125 Renewal, continuing medical education cycle, and maintenance of licensure.

(1) Under WAC 246-12-020, an initial credential issued within 90 days of the anesthesiologist assistant's birthday does not expire until the anesthesiologist assistant's next birthday.

(2) An anesthesiologist assistant must renew their license every two years on their birthday. Renewal fees are accepted no sooner than 90 days prior to the expiration date.

(3) Each anesthesiologist assistant shall have four years to meet the continuing medical education requirements as required in this section. The review period begins at the second renewal after initial licensure or second renewal after reactivation of an expired license.

(4) An anesthesiologist assistant must complete 200 hours of continuing education every four years as required in chapter 246-12 WAC, which may be audited for compliance at the discretion of the commission.

(5) In lieu of 200 hours of continuing medical education, the commission will accept:

(a) Current certification with the NCCAA;

(b) Compliance with a continuing maintenance of competency program through NCCAA; or

(c) Other programs approved by the commission.

(6) The commission approves the following categories of creditable continuing medical education as accredited by the Accreditation Council for Continuing Medical Education (ACCME) or affiliated education providers. A minimum of 80 credit hours must be earned in Category I.

Category I	Continuing medical education activities with accredited sponsorship through ACCME or recognized affiliated education providers.
Category II	Continuing medical education activities with nonaccredited sponsorship and other meritorious learning experience.

(7) The commission adopts the standards approved by the ACCME for the evaluation of continuing medical education requirements in determining the acceptance and category of any continuing medical education experience.

(8) An anesthesiologist assistant does not need prior approval of any continuing medical education. The commission will accept any continuing medical education that reasonably falls within the requirements of this section and relies upon each anesthesiologist assistant's integrity to comply with these requirements.

(9) A continuing medical education sponsor does not need to apply for or expect to receive prior commission approval for a formal continuing medical education program. The continuing medical education category will depend solely upon the accredited status of the organization or institution. The number of hours may be determined by counting the contact hours of instruction and rounding to the nearest quarter hour. The commission relies upon the integrity of the program sponsors to present continuing medical education for the anesthesiologist assistant that constitutes a meritorious learning experience.

NEW SECTION

WAC 246-921-130 Training in suicide assessment, treatment, and management.

(1) A licensed anesthesiologist assistant must complete a one-time training in suicide assessment, treatment, and management. The training must be at least six hours in length and may be completed in one or more sessions.

(2) The training must be completed by the end of the first full continuing education reporting period after initial licensure.

(3) The training must be on the model list developed by the department of health under RCW 43.70.442.

(4) The hours spent completing training in suicide assessment, treatment, and management count toward meeting applicable continuing education requirements in the same categories specified in WAC 246-921-125.

(5) The commission exempts any licensed anesthesiologist assistant from the training requirements of this section if the anesthesiologist assistant has only brief, limited, or no patient contact.

NEW SECTION

WAC 246-921-135 Health equity continuing education training requirements.

(1) An anesthesiologist assistant must complete two hours of health equity continuing education training every four years as described in WAC 246-12-800 through 246-12-830.

(2) The two hours of health equity continuing education an anesthesiologist assistant completes count toward meeting applicable continuing education requirements in the same categories specified in WAC 246-921-125.

NEW SECTION

WAC 246-921-140 Retired license.

(1) To obtain a retired license, an anesthesiologist assistant must comply with chapter 246-12 WAC.

(2) An anesthesiologist assistant with a retired license must have a supervision arrangement with an anesthesiologist in order to practice, except when serving as a "covered volunteer emergency worker" as defined in RCW 38.52.180 (5)(a) and engaged in authorized emergency management activities or serving under chapter 70.15 RCW.

(3) An anesthesiologist assistant with a retired license may not receive compensation for health care services.

(4) An anesthesiologist assistant with a retired license may practice under the following conditions:

(a) In emergent circumstances calling for immediate action; or

(b) Intermittent circumstances on a part-time or full-time nonpermanent basis.

(5) A retired license expires every two years on the license holder's birthday. Retired credential renewal fees are accepted no sooner than 90 days prior to the expiration date.

(6) An anesthesiologist assistant with a retired license shall report 100 hours of continuing education at every renewal.

NEW SECTION

WAC 246-921-145 Returning to active status when a license has expired.

(1) To return to active status the anesthesiologist assistant must meet the requirements of chapter 246-12 WAC, which includes paying the applicable fees under WAC 246-921-990 and meeting the continuing medical education requirements under WAC 246-921-125.

(2) If the license has expired over three years, the anesthesiologist assistant must:

(a) Meet requirements in subsection (1) of this section;

(b) Meet the current licensure requirements under WAC 246-921-105; and

(c) Satisfy any demonstration of competence requirements deemed necessary by the commission. Demonstration of competence may take the form of clinical knowledge examinations or fitness for duty evaluations conducted by commission-approved entities.

NEW SECTION

WAC 246-921-150 Anesthesiologist assistant identification.

(1) An anesthesiologist assistant must clearly identify themselves as an anesthesiologist assistant and must appropriately display on their person identification as an anesthesiologist assistant. An anesthesiologist assistant may identify themselves as an anesthesiologist assistant (AA) or a certified anesthesiologist assistant (CAA).

(2) An anesthesiologist assistant must not present themselves in any manner which would tend to mislead the public as to their title.

NEW SECTION

WAC 246-921-155 Mandatory reporting.

The commission adopts the rules for mandatory reporting in chapter 246-16 WAC.

NEW SECTION

WAC 246-921-160 Practice limitations and scope of practice.

(1) An anesthesiologist assistant is required to have a supervision arrangement with an anesthesiologist or anesthesiologists of the same group or department as provided by this chapter. The supervision arrangements are not required to be filed with the commission.

(2) Duties which an anesthesiologist may delegate to an anesthesiologist assistant include, but are not limited to:

(a) Assisting with preoperative anesthetic evaluations, postoperative anesthetic evaluations, and patient progress notes, all to be cosigned by the supervising anesthesiologist within 24 hours;

(b) Administering and assisting with preoperative consultations;

(c) Under the supervising anesthesiologist's consultation and direction, order perioperative pharmaceutical agents, medications, and fluids, to be used only at the facility where ordered including, but not limited to, controlled substances, which may be administered prior to the cosignature of the supervising anesthesiologist. The supervising anesthesiologist may review and if required by the facility or institutional policy must cosign these orders in a timely manner;

For the purposes of this section, an anesthesiologist assistant may place an order for pharmaceutical agents, medications, and fluids under the consultation, direction, and prescriptive authority of the anesthesiologist. The anesthesiologist assistant does not have independent prescriptive authority.

(d) Changing or discontinuing a medical treatment plan, after consultation with the supervising anesthesiologist;

(e) Calibrating anesthesia delivery systems and obtaining and interpreting information from the systems and monitors, in consultation with an anesthesiologist;

(f) Assisting the supervising anesthesiologist with the implementation of medically accepted monitoring techniques;

(g) Assisting with basic and advanced airway interventions including, but not limited to, endotracheal intubation, laryngeal mask insertion, and other advanced airways techniques;

(h) Establishing peripheral intravenous lines, including subcutaneous lidocaine use;

(i) Establishing radial and dorsalis pedis arterial lines;

(j) Assisting with general anesthesia, including induction, maintenance, and emergence;

(k) Assisting with procedures associated with general anesthesia such as, but not limited to, gastric intubation;

(l) Administering intermittent vasoactive drugs and starting and titrating vasoactive infusions for the treatment of patient responses to anesthesia;

(m) Assisting with spinal and intravenous regional anesthesia;

(n) Maintaining and managing established neuraxial epidurals and regional anesthesia;

(o) Assisting with monitored anesthesia care;

(p) Evaluating and managing patient-controlled analgesia, epidural catheters, and peripheral nerve catheters;

(q) Obtaining venous and arterial blood samples;

(r) Assisting with, ordering, and interpreting appropriate preoperative, point of care, intraoperative, or postoperative diagnostic tests or procedures as authorized by the supervising anesthesiologist;

(s) Obtaining and administering perioperative anesthesia and related pharmaceutical agents including intravenous fluids and blood products;

(t) Participating in management of the patient while in the preoperative suite and recovery area;

(u) Providing assistance to a cardiopulmonary resuscitation team in response to a life-threatening situation;

(v) Participating in administrative, research, and clinical teaching activities as authorized by the supervising anesthesiologist; and

(w) Assisting with such other tasks not prohibited by law under the supervision of a licensed anesthesiologist that an anesthesiologist assistant has been trained and is proficient to assist with.

(3) Nothing in this section shall be construed to prevent an anesthesiologist assistant from having access to and being able to obtain drugs as directed by the supervising anesthesiologist.

(4) An anesthesiologist assistant may not prescribe, order, compound, or dispense drugs, medications, or devices of any kind except as authorized in subsection (2) of this section.

(5) An anesthesiologist assistant may sign and attest to any certificates, cards, forms, or other required documentation that the anesthesiologist assistant's supervising anesthesiologist may sign, provided that it is within the anesthesiologist assistant's scope of practice.

NEW SECTION

WAC 246-921-165 Supervision ratios and group supervision.

(1) An anesthesiologist may themselves supervise no more than four anesthesiologist assistants. If a supervision ratio above 4:1 is needed, the anesthesiologist may submit a request for an exception to the commission using a form provided by the commission.

(2) In the exception request, the anesthesiologist must provide:

(a) A descriptive justification of need;

(b) What quality review and improvement mechanisms are in place to maintain the patient safety and the standard of care; and

(c) What escalation and anesthesiologist backup procedures are in place should multiple anesthesiologist assistants require the presence or assistance of the anesthesiologist.

(3) Those submitting exception requests may, at the sole discretion of the commission, be denied. In the event of a request denial, requestors are entitled to appeal the decision utilizing the brief adjudication process as defined in WAC 246-11-420 through 246-11-450.

(4) The commission permits a group supervision model for anesthesiologist assistants in settings where the anesthesiologist led anesthesia care team:

(a) Operates in a single physical location such as a hospital or clinic;

(b) Does not operate above the 4:1 ratio without a commission granted exemption as required in this section; and

(c) Has protocols and staffing available to designate backup and on-call anesthesiologists.

NEW SECTION

WAC 246-921-170 Notification of investigation or disciplinary action.

The anesthesiologist assistant shall notify their supervising anesthesiologist whenever the anesthesiologist assistant is the subject of an investigation or disciplinary action by the commission. The commission may notify the supervising anesthesiologist or other supervising anesthesiologist of such matters as appropriate.

NEW SECTION

WAC 246-921-305 Sexual misconduct.

(1) The following definitions apply throughout this section unless the context clearly requires otherwise.

(a) "Patient" means a person who is receiving health care or treatment or has received health care or treatment without a termination of the anesthesiologist assistant-patient relationship. The determination of when a person is a patient is made on a case-by-case basis with consideration given to a number of factors, including the nature, extent, and context of the professional relationship between the anesthesiologist assistant and the person. The fact that a person is not actively receiving treatment or professional services is not the sole determining factor.

(b) "Key third party" means a person in a close personal relationship with the patient and includes, but is not limited to, spouses, partners, parents, siblings, children, guardians, and proxies.

(2) An anesthesiologist assistant shall not engage, or attempt to engage, in sexual misconduct with a current patient or a key third party, inside or outside the health care setting. Sexual misconduct shall constitute grounds for disciplinary action. An anesthesiologist assistant engages in sexual misconduct when they engage in the following behaviors with a patient or a key third party:

(a) Sexual intercourse;

(b) Touching the breasts, genitals, anus or any sexualized body part except as consistent with accepted community standards of practice for examination, diagnosis, and treatment and within the health care practitioner's scope of practice;

(c) Rubbing against a patient or client or key third party for sexual gratification;

(d) Kissing;

(e) Hugging, touching, fondling, or caressing of a romantic or sexual nature;

(f) Examination of or touching genitals without using gloves;

(g) Not allowing a patient or client privacy to dress or undress except as may be necessary in emergencies or custodial situations;

(h) Not providing the patient or client a gown or draping except as may be necessary in emergencies;

(i) Dressing or undressing in the presence of the patient, client, or key third party;

(j) Removing patient or client's clothing or gown or draping without consent, emergent medical necessity, or being in a custodial setting;

(k) Encouraging masturbation or other sex act in the presence of the health care provider;

(l) Masturbation or other sex act by the health care provider in the presence of the patient, client, or key third party;

(m) Suggesting or discussing the possibility of a dating, sexual or romantic relationship after the professional relationship ends;

(n) Terminating a professional relationship for the purpose of dating or pursuing a romantic or sexual relationship;

(o) Soliciting a date with a patient, client, or key third party;

(p) Discussing the sexual history, preferences, or fantasies of the health care provider;

(q) Any behavior, gestures, or expressions that may reasonably be interpreted as seductive or sexual;

(r) Making statements regarding the patient, client, or key third party's body, appearance, sexual history, or sexual orientation other than for legitimate health care purposes;

(s) Sexually demeaning behavior including any verbal or physical contact which may reasonably be interpreted as demeaning, humiliating, embarrassing, threatening or harming a patient, client, or key third party;

(t) Photographing or filming the body or any body part or pose of a patient, client, or key third party, other than for legitimate health care purposes; and

(u) Showing a patient, client, or key third party sexually explicit photographs, other than for legitimate health care purposes.

(3) Sexual misconduct also includes sexual contact with any person involving force, intimidation, or lack of consent; or a conviction of a sex offense as defined in RCW 9.94A.030.

(4) An anesthesiologist assistant shall not:

(a) Offer to provide health care services in exchange for sexual favors;

(b) Use health care information to contact the patient, client, or key third party for the purpose of engaging in sexual misconduct;

(c) Use health care information or access to health care information to meet or attempt to meet the anesthesiologist assistant's sexual needs.

(5) An anesthesiologist assistant shall not engage in any of the conduct described in subsection (2) of this section with a former patient or key third party if:

(a) There is a significant likelihood that the patient, client, or key third party will seek or require additional services from the health care provider; or

(b) There is an imbalance of power, influence, opportunity, and/or special knowledge of the professional relationship.

(6) To determine whether a patient is a current patient or a former patient, the commission will analyze each case individually, and will consider a number of factors including, but not limited to, the following:

(a) Documentation of formal termination;

(b) Transfer of the patient's care to another health care provider;

(c) The length of time that has passed;

(d) The length of time of the professional relationship;

(e) The extent to which the patient has confided personal or private information to the anesthesiologist assistant;

(f) The nature of the patient's health problem;

(g) The degree of emotional dependence and vulnerability.

(7) This section does not prohibit conduct that is required for medically recognized diagnostic or treatment purposes if the conduct meets the standard of care appropriate to the diagnostic or treatment situation.

(8) These rules do not prohibit:

(a) Providing health care services in case of emergency where the services cannot or will not be provided by another health care provider;

(b) Contact that is necessary for a legitimate health care purpose and that meets the standard of care appropriate to that profession; or

(c) Providing health care services for a legitimate health care purpose to a person who is in a preexisting, established personal relationship with the health care provider where there is no evidence of, or potential for, exploiting the patient or client.

(9) It is not a defense that the patient, former patient, or key third party initiated or consented to the conduct, or that the conduct occurred outside the professional setting.

(10) A violation of any provision of this rule shall constitute grounds for disciplinary action.

NEW SECTION

WAC 246-921-310 Abuse.

(1) An anesthesiologist assistant commits unprofessional conduct if the anesthesiologist assistant abuses a patient. An anesthesiologist assistant abuses a patient when they:

(a) Make statements regarding the patient's body, appearance, sexual history, or sexual orientation that have no legitimate medical or therapeutic purpose;

(b) Remove a patient's clothing or gown without consent;

(c) Fail to treat an unconscious or deceased patient's body or property respectfully; or

(d) Engage in any conduct, whether verbal or physical, which unreasonably demeans, humiliates, embarrasses, threatens, or harms a patient.

(2) A violation of any provision of this rule shall constitute grounds for disciplinary action.

Washington State Medical Association
Physician Driven, Patient Focused

April 30, 2025

Amelia Boyd
Program Manager
Washington Medical Commission

RE: CR-102 implementing SB 5184/ anesthesiologist assistants (WSR 25-08-028)

Dear Ms. Boyd,

On behalf of the Washington State Medical Association and our over 13,000 physician and physician assistant members, thank you for the opportunity to comment on the CR-102 regulating the licensure of Certified Anesthesiologist Assistants (CAAs). The WSMA supported the creation of this profession when the proposal was under sunrise review, as well as when SB 5184 was in front of the legislature, and we are proud to offer our support for the CR-102 implementing the legislation. These rules will increase our health care workforce and expand access to highly trained, skilled, and professional anesthesia care for patients.

The proposed rules reflect the legislature's intent when they approved SB 5184. The scope of practice contemplated in RCW 18.71D provides a comprehensive and detailed framework for licensure that is consistent with their education and training. It is also reflective of the work they perform safely and effectively in the 22 states where they currently practice.

The swift adoption of these rules will allow for CAAs to work alongside physician anesthesiologists to provide safe and effective anesthesia care at a critical time for our health care system. We urge the commission to adopt the CR-102 as drafted. Should follow up questions arise, please contact billie@wsma,org.

Sincerely,

Billie Dickinson

Billie Dickinson
WSMA Associate Policy Director

Seattle Office
1215 Fourth Avenue, Suite 1901
Seattle, WA 98161
o / 206.441.9762 *fax* / 206.441.5863
email / wsma@wsma.org

Olympia Office
1800 Cooper Point Road SW
Building 7, Suite A
Olympia, WA 98502
o / 206.441.9762 *fax* / 206.441.5863

Washington Academy of Anesthesiologist Assistants

April 27, 2025

Washington Medical Commission
P.O. Box 47866
Olympia, WA 98504-7866
ATTN: Amelia Boyd, Program Manager

RE: PLEASE SUPPORT WSR 25-08-028 – RULES IMPLEMENTING SB 5184 (ANESTHESIOLOGIST ASSISTANTS)

Dear Members of the Washington Medical Commission,

I am writing on behalf of the Certified Anesthesiologist Assistant (CAA) community to express our strong and urgent support for the rules implementing Senate Bill 5184, licensing Anesthesiologist Assistants in Washington State. This legislation represents an important step forward in improving patient access to care in Washington State. Many trained CAAs are already living in Washington or are prepared to move here, growing as the profession gains recognition in the state. Additionally, with hundreds of students expected to graduate from CAA programs across the country in the next two years, Washington has a unique opportunity to attract these highly trained anesthesia professionals. Adoption of these rules is a key to addressing the state's growing anesthesia workforce needs.

The rules, as drafted, strike the right balance between safety, supervision, and flexibility. They closely align with how CAAs work with their supervising anesthesiologists in hospitals and clinics across the country. When it comes to the scope of practice for CAAs, the rules align with the language of SB 5184, which was noted in a letter from the bill's sponsors, Senators Rivers and Cleveland, during the stakeholder process on November 1, 2024:

- Sec 4 (1) very clearly states that "An anesthesiologist assistant may not exceed the scope of their supervising anesthesiologist's practice and may assist with those duties and responsibilities delegated to them by the supervising anesthesiologist, and for which they are competent to assist with based on their education, training and experience." This gives the supervising anesthesiologist the ability in the law to determine the duties for the Anesthesiologist Assistant based on the needs of their practice.

- Sec 4 (1) also states, "Duties which an anesthesiologist may delegate to an anesthesiologist assistant include but are not limited to:" and then lists the explicit

authorized duties. However, the “include but are not limited to” language in this bill, combined with the first sentence clearly states that the supervising anesthesiologist is the ultimate arbiter of the delegation of duties. The language of the law clearly indicates that the statute itself is not a limiting document.

- In addition, in Sec 4 (1) (w) the law states within the explicit delegation of duties “Assisting with other tasks not prohibited by law under the supervision of a licensed anesthesiologist that an anesthesiologist assistant has been trained and is proficient to assist with.” Once again, this is clearly ensuring the only duties that are prohibited are those specifically prohibited within the statute.

The rules also ensure proper identification when CAAs are working with patients and accurately clarify CAA authority for ordering prescription drugs when working with their supervising anesthesiologist.

We urge adoption of these rules and look forward to including CAAs in Washington State’s quality health care workforce.

Sincerely,

Sarah Brown, President
WA Academy of Anesthesiologist Assistants
Spokane, WA
770-654-3485
Sarah.rebecca.brown@gmail.com

American Society of Anesthesiologists®

1061 American Lane | Schaumburg, IL 60173-4973 | (847) 825-5586
905 16th Street N.W., Suite 400 | Washington, D.C. 20006 | (202) 289-2222

April 30, 2025

Washington Medical Commission
Attn: Amelia Boyd
111 Israel Rd S
Tumwater, WA 98501

Re: Support of Rules Regarding Certified Anesthesiologist Assistant Practice

Dear Ms. Boyd:

On behalf of the more than 59,000 members of the American Society of Anesthesiologists (ASA), **I strongly encourage the Washington Medical Commission to adopt Chapter 246-921 WAC as proposed**, so your citizens can begin benefitting from the highly trained care CAAs already provide to patients in nearly half the United States. This important regulatory language would implement Senate Bill 5184, a 2024 law authorizing certified anesthesiologist assistants (CAAs) to practice in Washington. I confirm that the proposed language accurately reflects the enabling legislation – any comments to the contrary from special interest nursing groups reflect their political goals to restrict CAA practice in the state.

CAAs are Key Members of the Anesthesia Care Team

ASA strongly believes in the Anesthesia Care Team (ACT) and supports CAA practice authorization in all states.[1] CAAs are highly trained non-physician anesthetists. They work under the medical direction of anesthesiologists to implement anesthesia care plans. CAAs work exclusively within the ACT environment as described by ASA. ACTs consist of a supervising anesthesiologist and from 1 to 4 non-physician anesthetists (i.e., CAAs and nurse anesthetists). All CAAs possess a pre-medical undergraduate background and complete a comprehensive didactic and clinical program at the graduate school level. They are trained extensively in the delivery and maintenance of quality anesthesia care as well as advanced patient monitoring techniques.

Education & Training

CAAs undergo rigorous and advanced graduate education focusing on the ACT approach to anesthesia practice. AA programs are 24 to 28 months in length and are frequently housed within university schools of medicine, similar to physician assistant programs. As a prerequisite for admissions, applicants must hold a bachelor's degree, complete the same pre-medical course work that physicians complete, and often score competitively in upper percentiles on the MCAT (Medical College Admission Test). AA degree programs are accredited by the Commission on Accreditation of Allied Health Educational Programs (CAAHEP), a national accrediting body certifying 2000 educational programs in 23 different allied health professions. AAs must pass a certification examination administered by the NCCAA (National Commission for Certification of Anesthesiologist Assistants) in collaboration with the National Board of Medical Examiners. Finally, they must complete 40 hours of continuing medical education every two years and complete a recertification exam every six years.

Conclusion

Given the extensive training and education CAAs complete, the proposed rule is appropriately drafted for their skill set and carefully aligns with Wash. Rev. Code Ann. § 18.71D.010-.070, the statute governing

[1] See ASA Standards, Guidelines and Statements: Statement on the Anesthesia Care Team available at https://www.asahq.org/standards-and-practice-parameters/statement-on-the-anesthesia-care-team

CAA practice in Washington. Any efforts to revise the proposed rules to limit or alter CAA scope of practice would be misguided and depart from the legislature's intent and recognition of these anesthesia professionals. I urge the Washington Medical Commission to adopt Chapter 246-921 WAC as proposed, to further clarify how CAAs will utilize their unique team-based skills in Washington and so your citizens can begin benefitting from the highly trained care CAAs already provide to patients in nearly half the United States. Thank you for your consideration. Should you have any questions, please feel free to contact Jason Hansen, JD, MS, Director of State Affairs, at j.hansen@asahq.org.

Sincerely,

Donald E. Arnold, MD, FACHE, FASA
President

Washington State Society of Anesthesiologists

April 16, 2025

Washington Medical Commission
P.O. Box 47866
Olympia, WA 98504-7866
ATTN: Amelia Boyd, Program Manager

RE: COMMENTS FOR WSR 25-08-028 – RULES IMPLEMENTING SB 5184 (ANESTHESIOLOGIST ASSISTANTS)

Ms. Boyd,

Thank you for the opportunity to comment on proposed regulations for the licensure of Certified Anesthesiologist Assistants (CAAs) in our state. On behalf of the members of the Washington State Society of Anesthesiologists, we urge the Commission to take swift action on these rules for licensure, so we can increase our health care workforce and expand access to trained, skilled and professional anesthesia care for patients.

The scope of practice outlined in RCW 18.71D provides a comprehensive and detailed framework for CAA licensure that is consistent with their education and training, and reflects the work they perform in the 22 other states where they currently practice. The proposed rules adhere closely to the legislation adopted by lawmakers earlier this year and we support their adoption.

This is a challenging time in health care. Hospital bed shortages have resulted in unprecedented wait times for patients who often need critical care. And operating rooms aren't functioning at full capacity because we don't have enough people to staff them. We hope the Commission will act expeditiously to implement these rules for CAA licensure, and that our members will be working alongside their CAA colleagues in 2025.

Thank you for your consideration.

Erik J. Condon, MD, FASA
WSSA President
Erik.Condon@providence.org
509-999-4587

Public Comment on Rulemaking for Anesthesiologist Assistants (AAs)
Submitted by: Washington Association of Nurse Anesthesiology (WANA)
Date: May 2, 2025

Dear Members of the Washington Medical Commission,

On behalf of the Washington Association of Nurse Anesthesiology (WANA), we appreciate the opportunity to provide formal comment on the proposed rules for the implementation of Anesthesiologist Assistants (AAs) in Washington State.

While WANA respects the legislative decision to introduce this new provider type, we submit these comments with **grave concern** over several aspects of the current rulemaking draft—particularly where the proposed rules appear to **contradict both federal law and state statute**, and where public input has not yet been fully integrated.

---

1. DEA Conflicts Regarding Ordering Privileges

The draft rule includes language that grants AAs authority to order medications, including controlled substances. However, this directly contradicts **federal law**, as AAs are not classified as independent providers and are **not eligible to obtain their own DEA registration numbers**. This discrepancy creates a significant legal risk for institutions, physicians, and supervising anesthesiologists who could be seen as violating DEA regulations by permitting such orders under their supervision.

WANA strongly urges the Commission to **remove or revise this language** to ensure alignment with DEA authority and avoid regulatory confusion. We have attached correspondence from the DEA that clarifies this limitation (Appendix A).

How does the Commission propose to change these rules to comply with Federal DEA regulations to ensure public safety?

---

2. Epidural and Neuraxial Block Placement Misrepresentation

The proposed rules also do not address the limitation on **placement** of epidural and regional blocks by AAs—despite negotiations and clear legislative action during the 2024 session that **specifically removed such authority**. The final statute authorizes AAs only to "**manage and maintain**" these procedures once they have been placed by a qualified provider. This distinction was debated and **intentionally revised during legislative negotiations** after serious concerns were raised about the limited and inconsistent training AAs receive in these high-risk techniques.

The lack of specificity and expansive scope discussion during rulemaking workshops regarding the rule language about the placement of epidurals in rule language directly **contradicts the statute and violates legislative intent**. WANA urges the Commission to respect the clear language and intent of the law by revising this section of the rules accordingly. We are including the striker amendment with its "effects" and communications from Chair Riccelli involved in the

negotiation process that affirm this intent (Appendix B).

Has the Commision verified or shown proof that AAs are taught these invasive procedures? WANA has done research on this matter: AA programs do not consistently cover these invasive and dangerous procedures (Appendix C).

---

3. Unaddressed Concerns and Accelerated Timeline

Throughout the public workshops and drafting process, numerous organizations—including WANA—voiced concerns about the clinical supervision model, training variability, and the potential for patient safety risks if implementation is not handled thoughtfully. While some discussion occurred, many of these issues remain **unresolved or insufficiently addressed** in the proposed rule language.

Additionally, the **accelerated rulemaking timeline** is alarming given that this is the first time AAs will practice in Washington. Introducing a new provider type into a complex and high-acuity field like anesthesia demands careful, thorough, and transparent policy development—not haste.

---

4. Conflict of Interest by the WMC Chair

The chair of the AA rulemaking workshops — **a physician anesthesiologist** — did not initially identify herself as such during the first public workshop. While she later disclosed her profession in subsequent meetings, she continued to exert outsized influence over the process, often directing the conversation and determining how items were discussed.

Given her dual role as both a voting commissioner and a physician anesthesiologist with an inherent professional stake in the introduction of AAs to Washington, she holds a clear conflict of interest. RCW 42.52, as well as the WMC's own Code of Ethics, make clear that commissioners should **recuse** themselves from rulemaking where impartiality may ***reasonably*** be questioned. This principle exists to ensure public trust and transparency — especially in decisions that shape the future of Washington's healthcare workforce.

We urge the WMC to reflect on this issue, evaluate whether the integrity of the process has been compromised, and consider formal mechanisms to avoid similar concerns in future rulemaking. Washingtonians deserve a fair, open, and impartial process when establishing the scope and role of new healthcare providers in our state. Why did the chair, who is a physician anesthesiologist, not recuse herself? Why did the chair state that the Commission would not be breaking DEA rules rather than taking an approach that is safer and consult with the DEA before completing rule-making?

Final Recommendations

WANA respectfully calls on the Washington Medical Commission to:

- **Revise rule language** to remove ordering privileges inconsistent with DEA regulations;
- **Clarify rule language to align with statutory authority** by clearly prohibiting epidural and regional block placement by AAs;
- **Address unresolved safety and training concerns** raised during the public workshops;
- **Reconsider the timeline** to allow for more complete stakeholder engagement and safer implementation.
- **Reengage in rulemaking workshops** (CR-101) to allow these proceedings to be led by individuals without clear professional or financial conflicts of interest.

Our association remains committed to ensuring that any new provider entering the Washington healthcare system does so in a way that supports safe, high-quality care and honors both the legal framework and public trust.

We appreciate your service and your attention to this vital matter. This information is being sent via email to ensure receipt of attachments.

Sincerely,
Washington Association of Nurse Anesthesiology (WANA)
Kelli Camp, DNP, CRNA, ARNP
WANA President

Appendix A

https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section822&num=0&edition=prelim

From: DPY <DPY@dea.gov>
Sent: Thursday, December 5, 2024 10:35:42 AM
To: Dee Bender <dbender@evergreenhealthmonroe.com>
Subject: RE: Regulation questions

Good morning, Ms. Bender,

This is in response to your email dated November18, 2024, to the Drug Enforcement Administration (DEA) Policy Section regarding administering controlled substances by a certified anesthesiologist assistants (CAAs). You asked for clarification if the delivery, ordering, dispensing, administration of controlled substances immediately to a patient in the OR after ordered by the AA (under the physician anesthesiologist name) is regulated in any way in order to monitor and control the administration and possible diversion of controlled substances if this type of practice is allowed. DEA appreciates the opportunity to address your inquiry.

As a general matter, it is DEA's longstanding policy not to provide legal advice to private parties. To comply with the Administrative Procedure Act and ensure fairness, DEA's interpretations of the law and regulations are published in the Federal Register and/or on DEA's website, which allows all members of the general public to have equal access to such information. At the same time, DEA recognizes the importance of working with regulated entities and members of the public to help guide them toward compliance with the law and regulations. DEA's response to your inquiry must be limited to directing your attention to the pertinent provisions of the law, regulations, or other publicly disseminated documents issued by DEA. In that vein, DEA can provide general information. Please be advised that this is not meant to be an exhaustive list of every statutory provision or regulation that might apply to your inquiry.

Congress passed the Controlled Substance Act as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970. Below is a list of definitions that you may find useful.

21 USC 802: Definitions

2) The term "administer" refers to the direct application of a controlled substance to the body of a patient or research subject by-
(A) a practitioner (or, in his presence, by his authorized agent), or
(B) the patient or research subject at the direction and in the presence of the practitioner, whether such
application be by injection, inhalation, ingestion, or any other means.

(3) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

Please note in the definition for administer the phrase "in his presence." The only reasonable way to interpret "in his presence" is that it means in the *physical* presence of the practitioner.

21 U.S.C. 822(a)(2) Persons required to register

(a) Period of registration
(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.
(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

As stated in 21 U.S.C. 822(a)(2) Anyone who prescribes, administers, or dispenses a controlled substance shall obtain a registration from DEA. As such, CAAs would need to obtain a DEA Registration before prescribing, administering, or dispensing controlled substances.

At the present time, certified anesthesiologist assistants (CAAs) are not listed as a Practitioner or as a Mid-Level Practitioner. Below is the link to the list of Mid-Level Practitioners that may or may not hold a DEA registration by every state.

MID LEVEL PRACTITIONERS - Controlled Substance Authority by Discipline within State. Also refer to Mid-Level Exemptions: https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf

To further inquire about registrations for CAAs, please reach out to the DEA Registration Section vit telephone at 1-800-882-9539 or via e-mail to DEA.Registration.Help@dea.gov

Thank you for your e-mail regarding this matter and the opportunity to address your questions. For information regarding the DEA Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have any additional questions on this issue, please contact the Diversion Control Division Policy Section at (571) 362-3260.

DEA Diversion Control Division, Policy Section
Main Number: (571) 362-3260
www.DEAdiversion.usdoj.gov

James N. Stevens, Staff Coordinator
DEA Diversion Control Division
Attn: Policy Section
8701 Morrissette Drive
Springfield, VA 22152
Office: 571-362-3260
Direct Line: (571) 362-7113
Cell: (615) 642-9631
e-mail: james.n.stevens@dea.gov

Appendix B

EFFECT: Requires the medically directing anesthesiologist to personally participate in the most demanding procedures of the anesthesia plan, including induction and emergence. Allows the responsibilities of supervision to be met through coordination among anesthesiologists of the same group or department.

Adds to the definition of an "anesthesiologist" that they must be an actively practicing, board-eligible physician.

Eliminates the issuance of a temporary license for persons who have completed an anesthesiologist assistant program, but not passed a certification examination.

Prohibits anesthesiologist assistants from exceeding the scope of the supervising anesthesiologist's practice. Removes an anesthesiologist assistant's authority to order oxygen therapy and respiratory therapy. Removes an anesthesiologist assistant's authority to obtain informed consent for anesthesia and related procedures. Allows anesthesiologist assistants to maintain and manage neuraxial epidurals, rather than assist with epidurals. Removes an anesthesiologist assistant's authority to establish central lines. Prohibits anesthesiologist assistants from prescribing, ordering, compounding, or dispensing drugs, medications, or devices.

Corrects references to physicians to apply to anesthesiologists. Updates statutes to reflect changes made in the previous legislative session.

Final striker_House Health (2).pdf

chrome-extension://hbgjioklmpbdmemlmbkfckopochbgjpl/https://app.leg.wa.gov/committeeschedules/Home/Document/272116#toolbar=0&navpanes=0

From: Riccelli, Rep. Marcus <Marcus.Riccelli@leg.wa.gov>
Subject: FW: 5184 AMH HCW BLAC 174.docx

Hello,

Attached is a striking amendment that Rep. Schmick and I will offer (effect statement below) that incorporates discussions that have occurred. Of note 7 of the requested changes by the CRNA's were accepted by the AA's. Additional clarification occurred around supervision and it was agreed to remove an AA's authority to establish central lines. We think that this reflects very significant compromise. Please reply all with any questions, comments or concerns.

Best,

Marcus

EFFECT: Requires the medically directing anesthesiologist to personally participating in induction and emergence. Allows the responsibilities of supervision to be met through coordination among anesthesiologists of the same group or department.

Adds to the definition of an "anesthesiologist" that they must be an actively practicing board-certified physician.

Eliminates the issuance of a temporary license for persons who have completed an anesthesiologist assistant program, but not passed a certification examination.

Prohibits anesthesiologist assistants from exceeding the scope of the supervising anesthesiologist's practice. Removes an anesthesiologist assistant's authority to order oxygen therapy and respiratory therapy. Removes an anesthesiologist assistant's authority to obtain informed consent for anesthesia and related procedures. Removes an anesthesiologist assistant's authority to establish central lines. Prohibits anesthesiologist assistants from prescribing, ordering, compounding, or dispensing drugs, medications, or devices.

Corrects references to physicians to apply to anesthesiologists.

Updates statutes to reflect changes made in the previous legislative session.

Rep. Marcus Riccelli (not verified) - *Oct 28, 2024 03:30 PM*

Reply

The AA bill was agreed upon in the legislature to: Not allow AAs to do central lines. Not allow AAs to do epidurals. That AAs need to be supervised during induction and emergence. That there will not be a temporary license for AAs. This agreement allowed the legislation to get enough votes to be signed into law. Introducing these concepts in rulemaking will likely create more legislation in the future and could mean changes to newly established rules in the near future.

Attached below are the educational requirements for AA students. Please note that epidural and intrathecal techniques are not listed as separate requirements unlike the requirements for nurse or physician anesthesiologists. They *may* be part of "Regional Techniques" (unknown) where only *Management/Administration* is the educational requirement – **NOT** *Insertion* or *Placement* like the other skills listed.

Methods of Anesthesia	
General Anesthesia	400
Induction, Maintenance & Emergence	
Mask Induction	35
Mask Management	30
Supraglottic Airway Device	35
Tracheal Intubation	255
Oral	250
Nasal	5
Total Intravenous Anesthesia	10
Emergence from Anesthesia	250
Regional Techniques	
Management/Administration	40
Monitored Anesthesia Care	30

Screenshot

Other Anesthetic Management	
Alternative Airway Management	
Fiberoptic Intubation, Light Wand, etc. (all airway techniques other than direct laryngoscopy and supraglottic airway device)	10
Arterial Technique	
Arterial Puncture/Catheter Insertion	25
Intra-arterial BP monitoring	30
Central Venous Pressure Catheter	
Placement	5
Monitoring	15
Other	
Intravenous Catheter Placement	125
Gastric Tube Placement	5
Placement of One Lung Isolation Device	5

Fox Rothschild

1001 Fourth Avenue, Suite 4400
Seattle, WA 98154
206.624.3600 206.389.1708
www.foxrothschild.com

JAMES E. BREITENBUCHER
Direct No: 206.389.1775
Email: jbreitenbucher@foxrothschild.com

May 2, 2025

Washington Medical Commission
111 Israel Rd. SE
Tumwater, WA 98501

Dear Washington Medical Commission,

Fox Rothschild LLP was retained by the Washington Association of Nurse Anesthesiology (WANA) to review the Washington Medical Commission's (WMC) rulemaking process concerning anesthesiologist assistants (AAs). As explained below, Fox Rothschild has identified troubling irregularities during the AA rulemaking process that cannot be dismissed as harmless mistakes. Rather, it appears that actions were taken for the specific purpose of altering the outcome of the rulemaking process in a way that placed the business interests of anesthesiologists over patient safety concerns. Accordingly, WANA demands that the WMC restart the process by issuing a new CR-101, by designating a Rulemaking Committee of unbiased commissioners that complies with the WMC's Code of Ethics, and by maintaining rulemaking records as required by law.

DR. DOMINO IS BIASED AND INELIGIBLE TO SERVE ON THE AA RULEMAKING COMMITTEE

Dr. Karen Domino is Chair of the WMC and an anesthesiologist. Despite her term expiring in June 2024, Dr. Domino interjected herself into the AA rulemaking process, took the lead on the AA Rulemaking Committee, used her status as an anesthesiologist to quell viewpoints that differed from hers, and then pursued policies to protect the business interests of her fellow anesthesiologists at the expense of patient safety. Recognizing that such conflicts may arise and that patient safety is paramount, the WMC has formally adopted a Code of Ethics that requires commissioners to "recuse themselves and proactively disclose when there is a real or potential conflict of interest, or the appearance of such a conflict" and that "the determination will err on the side of recusal."

At its January 10, 2025, meeting, the WMC formalized the recusal process that applies when a real, potential or apparent conflict of interest arises: "A Commissioner must abstain from any discussion or vote taken by the Commission involving an action (including contracting, rulemaking, or policy decisions) . . . with which the Commissioner may benefit or be harmed (financially, personally, or professionally) and if a Commissioner abstains from voting because of such involvement, such Commissioner shall announce for the record their reason for their abstention." This policy was adopted to comply with guidance provided by the Washington State Executive Ethics Board and the Federation of State Medical Boards. As the policy lays out, the WMC commissioners are bound by the Ethics in Public Service Act (RCW 42.52), which prevents self-dealing and requires recusal for conflicts of interest.

During her term as the WMC Chair, Dr. Domino nominated every motion at every previous WMC meeting. But at the January 10, 2025, meeting, Dr. Domino did not nominate the motion to adopt the Commissioner recusal procedure. Instead, Vice-Chair Dr. Murphy nominated the motion—even though Dr. Domino was listed as present. And unlike the vast majority of WMC business that is adopted unanimously—the motion to adopt the commissioner recusal procedure was adopted only by a majority vote. If this matter requires a lawsuit, discovery will reveal why Dr. Domino did not chair this singular WMC meeting and which WMC Commissioner voted against formalizing the recusal process for conflicts of interest.

The Supreme Court of Washington has similarly recognized that improper bias requires disqualification in an administrative law context, such as where an agency member has "an interest whereby one stands to gain or lose by a decision either way." *Faghih v. Washington State Dep't of Health, Dental Quality Assurance Comm'n*, 148 Wn. App. 836, 842, 202 P.3d 962 (2009). Even the appearance of unfairness is grounds for disqualification. *Id.* ("The test is whether a disinterested person, having been apprised of the totality of a board member's personal interest in a matter being acted upon, would be reasonably justified in thinking that partiality may exist.") (emphasis added) (quoting *City of Hoquiam v. Pub. Employment Relations Comm'n of State of Wash.*, 97 Wn.2d 481, 488, 646 P.2d 129 (1982)). "Participation in the decision making process by a person who is potentially interested or biased is the evil which the appearance of fairness doctrine seeks to prevent." *City of Hoquiam*, 97 Wn.2d at 488.

Under the WMC's own Code of Ethics, Dr. Domino was without question required to recuse herself from participating in the AA rulemaking process. Her occupation as an anesthesiologist, at a bare minimum, creates an appearance of a conflict of interest that requires her disqualification under the WMC Code of Ethics and under Washington administrative law principles. And as further discussed below, the limited records maintained by the WMC from the workshops confirm that Dr.

Domino summarily dismissed patient safety concerns from stakeholders like WANA, ignored warnings from internal WMC staff that her accelerated timeline was unrealistic and pursued policies that favored her and her fellow anesthesiologists. Dr. Domino's influence on the AA Rulemaking Committee was particularly large, because other commission members deferred to her as the WMC Chair *and* as an anesthesiologist.

DR. DOMINO LED THE AA RULEMAKING COMMITTEE IN A BIASED WAY

The proposed rule pushed through by Dr. Domino does not comply with Drug Enforcement Administration (DEA) standards for ordering prescriptions that were adopted to stop diversion of controlled substances. During the rulemaking workshops, WANA provided correspondence from James Stevens of the DEA Diversion Control Division advising that AAs would need to obtain DEA registrations under 21 U.S.C. § 822(a)(2) to order prescriptions, a registration AAs cannot obtain. The proposed rule modifies the federal definition of "order" to allow AAs to order prescriptions within a hospital—which conflicts with the permissible scope of practice for a non-registered person under federal law. Dr. Domino dismissed WANA's concerns that the proposed rule conflicts with federal law, specifically DEA regulations, because she felt it would place an undue burden on her and other anesthesiologists to be physically present and solely accountable for all ordering, prescribing, dispensing, and administration of controlled substances. She expressed concern that requiring physician anesthesiologists to be present when an AA orders medications would be impractical, despite clear federal requirements assigning that responsibility exclusively to licensed, DEA-registered practitioners. As is clear in 21 U.S.C. 822(a)(2), only a practitioner that is registered with DEA may prescribe, administer, or dispense a controlled substance. Once again, Dr. Domino prioritized the business interests of anesthesiologists instead of ensuring that the proposed rule prioritizes patient safety and complies with federal law.

The proposed rule pushed through by Dr. Domino also allows Dr. Domino and her fellow anesthesiologists to delegate medical procedures to AAs beyond the scope authorized by the Legislature. For example, Dr. Domino insisted during the rulemaking workshops that AAs would not be prevented from placing an epidural or regional block, even though RCW 18.71D(1)(n) specifically limits AAs to "maintaining and managing established neuraxial epidurals and regional anesthesia." Expanding the scope of AA practice beyond the statutory scope would be financially advantageous for anesthesiologists like Dr. Domino but jeopardizes patient safety by allowing AAs to perform tasks they are not appropriately trained to do. Dr. Domino's attempts to modify the statutory framework is just another example of Dr. Domino's willingness to steer the rulemaking to her own benefit at the expense of patient safety.

Instead of addressing these issues, Dr. Domino accelerated the timeline for AA rulemaking over warnings from WMC staff that Dr. Domino's timeline was unrealistic and that the staff could not properly incorporate public comment. For example, at the November 5, 2024, WMC rulemaking workshop, after Dr. Domino said that she was urging for the rulemaking to be done in early 2025 and that she is "committed to having this done" by late 2025, Amelia Boyd had to remind Dr. Domino that "we have to have workshops" and "we have to have interested party feedback." Amelia Boyd also advised Dr. Domino that a "non controversial rule takes about 18 months just to complete the first interested parties process. So the fact that we're hoping to get this done by the end of next year when we just filed this year. That's a pretty quick turn around." Shortly thereafter, Amelia Boyd and Dr. Domino asked WANA representatives if their comments had been addressed and WANA representatives said that they had not been appropriately addressed. With no further discussion, Amelia Boyd concluded "I think for the most part, we have addressed the comments that have been received" and that in the final workshop "we will not likely discuss any changes that we made at this workshop," and ended the meeting. This entire exchange lasted fewer than five minutes.

Dr. Domino of course had a powerful incentive to rush the AA rulemaking process as her time in the catbird seat was limited. Dr. Dominio's term as a commissioner had already expired in June 2024 and would end as soon as the Governor appointed her replacement. Not only was Dr. Domino required to recuse herself from the AA Rulemaking Committee, the available record confirms that Dr. Domino failed to prioritize patient safety while leading the AA Rulemaking Committee. To maintain public confidence, the WMC must restart the process from the beginning with unbiased Commissioners.

THE WMC SUPPRESSED DISSENTING VIEWPOINTS IN VIOLATION OF ITS RECORDKEEPING OBLIGATIONS

Under Washington law, agencies that engage in rulemaking are required to keep broad records. *See* RCW 34.05.370. The record requires "all written petitions, requests, submissions, and comments received by the agency." RCW 34.05.370(2)(c); *see also Nat'l Ass'n of Chain Drug Stores v. U.S. Dep't of Health & Human Servs.*, 631 F. Supp. 2d 23, *26 (D.D.C. 2009) ("The administrative record consists of all documents and materials gathered by an agency when creating or revising a rule. The 'whole record' has been interpreted to include documents and materials directly and indirectly considered by the agency."). Failure to keep complete records exposes rules to future judicial challenges. *See, e.g.*, *Ctr. for Biological Diversity v. Dep't of Fish & Wildlife*, 14 Wn. App. 2d 945, 964–66, 474 P.3d 1107 (2020).

Here, WMC has failed to keep adequate records of the public comments it solicited as part of the AA rulemaking process and has deleted stakeholder concerns about patient safety. For example, at the rulemaking workshops Dr. Domino and the WMC directed WANA and other stakeholders to provide comments in the video workshop chats. But when WANA requested records of the workshop chat from October 14, 2024, WANA learned that the WMC had deleted records of these public comments. Those video comments are part of the records that the WMC is required to keep and they included patient safety concerns raised by WANA and others relating to among other things, the extent of supervision of AAs by Dr. Domino and her fellow anesthesiologists. Given WMC's failure to appropriately keep records, it is impossible to assess the full scope of the WMC's adherence to administrative rulemaking requirements.

The WMC has also recently changed their website page for AA rulemaking to no longer display any CR-101 materials, including the rulemaking workshop presentations where WANA and other stakeholders provided their public comment. It is concerning that to access these records (to the extent they have not also been deleted) members of the public are forced to look at other parts of the website archives to find out details of the AA rulemaking process. Deleting public comments and then hiding away the comments that do exist are not a sign of fair rulemaking. The failure to appropriately keep records is especially concerning where the limited existing record demonstrates that the WMC ignored patient safety concerns to expedite rulemaking at the behest of a biased commissioner. Again, to maintain public confidence, the WMC must restart the process from the beginning with proper recordkeeping.

In conclusion, patients deserve better than a rushed rulemaking process with a biased commissioner. WANA demands that the WMC restart the rulemaking process with a new CR-101 led by one of the many disinterested WMC commissioners. The new rulemaking process should be a thorough, deliberative process with proper recordkeeping.

Respectfully submitted,

James Breitenbucher

James Breitenbucher of
FOX ROTHSCHILD LLP

cc: Kelli Camp
Dee Bender

Washington State Hospital Association

April 16, 2025

Amelia Boyd, Program Manager
Washington Medical Commission
Sent via email: Amelia.Boyd@wmc.wa.gov

RE: Anesthesiologist Assistants Rulemaking (WSR 25-08-028)

Dear Amelia,

On behalf of more than 100 member hospitals and health systems across Washington, the Washington State Hospital Association (WSHA) thanks you for the opportunity to comment on the rulemaking establishing licensing regulations for anesthesiologist assistants (AAs).

WSHA supports this rulemaking and supported the authorizing legislation that established AAs as a new health profession. AAs serve as part of an anesthesia care team under the direction and supervision of a licensed anesthesiologist. Adding AAs to the health care workforce in Washington will help address the anesthesia workforce shortage, expand access to care for patients, and strengthen our state's health care infrastructure.

Thank you for your consideration.

Sincerely,

Katerina LaMarche, JD
Policy Director, Government Affairs
Washington State Hospital Association

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Anesthesiologist Assistants.							
50 Comments	2508028Anesthesiologist AssistantCR102combined.pdf	The Washington Medical Commission (commission) is proposing a new chapter of rule, chapter 246-921 WAC, Anesthesiologist Assistants, to implement Senate Bill (SB) 5184 (chapter 362, Laws of 2024) codified under chapter 18.71D RCW, which created the new Anesthesiologist Assistant license. The commission is proposing this new chapter to establish licensing regulations for anesthesiologist assistants.	25-08-028	Daidria A Boyd	WMC - WASHINGTON MEDICAL COMMISSION	360-236-2727	05/02/2025
Oppose (17)	Commenter	Commenter Phone	Commenter Email		Commenter Address		
Oppose	Ananth Krishna Ferguson Thitte	[redacted]	[redacted]		[redacted]		

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date

Dear Washington Medical Commission,

My name is Ananth Thitte, and I am a Certified Registered Nurse Anesthetist working in Vancouver, Washington. Thank you for the opportunity to share comments on the rulemaking process for Anesthesiologist Assistants (AAs) in our state.
I urge the Commission to prioritize patient safety and adhere to the intent of the Legislature as expressed in the final version of the bill passed in 2024. It's important to remember that the language of the original bill underwent significant changes before passage—certain procedures and elements of scope were deliberately removed after extensive stakeholder input and legislative debate.
Those changes must be reflected in the rules being drafted now. Expanding the scope of AAs beyond what lawmakers agreed to would not only disregard that process but could also compromise the safety of patients and the integrity of Washington's healthcare system.
I respectfully ask the Commission to draft rules that stay true to the legislative intent, are transparent, and ensure strong oversight as we bring this new profession into the state.
Sincerely,
Ananth Krishna Ferguson Thitte
Camas, WA
RN, BSN, MSN, CRNA

Oppose	**Kristina Hintzsche**	[redacted]		[redacted]	[redacted]		

As an anesthesia provider in the state of Washington, I am contacting you in order to encourage the commission to spend more time on the AA rules. We must make sure AAs are capable
Of performing the riskier procedures that us regular anesthesia providers are routinely performing. Additionally I
Hope more time allows for alignment with legislative intent and federal law.

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Oppose	Greg Clopp	[redacted]	[redacted]				

As WA DOH creates the framework to implement AA legislation in the state it will be important to prevent abuses of the system. Codifying into state rules the current federal TEFRA regulations is paramount given the current state of our federal regulatory agencies and the federal push to 'return control to the states'.
At present the WA RCW 18.71.D via sections 030 and 040 is somewhat vague as the the limit of how many AAs an anesthesiologist can supervise. Studies have shown that an anesthesiologist attempting to supervise more than 4 providers at a time fails to meet the TEFRA definition of supervision. In addition to number of delegates it is important to establish response times for said supervisor to be available for consultation and that such consultation must always be in person. Without provisions on response time and presence the opportunity to 'supervise' remotely could arise and effectively allow independent practice.

In addition, as the law provides no guidance on how AAs must introduce themselves to a patient this should be stipulated in the DOH rules. Anyone involved in administering anesthesia should be introducing themselves with their name and true full title.

The original bill contained language that could be construed to mean an AA could work in WA for a period of time before obtaining a state license - it falls to the DOH to eliminate and confusion and explicitly require AAs to be licensed before they can work. This would be consistent with any other licensed person in the state of Washington.

Oppose	Kate Uselman	[redacted]	[redacted]				

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Dear Members of the Commission, As a practicing CRNA in Washington, I wanted to share my thoughts regarding the rulemaking process for Anesthesiologist Assistants. The AA bill that passed in 2024 looked very different from the bill that was first introduced. The final language was the result of deliberate and collaborative adjustments—most notably, the removal of certain procedures and adjusted scope of practice to account for differences in training and aligning with federal law. That version reflected compromise and a clear intent to protect patient safety. As you finalize the rules for AA practice, I ask that you remain true to that legislative intent. This is not about opposing a new profession—it's about making sure it's implemented in a way that is safe, clearly defined, and consistent with the guardrails our lawmakers established. Thank you for considering this perspective as you move forward in the rulemaking process. Sincerely, Kate Uselman, CRNA Kenmore WA							
Oppose	**Tania Derington**	[redacted]		[redacted]			

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Dear Members of the Commission, As a practicing CRNA in Washington, I wanted to share my thoughts regarding the rulemaking process for Anesthesiologist Assistants. The AA bill that passed in 2024 looked very different from the bill that was first introduced. The final language was the result of deliberate and collaborative adjustments—most notably, the removal of certain procedures and adjusted scope of practice to account for differences in training and aligning with federal law. That version reflected compromise and a clear intent to protect patient safety. As you finalize the rules for AA practice, I ask that you remain true to that legislative intent. This is not about opposing a new profession—it's about making sure it's implemented in a way that is safe, clearly defined, and consistent with the guardrails our lawmakers established. Thank you for considering this perspective as you move forward in the rulemaking process. Sincerely, Tania Derington, CRNA Camas, WA							
Oppose	**Braden Hemingway**	[redacted]	[redacted]		[redacted]		

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Dear Members of the Washington Medical Commission, My name is Braden Hemingway, DNAP, CRNA, ARNP. I am a Certified Registered Nurse Anesthetist and an educator in the field of nurse anesthesia. I appreciate the opportunity to offer comments regarding the rulemaking process for the licensure and regulation of Anesthesiologist Assistants (AAs) in the State of Washington. I respectfully urge the Commission to give due consideration to patient safety and to adhere closely to the legislative intent reflected in the final version of the bill enacted in 2024. It is important to note that the original version of the bill was significantly revised during the legislative process. Several procedures and scope-of-practice provisions were intentionally removed following robust stakeholder input and thorough legislative deliberation. The rules currently under development should accurately reflect these carefully negotiated changes. Any expansion of the scope of practice for AAs beyond what was expressly authorized by the Legislature would not only contravene the legislative process, but also risk compromising patient safety and the integrity of Washington's healthcare system. Accordingly, I respectfully request that the Commission adopt rules that are consistent with the expressed intent of the Legislature, ensure transparency, and provide for rigorous oversight as this new provider role is introduced into the state's healthcare framework. Thank you for your attention to this important matter. Sincerely, Braden Hemingway, DNAP, CRNA, ARNP							
Oppose	**Dana M. Brown, CRNA**	[redacted]		[redacted]	[redacted]		

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Dear Washington Medical Commission, My name is Dana Brown, and I am a Certified Registered Nurse Anesthesiologist. Thank you for the opportunity to share comments on the rulemaking process for Anesthesiologist Assistants (AAs) in our state. I URGE the Commission to prioritize patient safety and adhere to the intent of the Legislature as expressed in the final version of the bill passed in 2024. It's important to remember that the language of the original bill underwent significant changes before passage—certain procedures and elements of scope were deliberately removed after extensive stakeholder input and legislative debate. This is not okay. Those changes must be reflected in the rules being drafted now. Expanding the scope of AAs beyond what lawmakers agreed to would NOT only disregard that process,but could also compromise the safety of patients and the integrity of Washington's healthcare system. The training, background, and lack of experience of AAs without restrictive practice measures would severely compromise the safety of patient care. I personally would NEVER allow any friend/family member to be cared for by an AA. I respectfully ask the Commission to draft rules that stay true to the legislative intent, are transparent, and ensure strong oversight as we bring this new profession into the state (as unfortunate as it is that they were allowed to in the first place, such a disappointment!) Sincerely, Dana M. Brown, CRNA Spokane, WA							
Oppose		**Emily Matheson**	[redacted]				

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date

Dear Washington Medical Commission,

My name is Emily, and I am a CRNA. Thank you for the opportunity to share comments on the rulemaking process for Anesthesiologist Assistants (AAs) in our state.

I urge the Commission to prioritize patient safety and adhere to the intent of the Legislature as expressed in the final version of the bill passed in 2024. It's important to remember that the language of the original bill underwent significant changes before passage—certain procedures and elements of scope were deliberately removed after extensive stakeholder input and legislative debate. Those changes must be reflected in the rules being drafted now. Expanding the scope of AAs beyond what lawmakers agreed to would disregard that process.

I respectfully ask the Commission to draft rules that stay true to the legislative intent, are transparent, and ensure strong oversight as we bring this new profession into the state.

Sincerely,
Emily Matheson, ARNP, CRNA

Oppose	**Michael Mielniczek**	[redacted]		[redacted]	[redacted]		

Dear Washington Medical Commission,

My name is Michael Mielniczek, a Certified Registered Nurse Anesthetist (CRNA) practicing in Washington. I have provided anesthesia across a wide range of settings, including major hospitals, ambulatory surgery centers, and office-based practices. I previously served as Chief CRNA for one of the largest private anesthesia groups in the state, overseeing more than 19,000 anesthetic cases annually across multiple surgical sites. My experience spans general surgery, orthopedics, plastic surgery, and complex outpatient procedures, always with a strong focus on patient safety and evidence-based care. Thank you for the opportunity to comment on the rulemaking process for Anesthesiologist Assistants (AAs) in Washington.

As this new profession is introduced into our state, I urge the Commission to uphold the Legislature's clear intent when passing the final version of the bill in 2024. The legislation was carefully crafted after extensive stakeholder input and deliberate revision—several procedures and scope elements were removed explicitly to preserve patient safety and ensure appropriate oversight.

One critical area of concern is the supervision model. Under federal billing rules known as TEFRA (the Tax Equity and Fiscal Responsibility Act), a physician anesthesiologist is allowed to supervise up to four anesthesia cases at once—but only if they meet seven very specific and detailed requirements for each patient. These include being present for important parts of the procedure, checking in frequently, and being available for emergencies.

In practice, it has proven extremely difficult for one doctor to meet all of these supervision steps consistently, especially when overseeing multiple patients at the same time. A study reported by Excel Anesthesia found that even when a physician was supervising just two cases, they failed to meet all the required steps 37% of the time. These lapses aren't just administrative—they pose real risks to patient safety and can also result in violations of federal billing laws.

Introducing Anesthesiologist Assistants into Washington under this same supervision model raises serious concerns. If AAs are to be safely integrated, the rules must reflect the reality of how difficult it is to maintain proper supervision under the TEFRA structure. Without strong safeguards, we risk introducing a model that looks compliant on paper but fails to protect patients in practice.

I respectfully request that the Commission develop rules that are transparent, enforceable, and consistent with the Legislature's intent—prioritizing patient safety, protecting public trust, and maintaining Washington's commitment to high-quality anesthesia care.

Sincerely,
Michael Mielniczek, CRNA
Seattle, WA
(978) 413-2215

Oppose	**Mikhail Nekhamis**	[redacted]	[redacted]

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Dear Washington Medical Commission, My name is Mikhail Nekhamis and I am a Certified Registered Nurse Anesthetist. I've practiced anesthesiology as an independent provider and in anesthesia care team models for the last 15 years. Thank you for the opportunity to share comments on the rulemaking process for Anesthesiologist Assistants (AAs) in our state. I urge the Commission to prioritize patient safety and adhere to the intent of the Legislature as expressed in the final version of the bill passed in 2024. It's important to remember that the language of the original bill underwent significant changes before passage—certain procedures and elements of scope were deliberately removed after extensive stakeholder input and legislative debate. It is gravely concerning, that there may be efforts to change the scope of an AA that was agreed upon during the legislative process. Those changes must be reflected in the rules being drafted now. Expanding the scope of AAs beyond what lawmakers agreed to would not only disregard that process but could also compromise the safety of patients and the integrity of Washington's healthcare system. We simply cannot unleash the assistants, onto unsuspecting recipients of anesthesia care in our state, without very close supervision and a very narrow/limited scope beyond their "assistant" training. I respectfully ask the Commission to draft rules that stay true to the legislative intent, are transparent, and ensure strong oversight as we bring this new profession into the state. Sincerely, Mikhail Nekhamis Vancouver, WA							
Oppose	**Shane Henning**	[redacted]		[redacted]			

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Dear Washington Medical Commission, My name is Shane Henning and I am a Certified Registered Nurse Anesthesiologist working at Peace Health Hospital South West in Vancouver Washington. Thank you for the opportunity to share comments on the rulemaking process for Anesthesiologist Assistants (AAs) in our state. I urge the Commission to prioritize patient safety and adhere to the intent of the Legislature as expressed in the final version of the bill passed in 2024. It's important to remember that the language of the original bill underwent significant changes before passage—certain procedures and elements of scope were deliberately removed after extensive stakeholder input and legislative debate. Those changes must be reflected in the rules being drafted now. Expanding the scope of AAs beyond what lawmakers agreed to would not only disregard that process but could also compromise the safety of patients and the integrity of Washington's healthcare system. I respectfully ask the Commission to draft rules that stay true to the legislative intent, are transparent, and ensure strong oversight as we bring this new profession into the state. Sincerely, Shane C. Henning Vancouver, WA DNP, CRNA							
Oppose	**Stephanie Huang**	[redacted]	[redacted]				

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Dear Washington Medical Commission, My name is Stephanie Huang and I am a CRNA practicing in a medically directed practice model at UWMC. Thank you for the opportunity to share comments on the rulemaking process for Anesthesiologist Assistants (AAs) in our state. I urge the Commission to prioritize patient safety and adhere to the intent of the Legislature as expressed in the final version of the bill passed in 2024. It's important to remember that the language of the original bill underwent significant changes before passage—certain procedures and elements of scope were deliberately removed after extensive stakeholder input and legislative debate. Those changes must be reflected in the rules being drafted now. Expanding the scope of AAs beyond what lawmakers agreed to would not only disregard that process but could also compromise the safety of patients and the integrity of Washington's healthcare system. I respectfully ask the Commission to draft rules that stay true to the legislative intent, are transparent, and ensure strong oversight as we bring this new profession into the state. Sincerely, Stephanie Huang, DNP, CRNA Seattle, WA							
Oppose	**Thomas Nigro** [redacted]		[redacted]		[redacted]		

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date

Dear Washington Medical Commission,

My name is Thomas Nigro, Jr. and I am the Chief of Anesthesia for Advanced Anesthesia Services. Thank you for the opportunity to share comments on the rulemaking process for Anesthesiologist Assistants (AAs) in our state.

I request the Commission to prioritize patient safety and adhere to the intent of the Legislature as expressed in the final version of the bill passed in 2024. It's important to remember that the language of the original bill underwent significant changes before passage. Notably, the removal of certain procedures and adjusted scope of practice that was meant to account for differences in AA training, and aligning with federal law. The final version passed in 2024 reflected compromise and a clear intent to protect patient safety.

Expanding the scope of AAs beyond what lawmakers agreed to would not only disregard that process but could also compromise the safety of patients and the integrity of Washington's healthcare system.

I respectfully ask the Commission to draft rules that stay true to the legislative intent, are transparent, and ensure strong oversight as we bring this new profession into the state.

Sincerely,

Thomas Nigro, Jr. DNP, CRNA

Chief of Anesthesia

Advanced Anesthesia Services

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Oppose	James Breitenbucher	[redacted]	[redacted]		[redacted]		

Dear WMC Commissioners:

Fox Rothschild LLP was retained by the Washington Association of Nurse Anesthesiology (WANA) to review the Washington Medical Commission's (WMC) rulemaking process concerning anesthesiologist assistants (AAs). As explained below, Fox Rothschild has identified troubling irregularities during the AA rulemaking process that cannot be dismissed as harmless mistakes. Rather, it appears that actions were taken for the specific purpose of altering the outcome of the rulemaking process in a way that placed the business interests of anesthesiologists over patient safety concerns. Accordingly, WANA demands that the WMC restart the process by issuing a new CR-101, by designating a Rulemaking Committee of unbiased commissioners that complies with the WMC's Code of Ethics, and by maintaining rulemaking records as required by law.

DR. DOMINO IS BIASED AND INELIGIBLE TO SERVE ON THE AA RULEMAKING COMMITTEE

Dr. Karen Domino is Chair of the WMC and an anesthesiologist. Despite her term expiring in June 2024, Dr. Domino interjected herself into the AA rulemaking process, took the lead on the AA Rulemaking Committee, used her status as an anesthesiologist to quell viewpoints that differed from hers, and then pursued policies to protect the business interests of her fellow anesthesiologists at the expense of patient safety. Recognizing that such conflicts may arise and that patient safety is paramount, the WMC has formally adopted a Code of Ethics that requires commissioners to "recuse themselves and proactively disclose when there is a real or potential conflict of interest, or the appearance of such a conflict" and that "the determination will err on the side of recusal."

At its January 10, 2025, meeting, the WMC formalized the recusal process that applies when a real, potential or apparent conflict of interest arises: "A Commissioner must abstain from any discussion or vote taken by the Commission involving an action (including contracting, rulemaking, or policy decisions) . . . with which the Commissioner may benefit or be harmed (financially, personally, or professionally) and if a Commissioner abstains from voting because of such involvement, such Commissioner shall announce for the record their reason for their abstention." This policy was adopted to comply with guidance provided by the Washington State Executive Ethics Board and the Federation of State Medical Boards. As the policy lays out, the

WMC commissioners are bound by the Ethics in Public Service Act (RCW 42.52), which prevents self-dealing and requires recusal for conflicts of interest.

During her term as the WMC Chair, Dr. Domino nominated every motion at every previous WMC meeting. But at the January 10, 2025, meeting, Dr. Domino did not nominate the motion to adopt the Commissioner recusal procedure. Instead, Vice-Chair Dr. Murphy nominated the motion even though Dr. Domino was listed as present. And unlike the vast majority of WMC business that is adopted unanimously, the motion to adopt the commissioner recusal procedure was adopted only by a majority vote. If this matter requires a lawsuit, discovery will reveal why Dr. Domino did not chair this singular WMC meeting and which WMC Commissioner voted against formalizing the recusal process for conflicts of interest.

The Supreme Court of Washington has similarly recognized that improper bias requires disqualification in an administrative law context, such as where an agency member has “an interest whereby one stands to gain or lose by a decision either way.” Faghih v. Washington State Dep’t of Health, Dental Quality Assurance Comm’n, 148 Wn. App. 836, 842, 202 P.3d 962 (2009). Even the appearance of unfairness is grounds for disqualification. Id. (“The test is whether a disinterested person, having been apprised of the totality of a board member’s personal interest in a matter being acted upon, would be reasonably justified in thinking that partiality may exist.”) (emphasis added) (quoting City of Hoquiam v. Pub. Employment Relations Comm’n of State of Wash., 97 Wn.2d 481, 488, 646 P.2d 129 (1982)). “Participation in the decision making process by a person who is potentially interested or biased is the evil which the appearance of fairness doctrine seeks to prevent.” City of Hoquiam, 97 Wn.2d at 488.

Under the WMC’s own Code of Ethics, Dr. Domino was without question required to recuse herself from participating in the AA rulemaking process. Her occupation as an anesthesiologist, at a bare minimum, creates an appearance of a conflict of interest that requires her disqualification under the WMC Code of Ethics and under Washington administrative law principles. And as further discussed below, the limited records maintained by the WMC from the workshops confirm that Dr. Domino summarily dismissed patient safety concerns from stakeholders like WANA, ignored warnings from internal WMC staff that her accelerated timeline was unrealistic and pursued policies that favored her and her fellow anesthesiologists. Dr. Domino’s influence on the AA Rulemaking Committee was particularly large, because other commission members deferred to her as the WMC Chair and as an anesthesiologist.

DR. DOMINO LED THE AA RULEMAKING COMMITTEE IN A BIASED WAY

The proposed rule pushed through by Dr. Domino does not comply with Drug Enforcement Administration (DEA) standards for ordering prescriptions that were adopted to stop diversion of controlled substances. During the rulemaking workshops, WANA provided correspondence from James Stevens

of the DEA Diversion Control Division advising that AAs would need to obtain DEA registrations under 21 U.S.C. § 822(a)(2) to order prescriptions, a registration AAs cannot obtain. The proposed rule modifies the federal definition of "order" to allow AAs to order prescriptions within a hospital—which conflicts with the permissible scope of practice for a non-registered person under federal law. Dr. Domino dismissed WANA's concerns that the proposed rule conflicts with federal law, specifically DEA regulations, because she felt it would place an undue burden on her and other anesthesiologists to be physically present and solely accountable for all ordering, prescribing, dispensing, and administration of controlled substances. She expressed concern that requiring physician anesthesiologists to be present when an AA orders medications would be impractical, despite clear federal requirements assigning that responsibility exclusively to licensed, DEA-registered practitioners. As is clear in 21 U.S.C. 822(a)(2), only a practitioner that is registered with DEA may prescribe, administer, or dispense a controlled substance. Once again, Dr. Domino prioritized the business interests of anesthesiologists instead of ensuring that the proposed rule prioritizes patient safety and complies with federal law.

The proposed rule pushed through by Dr. Domino also allows Dr. Domino and her fellow anesthesiologists to delegate medical procedures to AAs beyond the scope authorized by the Legislature. For example, Dr. Domino insisted during the rulemaking workshops that AAs would not be prevented from placing an epidural or regional block, even though RCW 18.71D(1)(n) specifically limits AAs to "maintaining and managing established neuraxial epidurals and regional anesthesia." Expanding the scope of AA practice beyond the statutory scope would be financially advantageous for anesthesiologists like Dr. Domino but jeopardizes patient safety by allowing AAs to perform tasks they are not appropriately trained to do. Dr. Domino's attempts to modify the statutory framework is just another example of Dr. Domino's willingness to steer the rulemaking to her own benefit at the expense of patient safety.

Instead of addressing these issues, Dr. Domino accelerated the timeline for AA rulemaking over warnings from WMC staff that Dr. Domino's timeline was unrealistic and that the staff could not properly incorporate public comment. For example, at the November 5, 2024, WMC rulemaking workshop, after Dr. Domino said that she was urging for the rulemaking to be done in early 2025 and that she is "committed to having this done" by late 2025, Amelia Boyd had to remind Dr. Domino that "we have to have workshops" and "we have to have interested party feedback." Amelia Boyd also advised Dr. Domino that a "non controversial rule takes about 18 months just to complete the first interested parties process. So the fact that we're hoping to get this done by the end of next year when we just filed this year. That's a pretty quick turn around." Shortly thereafter, Amelia Boyd and Dr. Domino asked WANA representatives if their comments had been addressed and WANA representatives said that they had not been appropriately addressed. With no further discussion, Amelia Boyd concluded "I think for the most part, we have addressed the comments that have been received" and that in the final workshop "we will not likely discuss any changes that we made at this workshop," and ended the meeting. This entire exchange lasted fewer than five minutes.

Dr. Domino of course had a powerful incentive to rush the AA rulemaking process as her time in the catbird seat was limited. Dr. Dominio's term as a commissioner had already expired in June 2024 and would end as soon as the Governor appointed her replacement. Not only was Dr. Domino required to recuse herself from the AA Rulemaking Committee, the available record confirms that Dr. Domino failed to prioritize patient safety while leading the AA Rulemaking Committee. To maintain public confidence, the WMC must restart the process from the beginning with unbiased Commissioners.

THE WMC SUPPRESSED DISSENTING VIEWPOINTS IN VIOLATION OF ITS RECORDKEEPING OBLIGATIONS

Under Washington law, agencies that engage in rulemaking are required to keep broad records. See RCW 34.05.370. The record requires "all written petitions, requests, submissions, and comments received by the agency." RCW 34.05.370(2)(c); see also Nat'l Ass'n of Chain Drug Stores v. U.S. Dep't of Health & Human Servs., 631 F. Supp. 2d 23, *26 (D.D.C. 2009) ("The administrative record consists of all documents and materials gathered by an agency when creating or revising a rule. The 'whole record' has been interpreted to include documents and materials directly and indirectly considered by the agency."). Failure to keep complete records exposes rules to future judicial challenges. See, e.g., Ctr. for Biological Diversity v. Dep't of Fish & Wildlife, 14 Wn. App. 2d 945, 964–66, 474 P.3d 1107 (2020).

Here, WMC has failed to keep adequate records of the public comments it solicited as part of the AA rulemaking process and has deleted stakeholder concerns about patient safety. For example, at the rulemaking workshops Dr. Domino and the WMC directed WANA and other stakeholders to provide comments in the video workshop chats. But when WANA requested records of the workshop chat from October 14, 2024, WANA learned that the WMC had deleted records of these public comments. Those video comments are part of the records that the WMC is required to keep and they included patient safety concerns raised by WANA and others relating to among other things, the extent of supervision of AAs by Dr. Domino and her fellow anesthesiologists. Given WMC's failure to appropriately keep records, it is impossible to assess the full scope of the WMC's adherence to administrative rulemaking requirements.

The WMC has also recently changed their website page for AA rulemaking to no longer display any CR-101 materials, including the rulemaking workshop presentations where WANA and other stakeholders provided their public comment. It is concerning that to access these records (to the extent they have not also been deleted) members of the public are forced to look at other parts of the website archives to find out details of the AA rulemaking process. Deleting public comments and then hiding away the comments that do exist are not a sign of fair rulemaking. The failure to appropriately keep records is especially concerning where the limited existing record demonstrates that the WMC ignored patient safety concerns to expedite rulemaking at the behest of a biased commissioner. Again, to maintain public confidence, the WMC must restart the process from the beginning with proper recordkeeping.

In conclusion, patients deserve better than a rushed rulemaking process with a biased commissioner. WANA demands that the WMC restart the rulemaking process with a new CR-101 led by one of the many disinterested WMC commissioners. The new rulemaking process should be a thorough, unbiased, deliberative process with proper recordkeeping.

Respectfully submitted,
James Breitenbucher of
FOX ROTHSCHILD LLP

Oppose	**Washington Association of Nurse Anesthesiology**	[redacted]	[redacted]	[redacted]

The Washington Association of Nurse Anesthesiology has submitted comments and attachments via email to Ms. Boyd @ amelia.boyd@wmc.wa.gov

Oppose	**Kelli Camp**	[redacted]	[redacted]	[redacted]

To the Washington Medical Commission,

I am writing to express serious personal concerns regarding the current rulemaking process for Anesthesiologist Assistants (AAs) in Washington State.

First, I urge the Commission to proceed with far greater caution and transparency. The rulemaking for a NON-controversial subject typically takes 18 months. The current rulemaking path of the WMC has been extremely accelerated. The introduction of a new provider type—especially in the high-risk space of anesthesia—requires thorough, unbiased review and a commitment to public safety above all else. The rapid pace of the current rulemaking process raises concerns that critical issues are not being fully addressed.

One significant concern is the allowance of medication ordering privileges for AAs. This appears to be in direct conflict with federal DEA requirements and raises substantial legal and regulatory questions that should be clarified with the DEA before rules are finalized. In addition, the rules are not clear

surrounding the ability of AAs to perform procedures such as epidural and neuraxial blocks. This, too, is contrary to the clear legislative intent in the final statute, which plainly limits their role only to managing and maintaining existing epidurals—not placing them.

Further, I must raise concerns about the integrity of the rulemaking process itself. The chair of the rulemaking workshops is a physician anesthesiologist who did not disclose her specialty role during the first public workshop and has since continued to heavily guide the conversation. As an appointed commissioner with a direct professional stake in the outcome, she should have recused herself in accordance with both RCW provisions related to conflict of interest and the WMC's own stated policy on commissioner conduct. Her continued leadership undermines the impartiality this process demands.

For the safety of Washington patients and the integrity of the rulemaking process, I strongly urge the Commission to:

Revisit and revise the proposed rules to align with legislative intent and federal regulatory limits;

Seek additional legal and clinical input on ordering authority and procedural limitations;

Pause or extend the rulemaking timeline to allow for meaningful stakeholder input;

Ensure adherence to ethical standards regarding conflicts of interest by those in leadership roles.

Washingtonians deserve a healthcare system built on patient safety, sound regulation, and transparent governance. Thank you for your attention to this important matter.

Sincerely,
Kelli Camp, DNP, CRNA, ARNP; Othello, WA

Oppose	**Madeline Hamlin-Rifai**	[redacted]	[redacted]

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
To the Washington Medical Commission, I'm writing as a CRNA who works at the University of Washington, and I appreciate the chance to weigh in on the rulemaking process for Anesthesiologist Assistants (AAs) in Washington. During the 2024 legislative session, the AA bill was substantially amended before being passed. The version that became law was the result of many hours of discussion and negotiation—especially in the House—where legislators responded to concerns by removing specific procedures and limiting the scope of practice. These decisions were intentional and should guide the rules now being developed. It's essential that the final rules do not permit AA practice beyond what lawmakers clearly intended. Doing so would not only go against the spirit of the law but could have serious consequences for patient care and provider oversight. Please adopt rules that reflect those changes and ensure that the introduction of this new profession in Washington maintains our high standard of patient safety. Thank you, Madeline Hamlin-Rifai Seattle, WA CRNA, DNP							

Support (33)	Commenter	Commenter Phone	Commenter Email	Commenter Address
	Trent Garcia	[redacted]	[redacted]	[redacted]

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
• The health care workforce shortage is a serious issue that directly affects patient care. • Implementing these rules will strengthen our health care workforce and enhance patient access to services in Washington. • CAAs have safely collaborated with anesthesiologists for more than 50 years in 22 other states. • These proposed rules will establish a licensing pathway for CAAs that prioritizes patient safety while increasing access to care. • The rules are consistent with the legislation passed by the Legislature and honor its intended purpose. • We urge the swift adoption of these rules so that CAAs residing in Washington can begin providing patient care.							
		Jason Bluth [redacted]		[redacted]	[redacted]		
		Jeremy Hansen, MD [redacted]		[redacted]	[redacted]		
		Charlie Chase [redacted]		[redacted]	[redacted]		

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Dear Members of the WMC, My name is Charlie Chase, I am an Anaesthesiologist Assistant at St. Louis university hospital in St. Louis Missouri. We are an acute level 1 inner city trauma centre with regular high acuity cases. I attended University of Missouri Kansas City School of medicine to obtain my Master of Science in Anaesthesia and I have been practising since 2022. Prior to beginning this journey in 2018 I was aware that we C-AAs could not yet obtain licensure in the state of Washington, it has been my desire and goal from the outset to change this. My mom's side of the family have always lived in Snohomish County, (Grandma, uncles, aunts, cousins, and many friends) mostly Mukilteo and Monroe. From the 1st time I started visiting when I was young, I knew that Washington was where I wanted to live my life. I am so grateful that we are on the edge of making that a reality. I practise in the anaesthesia care team model and enjoy the good rapport with my physicians by having both the ability to treat my patients how I see fit, while also having an extra set of skilled hands to call on, should the patient need extra care. The ACT in all circumstances is shown to be the safest model of anaesthetic care for patients in any setting. The ACT allows anaesthesiologists to delegate tasks effectively and ensures a collaborative approach to care of patients. Many eyes on one patient's care is better than one. As a C-AA in training, I was taught at a school of medicine by the same professors who taught the medical students and directed by a physician anaesthesiologist who reinforced the rigour and standards of our professional training. Having read the proposed rules for C-AAs in Washington, I find they are consistent with the scopes of practise found in other sates and provide adequate flexibility for the providers and the attending anaesthesiologist. I'd like to extend personal thanks to the medical commission for your support of our profession in this ongoing endeavour Warmest regards, Charlie Chase, C-AA Secretary and Treasurer of WAAAA				**Katherine Nguyen**	[redacted]	[redacted]	[redacted]

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Dear Members of the Commission, My name is Katherine Nguyen, and I look forward to beginning my anesthesiologist assistant program at Case Western Reserve University this May in Austin, Texas. I chose this career path because I have confidence in the ability of certified anesthesiologist assistants (CAAs) to provide safe and effective care within the anesthesia care team model. The inclusion of CAAs expands the physician-led anesthesia care team model, which strengthens collaboration, allows for delegation of tasks, and invites multiple minds to contribute to treatment decisions. Furthermore, CAA employment will help to alleviate the anesthesia provider shortage, facilitating access and streamlining care. I selected my training program knowing that it will allow me to become a competent anesthesiologist assistant, as the focused didactic curriculum and extensive clinical experiences are standardized across accredited schools to ensure that graduates are ready to be safe and qualified providers. Prior to starting my schooling, I lived in Kirkland, Washington for two years and grew captivated by the beauty and liveliness of the Pacific Northwest. I am so thrilled by the prospect of being able to return after graduation to provide anesthesia care there. All over the state, the communities that I have met have welcomed me warmly, and I would like to be able to contribute towards their health and wellbeing. I fully support the Department of Health's proposed rules for CAA licensure and wish to sincerely thank the Washington Medical Commission for their consideration.							
	Christine Kohlsaat	[redacted]		[redacted]	[redacted]		

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Dear Members of the Commission, My name is Christine Kohlsaat and I am a CAA from Miami, FL. I work at Memorial Hospital West and have been practicing since 2015 in the Anesthesia Care Team (ACT) model, under the direct supervision of an anesthesiologist. My family is from the Tacoma area (dad- Federal Way, brother- Lakewood) and I am hoping to move back to the West coast once CAAs are licensed in Washington. I am in support of the Department of Health's proposed rules for licensing CAAs. Incorporating CAA's into the ACT promotes a collaborative approach, allowing anesthesiologists to delegate tasks effectively and focus on critical aspects of patient care, thereby improving overall efficiency and patient outcomes. CAA's undergo rigorous, standardized education and training programs accredited by recognized bodies, ensuring a consistent level of competence and patient safety across the profession. The proposed rules establish clear guidelines for licensure, scope of practice, and supervision, ensuring that AA's practice safely under the oversight of the Washington Medical Commission. I wanted to thank you, the Medical Commission, for your time and for your support of my profession. Sincerely, Christine Kohlsaat, CAA							
	Jacob Trapp [redacted]			[redacted]			

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date

Dear Members of the Commission,

My name is Jacob Trapp, CAA, currently practicing in St. Louis, Missouri. I graduated from South University – West Palm Beach in 2024 and have been practicing since January.

Although my education took me far from the West Coast, I am excited at the prospect of returning to practice in the great state of Washington. I have spent many summers and winters visiting family in Poulsbo, Wenatchee, and Seattle. During a thru-hike of the Pacific Crest Trail, I fell in love with Washington's diverse and breathtaking landscape, and since then, I have dreamed of making it my home.
Currently, I work at Mercy Hospital in St. Louis as part of an anesthesia care team (ACT) model under the direct supervision of anesthesiologists. In my experience, the inclusion of Certified Anesthesiologist Assistants (CAAs) within the ACT model enhances patient care by allowing anesthesiologists to focus on critical tasks such as ICU transfers, central line placements, and code management.

I am writing in support of the proposed rules for licensing CAAs in Washington. These rules are consistent with standards in other states and offer the appropriate level of flexibility for supervising anesthesiologists to ensure the safe and effective practice of CAAs. During my clinical training, I had the opportunity to work in seven different states, and it is clear to me that the well-defined guidelines proposed for the implementation of SB5184 will support the full scope of CAA practice while maintaining high standards for patient safety.

In addition to strengthening clinical practice, the integration of CAAs into Washington's healthcare system will help address the growing shortage of anesthesia providers. This will improve access to timely, essential surgical and procedural care for residents across the state.
Thank you for your consideration and for your commitment to advancing safe, high-quality anesthesia care in Washington.

Sincerely,
Jacob Trapp, CAA

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
	Julianna Duncan	[redacted]	[redacted]		[redacted]		

Dear Members of the Commission,

My name is Julianna Duncan, and I am an incoming first year SAA beginning training in the Anesthesia Care Team model at Case Western Reserve University in Cleveland, Ohio. After graduating with my bachelor's degree, I moved from Ohio to Washington to begin my career and fell in love with everything the state has to offer. While I have recently moved back to Ohio to begin AA school, I was excited by the possibility of one day returning to Washington to provide anesthesia care after the passing of SB 5184 and am in support of the Department of Health's proposed rules for licensing CAAs.

As members of the Anesthesia Care Team, the addition of CAAs in the operating room creates a collaborative environment that gives anesthesiologists the flexibility to delegate tasks while focusing on other critical aspects of patient care. This model improves efficiency, maintains positive patient outcomes, and contributes to a reduction in the anesthesia provider shortage. As I have observed firsthand while shadowing in Ohio operating rooms, the rigorous education and training that CAAs undergo makes them an asset to the Anesthesia Care Team. Additionally, the proposed rules and scope of practice of CAAs in Washington are in alignment with those of other states where CAAs are licensed.

Thank you for your diligence in reviewing the Department of Health's proposed rules for licensing CAAs and for taking the time to read this statement.

	Kayla Kerr	[redacted]	[redacted]		[redacted]		

Dear Members of the Commission,

My name is Kayla Kerr and I am a graduating AA student at Case Western Reserve University in Houston, TX. I am writing to state that I am in support of the Department of Health's proposed rules for licensing CAAs.

Before starting my CAA training, I lived in Seattle for two years after graduating from university. I initially worked for UW in Eastlake doing specimen processing for COVID-19 samples during the pandemic. After that, I worked as a neuroscientist at UW Montlake for about a year. One night, I happened to discover the CAA program and immediately knew that was what I wanted to do with my life. However, the one thing that made me have to stop and reevaluate was the fact that I would not be able to return to Washington to work. Having to make that choice was honestly one of the hardest decisions ever, since I felt welcome in Seattle. I really did not want to leave my friends and the community that I became a part of behind. Hearing that SB 5184 passed in Washington has inspired me to do whatever I can to return to the first place that truly felt like home.

I have rotated at over 10 different hospitals in Houston. This includes Memorial Hermann TMC, a level 1 trauma center that is one of, if not the biggest, medical complexes worldwide. Being at this hospital, one can experience managing a wide array of some of the sickest patients in our nation. This hospital and many of the other top hospitals in Texas have implemented and utilized the anesthesia care team (ACT) model. The ACT model allows for anesthesiologists and CAAs to work together to create the best possible care for our patients. This model also allows anesthesiologists to delegate tasks to multiple teams, thereby improving overall efficiency and patient outcomes. It has been proven to work and more hospitals in Texas are starting to realize this and have followed suit by opening their doors to this model as well. At the end of the day, we just want to take care of people during their most vulnerable time and moving forward with the implementation of SB5184 will allow this to become a reality.

In addition, many CAAs, like myself, were on the pre-med track with plans to go to medical school until finding out about the CAA profession. To be competitive for medical school, undergrad students are expected to take a strict course load and most apply for jobs in research and/or in the medical field while in school to help them stand out. In fact, many CAAS were previously emergency medical technicians, nurses, flight medics, or trauma nurses. After entering AA school, students undergo rigorous, standardized education ensuring a consistent level of competency and patient safety across the profession.

Today there is a massive shortage of anesthesia providers nationwide and we are an untapped market that can be used to help alleviate the load. CAAs being licensed practitioners will only help to ensure everyone in Washington can receive excellent and timely anesthesia care. Thank you all for your time.

Kristina Krepinski [redacted] [redacted]

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Dear Members of the Commission, My name is Kristina Krepinski, and I am a Certified Anesthesiologist Assistant (CAA) currently working in Aurora, Colorado. My spouse has recently started a job in Seattle. I have stayed behind in Colorado until CAA licensure is established and career opportunities become available in Washington. I am eager to officially move to Washington and be among the first CAAs to provide anesthesia care once we are licensed. I am commenting to voice my support of the rules proposed by the Department of Health. These rules will establish definitive guidelines for CAA licensure in the state of Washington, paving the way for safe CAA practice under the oversight of the Washington Medical Commission. The scope of practice outlined in these rules parallel what is already implemented in other states with well established CAA licensure. The proposed rules additionally provide appropriate flexibility for supervising physician anesthesiologists, allowing for a collaborative approach to patient care. At the University of Colorado Hospital, my current place of work, the Anesthesia Care Team (ACT) model is integral to our practice. I work under the direct supervision of an anesthesiologist, allowing them to effectively delegate tasks and focus on the critical aspects of patient care. Incorporating CAAs into this care team model improves overall efficiency and patient outcomes. Thank you for your time and consideration of these rules. Best, Kristina Krepinski Certified Anesthesiologist Assistant and Clinical Instructor University of Colorado Anschutz Medical Campus							
	Theresa Bakare	[redacted]		[redacted]	[redacted]		

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date

Dear Members of the Commission,
My name is Theresa Bakare and I'm a Student Anesthesiologist Assistant (SAA) about to graduate from the Master of Science in Anesthesia (MSA) program at Case Western Reserve University. My family and I have lived in Washington for the last 9 years. I only moved out of state for my education and training, but my goal has always been to return home and practice in the state I know and love.
During my clinical rotations, I've trained in the Anesthesia Care Team (ACT) model under the direct supervision of anesthesiologists to provide safe and effective care. I'm writing to share my strong support for the Department of Health's proposed rules to license Certified Anesthesiologist Assistants (CAAs) in Washington.
Allowing CAAs to practice in Washington will help ease the growing shortage of anesthesia providers and ensure patients across the state have access to timely, high-quality care. Our training is rigorous and nationally standardized, and I feel confident and well-prepared to step into this role as part of a collaborative team.
Thank you for taking the time to consider these rules. I truly hope the Medical Commission adopts them so that I, and others like me, can come home and serve the people of Washington.

Nicole Boerema [redacted] [redacted] [redacted]

Dear Members of the Commission,

My name is Nicole Boerema. I'm a certified anesthesiologist assistant (cAA). I currently living in Austin, but am actively preparing to move to the Pacific Northwest this coming October with my partner, who has accepted a job in the Portland region. I am hoping to work in Vancouver WA once cAAs are licensed and look forward to to building a life in the area with my partner and our family in the region. I received my anesthesia training at the University of Colorado, worked at UCHealth, and currently work for a private practice in Texas. I have been practicing a little over 7 years now. I enjoy working within the Anesthesia Care Team model under the direct supervision of an anesthesiologist and would like to express my support for the Department of Health's proposed rules for licensing CAAs.

I highly value my work and training as a CAA and look forward to building a positive reputation among medical providers and patients alike in

Washington. It is a great time to be in anesthesia, a specialty required now more than ever. There is a shortage in anesthesia providers nation wide and this trend will likely continue with aging patient populations requiring surgery and the current healthcare provider population beginning to retire. Licensing cAAs will help mitigate the shortage of providers in Washington and ensure patient's receive timely access to care and anesthesia services. The ACT model helps facilitate these needs via a collaborative approach. This is a safe and effective model which allows anesthesiologists to appropriately delegate care while being present for critical moments in the deliverance of anesthesia, while also trusting capable providers like cAAs to provide quality, competent, and compassionate care. The ACT model has proven to be extremely effective and also improves care efficiency without sacrificing patient outcomes. In fact, outcomes are improved in the care team model. In my training, I've worked alongside all types of anesthesia providers in all stages of training and I look forward to having the opportunity to continue to build those relationships in Washington. I appreciate teaching students and being involved in a profession of lifelong learning.

CAA's undergo rigorous training and standardized education, with prerequisites being almost identical to those applying to medical school. I applied and was accepted to medical school with the same pre-requisites and MCAT scores as applying to cAA school, but decided this profession was a better fit for me personally. Im proud to be a part of its growth and recognition. We are accredited by recognized bodies and undergo routine recertification to ensure our education and skill levels are up to date and meet high standards.

The cAA scope of practice aligns well with Washington State Law requirements and proposed rules for ensuring AAs practice safely under the oversight of the Washington Medical Commission.

Thank you for your time and I look forward to answering any questions you may have.

Ryan Barata [redacted] [redacted] [redacted]

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Dear Members of the Commission, my name is Ryan Barata, and I am an SAA with the Case Western Reserve University program in Houston, Texas. My family and I have lived in Spokane for over a decade. I am looking for the opportunity to return to my home state, and my loved ones, once AA's receive licensure. I currently train under the Anesthesia Care Team (ACT) model across multiple nationally recognized hospitals within the Texas Medical Center, including Memorial Hermann, MD Anderson, and Baylor St. Luke's. I am consistently challenged by innovative medical procedures, and some of the highest acuity patient populations in the United States. All AA's undergo rigorous clinical and educational training from accredited programs. This ensures that a consistent level of competence and patient safety is met across the profession. There is a clear need for additional anesthesia providers throughout the state of Washington. We have proven to be a safe and effective solution to help combat this provider shortage in several states for over 40 years. I support the Department of Health's proposed rules for licensing CAAs as a means to provide Washingtonians with timely access to quality anesthesia care. I thank you for your time and look forward to your decision.							
Sarah Brown [redacted]							
Dear Members of the Washington Medical Commission, I am writing on behalf of the Certified Anesthesiologist Assistant (CAA) community to express our strong and urgent support for the rules implementing Senate Bill 5184, licensing Anesthesiologist Assistants in Washington State. This legislation represents an important step forward in improving patient access to care in Washington State. Many trained CAAs are already living in Washington or are prepared to move here, growing as the profession gains recognition in the state. Additionally, with hundreds of students expected to graduate from CAA programs across the country in the next two years, Washington has a unique opportunity to attract these highly trained anesthesia professionals. Adoption of these rules is a key to addressing the state's growing anesthesia workforce needs. The rules, as drafted, strike the right balance between safety, supervision, and flexibility. They closely align with how CAAs work with their supervising anesthesiologists in hospitals and clinics across the country. When it comes to the scope of practice for CAAs, the rules align with the language of SB 5184, which was noted in a letter from the bill's sponsors, Senators Rivers and Cleveland, during the stakeholder process on November 1, 2024: Sec 4 (1) very clearly states that "An anesthesiologist assistant may not exceed the scope							

of their supervising anesthesiologist's practice and may assist with those duties and responsibilities delegated to them by the supervising anesthesiologist, and for which they are competent to assist with based on their education, training and experience." This gives the supervising anesthesiologist the ability in the law to determine the duties for the Anesthesiologist Assistant based on the needs of their practice.

Sec 4 (1) also states, "Duties which an anesthesiologist may delegate to an anesthesiologist assistant include but are not limited to:" and then lists the explicit authorized duties. However, the "include but are not limited to" language in this bill, combined with the first sentence clearly states that the supervising anesthesiologist is the ultimate arbiter of the delegation of duties. The language of the law clearly indicates that the statute itself is not a limiting document.

In addition, in Sec 4 (1) (w) the law states within the explicit delegation of duties "Assisting with other tasks not prohibited by law under the supervision of a licensed anesthesiologist that an anesthesiologist assistant has been trained and is proficient to assist with." Once again, this is clearly ensuring the only duties that are prohibited are those specifically prohibited within the statute.

The rules also ensure proper identification when CAAs are working with patients and accurately clarify CAA authority for ordering prescription drugs when working with their supervising anesthesiologist.

We urge adoption of these rules and look forward to including CAAs in Washington State's quality health care workforce.

Sincerely,
Sarah Brown, CAA, Washington AAA President

Shane Angus [redacted] [redacted] [redacted]

Dear Members of the Washington Medical Commission,

I write in support of WSR 25-08-028, which implements the provisions of SB 5184 concerning the licensure and regulation of Certified Anesthesiologist Assistants (CAAs) in Washington State.

I am a CAA and serve in national leadership roles supporting the growth, accreditation, and educational quality of anesthesiologist assistant programs. This work has deepened my understanding of how CAAs strengthen patient-centered care, particularly in underserved areas. I also have close family living in Spokane, Bellingham, and Seattle, and I care deeply about the quality and accessibility of care across the state.

CAAs are trained in nationally accredited, graduate-level programs focused specifically on anesthesia care. Their education is standardized, professionally consistent, and tightly aligned with patient safety. Today, there are 23 accredited CAA programs in the United States. Graduates must also pass a national certification exam and maintain ongoing professional development to remain in practice.

The proposed rules align with SB 5184, which clearly states that a CAA may perform duties delegated by a supervising anesthesiologist for which the CAA is trained and competent. The law uses the phrase “include but are not limited to,” indicating appropriate flexibility for physician delegation within safe clinical boundaries. The rules mirror this legislative intent accurately and responsibly.

In short, the proposed rules:

Reflect SB 5184 as approved by the Washington Legislature and signed by the Governor.

Preserve and protect patient safety by adhering to proven models of care.

Expand access to anesthesia services while maintaining physician oversight.

Strengthen Washington’s workforce at a critical time.

I respectfully urge the Commission to adopt the rules as drafted without delay. Washington patients deserve timely, safe, and collaborative anesthesia care, and CAAs are prepared to help meet that need.

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
	Tom Breazeal	[redacted]		[redacted]	[redacted]		

Dear Washington Medical Commission,

I am writing to state that I am in support of the Department of Health's proposed rules for licensing CAAs to practice in your beautiful state. I lived in Coeur d'Alene for 25 years before moving to Houston so I could start my training as a CAA. Before heading back to school, I worked in Spokane Valley for 7 years at the former Pearle Vision off Sullivan. The owner sold the practice a few years ago but it still remains an eye clinic. Growing up, I would attend football camp at EWU in Cheney each year before the season started. I visited eastern Washington a lot, Seattle multiple times, and have been to the amazing little gem of Leavenworth a handful of times! Each time I fly back home, I fly into Spokane. The area has been a big part of my life and will continue to be especially since my family is still in Idaho. This is the main reason for my email. Job prospects when my training is finished and having spots near home would be amazing.

I've rotated at 11 different hospitals in the large state of Texas. These have included the Texas Heart Institute and the Texas Medical Center. Texas Heart see's some of the sickest hearts in the country and it was a great experience. The Texas Medical Center is the largest medical complex in the world. Being a level 1 hospital, you can see everything there. You have to take care of extremely sick patients and the learning experiences are robust. With the acuity of care being so critical and high, you think they'd have the best anesthesia model for patient outcomes. TMC (Texas Medical Center) uses the ACT model (anesthesia care team). The ACT consists of attending anesthesiologists and CAAs. I've also been to much smaller hospitals during my rotations and they utilize the exact same model.

Thank you for your time and consideration.

Grace and peace,

Thomas R. Breazeal

Second-year SAA, Houston

Master of Science in Anesthesia Program

Case Western Reserve University

case.edu/medicine/msa-program

Timothy W. Clement [redacted]

Hi, Writing to support the rules as written as they balance patient safety and CAA scope. As a stakeholder that worked on the legislative process, I can attest that the rules align with the bill passed by the Legislature and reflect its intent. CAAs have a proven record of safety. They have worked safely with anesthesiologists for over 50 years in 22 other states. The health care workforce shortage is real and impacts patient care. My group needs 5 additional anesthesia providers. Adopting these rules will help expand our workforce and improve access to care in Washington. Time is of the essence with many patients waiting on anesthesia services. Please adopt these rules quickly so CAAs living in Washington can begin caring for patients here.

Michelle Marie Tully [redacted]

I am a board certified anesthesiologist practicing in Spokane, WA. I support the licensure of Certified Anesthesiologist Assistants in WA state. CAAs practice in the Anesthesia Care Team model under the medical direction of an anesthesiologist. Licensure of CAAs will expand access to care while protecting patient safety because they work in a care team model. CAAs have worked safely with anesthesiologists for over 50 years in 22 other states. Please adopt these rules quickly so CAAs living in Washington can begin caring for patients here.

Jennifer Meyer [redacted]

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
I am an anesthesiologist serving in Olympia, WA. We are in a severe shortage of anesthesia providers. It has been very difficult to recruit both doctors and nurse anesthetists to our practice. Thus requiring the hospital pay exorbitant fees for locum tenens providers (travellers) to keep our operating rooms open. By adopting Anesthesiology Assistants we can improve our residents' access to care and decrease the overall cost. This is a necessary evolution of anesthesia care. Thank you.							
		Stephan Thilen [redacted]		[redacted]	[redacted]		
I am writing regarding the proposed rules which will allow Certified Anesthesiologist Assistants to become licensed in WA. I now practice as an anesthesiologist in Seattle. Prior to moving to Washington state, I worked with Anesthesiologist Assistants in both West Virginia and Wisconsin and found them to be excellent. CAAs are highly trained and can safely perform a wide range of anesthesia-related tasks under the medical direction of an anesthesiologist. In fact, I have found their competency 100% equivalent to that of nurse anesthetists (often referred to as CRNAs, Certified Registered Nurse Anesthetists). We have a shortage of anesthesia providers in Washington, however, we also have CAAs living in Washington. It is therefore a time sensitive issue to finalize the rules so that these CAAs can start working here. Respectfully, Stephan Thilen, MD, MS Associate Professor, UW							
		Paul Aaron [redacted]		[redacted]	[redacted]		

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
I had the opportunity to work closely with Anesthesiologist Assistants (AAs) during my residency, and I can confidently say they are highly skilled, competent, and valuable members of the anesthesia care team. Their training, clinical knowledge, and dedication to patient safety make them more than capable of providing safe and effective anesthetic care under the direction of an Anesthesiologist. AAs play a crucial role in expanding access to high-quality anesthesia services, and I fully support their integration into anesthesia care models nationwide. Anesthesiologist in Spokane Washington							
	Paul Aaron [redacted]		[redacted]		[redacted]		
I had the opportunity to work closely with Anesthesiologist Assistants (AAs) during my residency, and I can confidently say they are highly skilled, competent, and valuable members of the anesthesia care team. Their training, clinical knowledge, and dedication to patient safety make them more than capable of providing safe and effective anesthetic care under the direction of an Anesthesiologist. AAs play a crucial role in expanding access to high-quality anesthesia services, and I fully support their integration into anesthesia care models nationwide.							
	David Hepburn [redacted]		[redacted]		[redacted]		
I recommend support of any legislation that pushes for expanded anesthesia care utilizing AAs in a team care model, with supervision of anesthesiologists.							
	Joseph Strunk		[redacted]				
I strongly support the adoption of proposed rules to license Certified Anesthesiologist Assistants (CAAs) in Washington. These rules align with the intent of the legislation passed by the Legislature and ensure CAAs are licensed in a way that protects patient safety while expanding access to high-quality anesthesia care. CAAs are highly trained, master's-level professionals who work under the direct supervision of anesthesiologists as part of the proven anesthesia care team model. They have provided safe, effective care for over 50 years in 22 other states. With Washington facing a growing healthcare workforce shortage—particularly in rural and underserved areas—licensing CAAs offers a practical solution to improve access, reduce delays, and strengthen care delivery. Please act quickly so qualified CAAs already living in our state can begin caring for patients and contributing to our healthcare system.							

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
	Stephanie Davis, MD	[redacted]	[redacted]		[redacted]		
I support the proposed rules and urges the Commission to adopt them without delay. These proposed rules will allow CAAs to become licensed in a way that protects patient safety while expanding access to care. The rules align with the bill passed by the Legislature and reflect its intent. CAAs have worked safely with anesthesiologists for over 50 years in 22 other states. The health care workforce shortage is real and impacts patient care. Adopting these rules will help expand our workforce and improve access to care in Washington. Please adopt these rules quickly so CAAs living in Washington can begin caring for patients here.							
	Corey Tingey	[redacted]	[redacted]		[redacted]		
I'm an Anesthesiologist who has experience working with CAAs in another state and I have no concerns about transitioning our practice into including them in our patient care. The shortage of anesthesia providers is very real and impacts patient care and adopting these rules quickly will help expand our workforce and improve access to patient care.							
	Eric Ehieli	[redacted]	[redacted]		[redacted]		
In our current climate there is a demand for access to care in the anesthesia community. The proposed rules would allow CAAs to become licensed in a way that allows patients more access to care. CAAs have worked well with anesthesiologists in 22 other states for many years, and it has been proven to be a safe and effective model of anesthesiology care. The proposed rules will allow CAAs to become licensed and would allow another safe team to deliver anesthesia care across the state. Please adopt these rules so that we can have the CAAs currently living in Washington state begin to care for patients here.							
	Nicole Moore	[redacted]	[redacted]		[redacted]		

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date

Members of the Commission,

My name is Nicole Moore, I am the current President of the American Academy of Anesthesiologist Assistants and I am a CAA of 8 years currently practicing in Washington, DC at Sibley Memorial Hospital within the Anesthesia Care Model under the supervision of an anesthesiologist. Although I currently practice in DC, I would love the opportunity to one day practice in Washington as my sister and the majority of my extended family reside in the Seattle area. I am writing in support of the rules as written and proposed for licensing CAAs in Washington state. Licensing AAs in Washington will help mitigate the current shortage of anesthesia providers in the state and ensure patients have timely access to safe anesthesia care. The scope of practice defined in the rules and the law align with the scope of practice for AA's in other states while also providing appropriate flexibility for the supervising physician anesthesiologist. The proposed rules establish clear guidelines for licensure, scope of practice, and supervision, ensuring that AA's practice safely under the oversight of the Washington Medical Commission. I once again would like to voice my support for the rules proposed by the Department of Health for licensing AAs and thank the Medical Commission for their time and work on this important endeavor.

Dee Bender [redacted] [redacted]

Please add these additional comments that were sent to Amelia.Boyd @wmc.wa.govto the comment packet provided on behalf of WANA and forward to all commissioners.

Thanks,
Dee Bender, DNAP, CRNA, MNNA, ARNP
Vice President WANA

David Reeder MD [redacted] [redacted] [redacted]

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Recommend approval							
	Nicholas R Simmons, MD	[redacted]	[redacted]		[redacted]		
The goal is having an Anesthesiologist Assistant practice in the same manner that a CRNA practices within a Medically Directed Anesthesia Care Team mode. These rules seem to meet that goal. I have personally worked for years with both anesthesiologist assistants and CRNAs within an anesthesia care team model. In fact, i was present during the introduction of anesthesiologist assistants (AA) to practice in Missouri. My personal experience is that, under direct supervision by an anesthesiologist, AAs provide safe and effective anesthesia within the care team, and expand access to all patients and much needed relief to overworked anesthesia team members. In fact, on a day to day basis, I often had to remind myself which mid-level anesthesia providers were CRNAs and which were AAs.							
	B Stephen Lee, MD	[redacted]	[redacted]				
The health care workforce shortage is real and impacts patient care. Anesthesiology care is especially impacted in the recent years and in the near and long term future. Adopting these rules will help expand our anesthesiology workforce and improve access to anesthesia care in Washington. These proposed rules will allow Certified Anesthesiologist Assistants to become licensed in a way that protects patient safety while expanding access to this care. The rules align with the bill passed by the Legislature and reflect its intent. Please adopt these rules quickly so Certified Anesthesiologist Assistants living in Washington can begin caring for patients here. Many thanks.							
	Michael Karbowski, MD PhD	[redacted]	[redacted]		[redacted]		

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
This will expand the ability for anesthesiologists to supervise anesthesia assistants in a safe, less expensive manner .Other states have allowed this with great success.The only group opposing this is nurse anesthtists (CNRA'S), who are always pushing to practice independently which I think is not a safe alternative. I say this as a physician who practiced 40 years in a team approach with nurse anesthetists at Group Health in Washiungton.The nurses praciced under our direct supervision and that team model worked. And it became obvious in the breadth of training required to safely provide anesthesia. Clearly the rigourous training of an MD provides far more experience and knowledge regarding the overall health of a patient and what it takes to engineer an approprite anesthetic. Nurse anesthetists have pushed for independence, which i view as a disaster, where as nurse assistants have always ageered to pracxtice only directly under a physicians (anesthesiologist's) guidance. Nurse Anesthetists (CNRA's) have always pushed for independent practice and equal pay, despite years less training than a physician Anesthesiologist. While I've worked with very talented CRNAs, their shorter training and lack of experince in cardiology, emergency medicine , pediatrics, obstetrics, and internal medicine that all physician anesthesiologists get, makes CNRA's far less equipped to handle the patient with multiple heath problems. Anesthesia Assisstants, on the other ther hand, recognize their shortcomings and always work under anesthesiologist supervision.They are also less expensive than CRNA'S.						
0 Comments	**SAAnesthsiologistAssistants.pdf**	**Significant Analysis**	**25-08-028**	**Daidria A Boyd**	**WMC - WASHINGTON MEDICAL COMMISSION**	**360-236-2727**	**05/02/2025**

Business Meeting Minutes
March 14, 2025

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Virtual Meeting via Teams Webinar
Link to recording: https://youtu.be/sks7tMUYwnk

Commission Members

Michael Bailey, Public Member – Absent
Christine Blake, Public Member
Toni Borlas, Public Member – Absent
Daniel Cabrera, MD – Absent
Po-Shen Chang, MD
Jimmy Chung, MD – Absent
Diana Currie, MD (V)
Karen Domino, MD, Chair (V)
Arlene Dorrough, PA-C – Absent
Anjali D'Souza, MD (V)
Harlan Gallinger, MD – Absent
April Jaeger, MD (V)
Jamie Koop, Public Member – Absent
Ed Lopez, PA-C, Officer-at-Large
Sarah Lyle, MD
Terry Murphy, MD, Vice Chair
Elisha Mvundura, MD – Absent
Robert Pullen, Public Member – Absent
Scott Rodgers, JD, Public Member
Claire Trescott, MD (V)
Richard Wohns, MD – Absent

WMC Staff in Attendance

Taylor Bacharach-Nixon, Management Analyst (V)
Colleen Balatbat, Staff Attorney (V)
Jennifer Batey, Legal Support Staff Manager
Anjali Bhatt, Bus. Practices & Productivity Manager
Amelia Boyd, Program Manager
Carolynn Bradley, Mgmt Analyst/Contract Manager
Kayla Bryson, Executive Assistant
Jimi Bush, Director of Quality & Engagement
Adam Calica, Chief Investigator
Emily Cason, Licensing Specialist (V)
Carmen Challender, Health Services Consultant (V)
Sarah Chenvert, Performance Manager (V)
Marisa Courtney, Licensing Manager
Joel DeFazio, Staff Attorney (V)
Anthony Elders, Compliance Officer (V)
Gina Fino, Director of Compliance
Michael Farrell, Supervising Staff Attorney
Ryan Furbush, Paralegal
Rick Glein, Director of Legal Services (V)
Kayla Gregory, Healthcare Investigator (V)
Mike Hively, Director of Operations & Informatics
Jenelle Houser, Investigator
Ken Imes, Information Liaison
Kyle Karinen, Executive Director
Shelley Kilmer-Ready, Legal Assistant (V)
Sara Kirschenman, Staff Attorney (V)
Christopher Knight, Management Analyst (V)
Mike Kramer, Compliance Officer (V)
Lisa Krynicki, Staff Attorney (V)
Emma Marienthal, Licensing Lead (V)
Stephanie Mason, Public Information Officer & Legislative Liaison
Micah Matthews, Deputy Executive Director
Lynne Miller, Paralegal
Freda Pace, Director of Investigations
Stormie Redden, Legal Assistant
Kim Shiner, Forms & Records Analyst (V)
Chris Waterman, Complaint Intake Manager
Trisha Wolf, Staff Attorney (V)
Mahi Zeru, Equity & Social Justice Manager (V)

Others in Attendance

Marlon Basco-Rodillas, Dept. of Health (DOH)
Heather Carter, Assistant Attorney General (AAG)
Kristin Brewer, AAG
Billie Dickinson, Washington State Medical Association (WSMA) (V)
Hal Goldberg, Pro Tem Commissioner

PO Box 47866 | Olympia, Washington 98504-7866 | Medical.Commission@wmc.wa.gov | **WMC.wa.gov**

Others in Attendance continued

Maria Higginbotham
Cyndi Hoenhous, Co-Chair, Washington Patients In Intractable Pain
Hillary Norris, WSMA (V)
Gabriel S. (V)

(V) indicates the participant attended virtually

1.0 Call to Order

Terry Murphy, MD, Vice Chair, called the meeting of the Washington Medical Commission (WMC) to order at 9:36 a.m. on March 14, 2025.

2.0 Public Comment

Cindy Hoenhaus, Co-Chair of WashPIP, provided comments for patients struggling with opioid prescribing rules. She warned that current policies allow non-medical interference, leading to strict dose limits that harm those with intractable pain. She urged the WMC to clarify its stance, focusing on patient outcomes rather than rigid dosage rules. She stated that WashPIP supports clear language to prevent undertreatment and unnecessary tapering, ensuring doctors base treatment on documentation and overall patient well-being, not just dosage numbers.

3.0 Chair Report

Dr. Karen Domino, Chair, stated she was away attending the Federation of State Medical Boards workshop regarding the United States Medical Licensing Examination (USMLE). She went on to say she would provide a full report on the workshop at the next business meeting.

4.0 Consent Agenda

The Consent Agenda contained the following items for approval:

4.1 Agenda for March 14, 2025
4.2 Minutes from the January 10, 2025, Business Meeting

Motion: The Vice Chair entertained a motion to approve the consent agenda. The motion was seconded and approved unanimously.

5.0 New Business

5.1 Nominating Committee

Dr. April Jaeger, Committee member, stated the Nominating Committee recommends these candidates for the following positions:

- Chair – Terry Murphy, MD
- Vice Chair – Ed Lopez, PA-C
- Officer-at-Large – Elisha Mvundura, MD

Kyle Karinen, Executive Director, stated that the leadership election will be held during the Business Meeting on May 9, 2025. Commissioners interested in serving in leadership who are not among the three nominees are encouraged to put themselves forward at the meeting.

PO Box 47866 | Olympia, Washington 98504-7866 | Medical.Commission@wmc.wa.gov | **WMC.wa.gov**

5.2 Outstanding Performance Awards

Kyle Karinen, Executive Director, presented the awards as follows:

- Administrative Staff – Ken Imes, Information Liaison
- Investigative Staff – Meghan King, Complaint Intake Coordinator
- Legal Staff – Lisa Krynicki, Staff Attorney

5.3 Petition for Declaratory Order

Mr. Karinen presented the petition for declaratory order from Dr. David Penner regarding licensure requirements for independent medical examiners. He then asked Heather Carter, AAG, to provide additional information.

Ms. Carter explained that Under state law, when an agency receives a petition like this, it has 15 days to notify interested parties and 30 days to take one of three actions:

1. issue an order;
2. decline to issue an order; or
3. schedule proceedings for a later date.

She recommended WMC staff notify the interested parties and the petitioner within the 15-day window. Then, at the next business meeting on May 9, 2025, the Commission can discuss the petition, take public comment, and decide whether to issue an order or not. Since the law allows up to 90 days to take further action, the May meeting falls well within that timeframe.

This specific petition asks whether the Commission requires individuals performing IMEs (Independent Medical Examinations) in Washington to be licensed in Washington. Since this issue comes up periodically, it would be worth reviewing. Additional legal guidance can be prepared before the next meeting to assist with the discussion.

6.0 Old Business

6.1 Committee/Workgroup Reports

These reports were provided in writing and included in the meeting packet. There were no additional reports provided.

6.2 Rulemaking Activities

The rulemaking progress report was provided in the meeting packet. In addition to the written report, Amelia Boyd, Program Manager, made the following request:

6.2.1 Initiate a CR-102, Proposed Rulemaking, which is the next step in the rulemaking process for establishing the use of nitrous oxide in office-based surgery settings.

During the meeting, Ms. Boyd stated that the hearing was tentatively scheduled for May 9th; however, the correct tentative date is August 22, 2025.

Motion: The Vice Chair called for a motion to authorize the filing of a CR-102 to initiate the next step in the rulemaking process. The motion was seconded and passed unanimously.

6.3 Commissioner Code of Conduct

Mr. Karinen presented the document for review and discussion as part of its scheduled

PO Box 47866 | Olympia, Washington 98504-7866 | Medical.Commission@wmc.wa.gov | **WMC.wa.gov**

three-year review. He noted a minor wording change but otherwise recommended reaffirming the document with that revision.

Motion: The Vice Chair called for a motion to reaffirm the document with the noted amendment. The motion was seconded and passed unanimously.

6.4 Research Unit – Upcoming Projects

Jimi Bush, Director of Quality and Engagement, invited Commissioners to assist in the content creation and editing of two FSMB conference posters on practitioner support and healthcare discrimination.

7.0 Policy Committee Report

Christine Blake, Public Member, Policy Committee Chair, reported on the items discussed at the Policy Committee meeting held on February 27, 2025.

7.1 **Policy: Complaints Against Students, Residents, and Fellows**

Ms. Blake stated that the Committee recommended postponing consideration of this policy to a future meeting to allow for further revisions. Micah Matthews, Deputy Executive Director, noted that the document included in the packet had been updated per the Committee's request. Mr. Matthews then provided a summary of those amendments.

Motion: The Committee Chair entertained a motion to adopt this document with the noted amendments. The motion was seconded and approved unanimously.

7.2 **Guidance Document: Sexual Misconduct and Abuse (GUI2017-03)**

Ms. Blake stated that the Committee recommended approving the document with the noted amendments. Mr. Matthews provided a summary of the amendments.

Motion: The Committee Chair entertained a motion to adopt this document with the noted amendments. The motion was seconded and approved unanimously.

7.3 **Policy: Elective Educational Rotations (POL2020-01)**

Ms. Blake stated that this document was reviewed as part of its scheduled four-year review process. The Committee recommended approving the document for DOH Secretary review with the noted amendments and title change.

Motion: The Committee Chair entertained a motion to approve this document for DOH Secretary review with the noted amendments. The motion was seconded and approved unanimously.

7.4 **Interpretive Statement: Opioid Prescribing & Monitoring for Allopathic Physicians and Physician Assistants**

Ms. Blake stated that this document was reviewed and revised due to the recent changes in the WMC's opioid prescribing rules as well as a public request. The Committee recommended approving the document for DOH Secretary review with the noted amendments.

Motion: The Committee Chair entertained a motion to approve this document for DOH Secretary review with the noted amendments. The motion was seconded and approved unanimously.

7.5 **Interpretive Statement: Opioid Prescribing & Monitoring for Patients**
Ms. Blake stated that this document was reviewed and revised due to the recent changes in the WMC's opioid prescribing rules as well as a public request. The Committee recommended approving the document for DOH Secretary review with the noted amendments.

Motion: The Committee Chair entertained a motion to approve this document for DOH Secretary review with the noted amendments. The motion was seconded and approved unanimously.

9.0 Member Reports

Dr. Domino reported that the FSMB invited Commissioners to attend a workshop regarding USMLE exams. She reported that so far, the presentation has focused on how the USMLE exams are developed, rather than clarifying what they want from Commissioners. It seems they may be looking for board members to help write questions or contribute to exam development, especially for Step 3, which now includes computerized clinical scenarios. Over 400 people are involved in USMLE development, and board members do participate in various roles.

10.0 Staff Reports

The reports below are in addition to the written reports that were included in the meeting packet.

Mr. Karinen noted that the FSMB Annual Meeting is scheduled to take place in Seattle this April, with several staff members and Commissioners planning to attend. As part of the event, Dr. Domino will deliver the welcome remarks.

Mr. Matthews provided an update on legislative and budget matters. House Bill 1640, which updates the Uniform Disciplinary Act by adding compact provisions, has passed the House and is scheduled for a Senate Health Care Committee hearing next week, where Taylor Nixon will testify. Senate Bill 5118, which updates the International Medical Graduate Clinical Experience License, passed the Senate the week of March 3 and had a hearing on March 14, receiving no opposition and positive feedback. On the budget front, efforts are ongoing to ensure requested funds are included in the House and Senate budgets. While some requests were included in the Governor's proposal, none appeared in the revised Governor Ferguson budget, though this seems to be a broad cut across healthcare rather than a reflection of need. The next economic forecast, expected on March 18, is likely to indicate a worsening financial outlook, with House and Senate budget proposals following the next week, which will likely spark political disagreements due to the significant deficit. Key legislative deadlines include April 2 for policy bills to pass out of committee and April 16 for bills to clear their opposite chamber unless tied to the budget. The legislative session is set to conclude on April 27, but given the large deficit, a special session is expected rather than an on-time budget agreement.

PO Box 47866 | Olympia, Washington 98504-7866 | Medical.Commission@wmc.wa.gov | **WMC.wa.gov**

Ms. Boyd highlighted the correspondence section in the packet, which is included for informational purposes. The correspondence doesn't always relate to ongoing matters but is typically from the public wanting to share information with the Commission. Instead of sending individual emails, these messages are compiled in the business meeting packet for reference.

11.0 AAG Report

Ms. Carter reminded Commissioners of open public meeting rules when attending events like FSMB. They should refrain from discussing Commission business and keep conversations informal, avoiding official matters.

12.0 Adjournment

The Chair called the meeting adjourned at 10:28 am.

Submitted by

(signature on file)

Amelia Boyd, Program Manager

(signature on file)

Terry Murphy, MD, Chair Elect
Washington Medical Commission

Approved May 9, 2025

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

BEFORE THE WASHINGTON STATE DEPARTMENT OF HEALTH

In the matter of the petition of

David Penner MD

for a declaratory order

PETITION

1. Petitioner's Information

David Penner MD

1801 West Bay Drive NW, STE 104

Olympia, WA 98502

(360) 539-1736

davep@olympiatms.com

2. Rules or Statutes in Question

The petitioner requests a declaratory order regarding the applicability of the following rules and statutes:

RCW 18.71.011

RCW 18.71B

RCW 18.71.030

RCW 18.130.190

WAC 296-23-317 - 1(b)

RCW 18.122.030

WAC 182-501-0300

RCW 18.134.030 - 050

RCW 18.71.021

WAC 296-23-302

WAC 296-23-359

Washington Superior Court Civil Rule (CR) 35

3. Statement of Facts

The petitioner presents the following facts relevant to this request:

3.1. The practice of medicine defined by the state of Washington (RCW 18.71.011) requires appropriate professional in-state licensure (RCW 18.71.021, RCW 18.122.030, RCW 18.71B.) Clarification of exemptions to the practice of medicine is defined for certain situations, for example, commissioned medical officers serving in the armed forces, or an out-of-state physician consulting with an in-state physician with the in-state physician retaining primary care of the patient located in Washington state (RCW 18.71.030.)

3.2. With advancements in technology and telemedicine (WAC 182-501-0300), particularly in response to the COVID-19 pandemic, requirements for in-state licensure for telemedicine services provided to residents within the state of Washington appear to have been clarified (RCW 18.134.030-050.)

3.3. An Independent Medical Examination is defined by the Department of Labor and Industries (WAC 296-23-302) as "An objective medical-legal examination requested (by the department or self-insurer) to establish medical findings, opinions, and conclusions about a worker's physical condition." Particularly relevant and common in the field of psychiatry is the allowance for these examinations to be performed over telemedicine (WAC 296-23-359.)

3.4. A psychiatric Independent Medical Examination includes a review of relevant medical records, a clinical interview with a claimant or patient, conclusions on diagnosis, and may opine on recommendations for treatment or use instruments and measures intended to assist in assessing and diagnosing mental illness (psychological testing.)

3.5. While the requirement for in-state medical licensure for Independent Medical Examiners evaluators contracted with the Department of Labor and Industries is made clear (WAC 296-23-317), it is unclear as to the general applicability to all independent

medical examinations (i.e., expert witness evaluations and reports for the purposes of civil litigation or Civil Rule (CR) 35 examinations.)

3.6. The necessity for in-state licensure for Independent Medical Examinations provided over telemedicine appears implied as RCW 18.71.011 defines the practice of medicine as including *"(1) Offers or undertakes to diagnose, cure, advise, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality."* Independent Medical and Psychiatric Examinations contain portions of this definition, particularly diagnosing and advising on physical and mental health ailments by any means (a clinical interview) and instruments (psychological testing.)

3.7. Attempting to clarify with the Washington Medical Commission as to the necessity of in-state licensure requirements for out-of-state physicians performing Independent Medical Examinations over telemedicine to those residing in or physically present in Washington state resulted in the following supposition and guidance on consideration of this petition:

The issue of whether a physician not licensed in Washington but performing an independent medical examination in Washington, which would include a diagnostic clinical interview, medical record review, and arriving at a diagnosis and recommendations for treatment, has never been officially determined. There is a strong argument that this would fall under the definition of the practice of medicine in RCW 18.71.011, as you point out. But the Washington Medical Commission has never issued a ruling, policy statement, or other written opinion on the matter. Please note that the Washington Medical Commission does not handle cases of unlicensed practice. This is handled by the unlicensed practice unit of the Washington State Department of Health. You may consider filing a petition with the DOH for a declaratory order under RCW 34.05.240.

4. Request for Declaratory Order

Based on the above facts and legal considerations, the petitioner respectfully requests that the Washington State Department of Health issue a declaratory order determining:

Whether an Independent Medical / Psychiatric Examination conducted over telemedicine constitutes the practice of medicine and, therefore necessitates in-state professional licensure for an evaluator examining a subject individual present in the state of Washington at the time of the evaluation.

I, David Penner, declare under penalty of perjury under the laws of the State of Washington that I have read the foregoing petition and believe the contents to be true and correct to the best of my knowledge.

Date: 03/06/2025

Place: Olympia, Washington

Signature: _____

Printed Name: David Penner MD

Nick Brown

ATTORNEY GENERAL OF WASHINGTON

M E M O R A N D U M

DATE: May 5, 2025

TO: Washington Medical Commission

FROM: Heather Carter, AAG

SUBJECT: **Petition for Declaratory Order**

The Washington Medical Commission (Commission) received a petition for declaratory order on about March 10, 2025, from Dr. David Penner. At its meeting on March 14, 2025, the Commission voted to hold a proceeding to take public comment on the petition at its next business meeting. This memorandum provides general background information and a framework for considering a petition for declaratory order. I will be in attendance at your meeting to assist and answer any questions you may have.

PETITIONS FOR DECLARATORY ORDER

A declaratory order is an order issued by an agency with respect to the applicability to specified circumstances of a rule, order or statute which the agency enforces. RCW 34.05.240(1). "A declaratory order has the same status as any other order entered in an agency adjudicative proceeding." RCW 34.05.240(8).

Any person may petition an agency for a declaratory order. The Administrative Procedure Act sets out the requirements for a petition.

> The petition shall set forth facts and reasons on which the petitioner relies to show:
>
> (a) That uncertainty necessitating resolution exists;
> (b) That there is actual controversy arising from the uncertainty such that a declaratory order will not be merely an advisory opinion;
> (c) That the uncertainty adversely affects the petitioner;
> (d) That the adverse effect of uncertainty on the petitioner outweighs any adverse effects on others or on the general public that may likely arise from the order requested; and
> (e) That the petition complies with any additional requirements established by the agency under subsection (2) of this section.

RCW 34.05.240(1).

When considering a petition for declaratory order, an agency must either issue a declaratory order or decline to issue an order and state the reasons why. RCW 34.05.240(5).

PENNER PETITION FOR DECLARATORY ORDER

The petition for declaratory order received from Dr. David Penner asks:

> "Whether an Independent Medical/Psychiatric Examination conducted over telemedicine constitutes the practice of medicine and, therefore necessitates in-state professional licensure for an evaluator examining a subject individual present in the state of Washington at the time of the evaluation?"

First, the Commission must consider whether the statutory requirements to grant a petition are met. Specifically in this case, whether the petition sets out sufficient specified circumstances that show an "uncertainty necessitating resolution exists, that there is an actual controversy arising from the uncertainty such that a declaratory order will not be merely an advisory opinion, that the uncertainty adversely affects the petitioner, and that the adverse effect of uncertainty on the petitioner outweighs any adverse effects on others or on the general public that may likely arise from the order requested." RCW 34.05.240(1). These criteria show the importance of ensuring there are specific facts sufficient to issue a binding declaratory order and not an advisory opinion. If all these criteria are not shown, the Commission should decline to issue a declaratory order.

In this case you should specifically consider whether there the petitioner has shown there is an actual uncertainty and that the uncertainty adversely affects him. In addition, you should consider whether there are sufficient facts regarding the circumstances, purpose and use of the independent medical examination described to issue a declaratory order, rather than just an advisory opinion.

Second, the Commission should take note of the relevant statutes related to this petition. It is important to note that Washington has adopted the "the prevailing standard for licensure and affirms that the practice of medicine occurs where the patient is located at the time of the physician-patient encounter, and therefore, requires the physician to be under the jurisdiction of the state medical board where the patient is located." RCW 18.71B.010.

The practice of medicine defined in relevant part in RCW 18.71.011:

> "(1) Offers or undertakes to diagnose, cure, advise, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;
> (2) Administers or prescribes drugs or medicinal preparations to be used by any other person; ****

In addition, Washington has adopted the Uniform Telehealth Act which clarifies when an out-of-state practitioner must be licensed in Washington. It states:

> An out-of-state health care practitioner may provide telehealth services to a patient located in this state if the out-of-state health care practitioner:
>
> (1) Holds a current license or certification required to provide health care in this state or is otherwise authorized to provide health care in this state, including through a multistate compact of which this state is a member; or
> (2) Holds a license or certification in good standing in another state and provides the telehealth services:
>
> > (a) In the form of a consultation with a health care practitioner who has a practitioner-patient relationship with the patient and who remains responsible for diagnosing and treating the patient in the state;
> >
> > (b) In the form of a specialty assessment, diagnosis, or recommendation for treatment. This does not include the provision of treatment; or
> >
> > (c) In the form of follow up by a primary care practitioner, mental health practitioner, or recognized clinical specialist to maintain continuity of care with an established patient who is temporarily located in this state and received treatment in the state where the practitioner is located and licensed.

RCW 18.134.050.

Finally, it should be noted that the Commission does not prosecute unlicensed practice of medicine cases. It is the Secretary of Health who has the authority to bring those actions. RCW 18.130.190.

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

April 1, 2025

Kyle Karinen
Executive Director
Washington Medical Commission
111 Israel Road SE
Tumwater, Washington 98501

Re: Mounjaro® and Zepbound® and Continued Patient Safety Concerns

Dear Mr. Karinen,

I write on behalf of Eli Lilly and Company ("Lilly") to alert the Washington Medical Commission (the "Commission") regarding a recent development related to tirzepatide, the active ingredient in Lilly's Mounjaro® and Zepbound® medicines. As you may be aware, tirzepatide was removed from the Food and Drug Administration's ("FDA") drug shortage list last year. A Texas federal court denied an attempt to block FDA's decision, holding that "Lilly regains its statutory exclusivity over tirzepatide products" and all other sellers "must cease production of their versions of the drugs." See Attachment. Then, on March 10, 2025, FDA announced that it would immediately begin enforcing the essentially-a-copy prohibition in section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA").[1]

Nevertheless, it appears that some telehealth providers and associated physicians have continued to mass prescribe and mass produce unapproved, untested compounded tirzepatide, putting patients across Washington at risk. We are writing to alert you to these patient safety concerns and request your help in protecting the public from the dangers of large-scale marketing and sale of copies Lilly's FDA-approved medicines.

Lilly's FDA-Approved Medicines

Lilly's Mounjaro® and Zepbound® medicines are FDA approved to treat serious medical conditions. Mounjaro® is indicated in addition to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Zepbound® is indicated, in addition to diet and exercise, for adults with obesity or those who are overweight and also have at least one weight-related additional condition, such as hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease, to lose weight.

The active pharmaceutical ingredient ("API") in both Mounjaro® and Zepbound® is called tirzepatide. Lilly is the only lawful supplier of FDA-approved tirzepatide and does not provide tirzepatide API to compounding pharmacies, other manufacturers, or anyone else. Because these

---

1 FDA, "FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize," (March 10, 2025), https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

medicines are sterile injectables, Lilly manufactures Mounjaro® and Zepbound® under strict controls. Lilly only sells Mounjaro® and Zepbound® through authorized channels, such as licensed pharmacies authorized by the state to dispense FDA-approved medicines prescribed by a healthcare provider. And we own the intellectual property rights related to Mounjaro® and Zepbound®.

Mounjaro® and Zepbound® should only be used when prescribed by a licensed healthcare professional. Lilly does not promote or encourage use of Mounjaro®, Zepbound®, or any other Lilly medicine outside of the medicine's FDA-approved indication.

Unlawful Sale and Prescription of Tirzepatide Knockoffs Risks Harming Patients

Numerous entities are currently marketing and selling illegal copycat versions of Lilly's tirzepatide. These illegal sellers are purporting to offer "compounded" drugs. Drug compounding is a practice where a pharmacist combines, mixes, or alters ingredients to create a drug tailored to the unique needs of an individual patient. Compounding is permitted only in very limited circumstances, such as when an FDA-approved drug is not commercially available or where a particular patient's "medical needs cannot be met by commercially available drug products."[2]

Entities previously claimed they were permitted to compound tirzepatide because FDA deemed Lilly's FDA-approved medicines in "shortage" for a period of time. But Mounjaro® and Zepbound® have now been out of shortage for months. In October 2024, FDA announced that the shortage of tirzepatide injection had been resolved. On December 19, 2024, FDA re-confirmed that decision, concluding that Lilly's supply of its medicines Mounjaro® and Zepbound® were sufficient to meet demand. And, as noted, a Texas federal court recently denied an attempt to block FDA's decision, upholding Lilly's "statutory exclusivity over tirzepatide products" and making clear that compounders must "cease production of their versions of the drugs." See Attachment. And FDA subsequently announced that immediately begin enforcing the essentially-a-copy prohibitions in the FDCA.[3]

FDA has repeatedly cautioned that these compounded products are "risky for patients."[4] That's because compounded drugs do not have to meet the same stringent safety regulations that FDA-approved medications do. Compounded tirzepatide is not studied in clinical trials, and is never FDA-approved, which means that FDA does not review the product to evaluate it for the safety, efficacy, or quality American patients expect and deserve. Compounding pharmacies do not have to register or list their products with FDA, are not required to meet FDA's "Good Manufacturing Practices," and do not have to report adverse events. While some falsely equate compounded products with

---

2 21 U.S.C. § 353a(b)(1)(D).

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

4 https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

generic medicines, generics are FDA-approved and must be manufactured according to the same rigorous standards as branded medicines like Mounjaro® and Zepbound®—compounded drugs are neither.

As reported in JAMA Health Forum, most websites selling compounded GLP-1 drugs exclude important safety information and many mislead consumers about the safety and efficacy of their products.[5] The Obesity Action Coalition explained, "using a compounded medication is like playing a guessing game with your health. You don't know what you're getting, and if something goes wrong, it's hard to know why."[6] The American Diabetes Association recommended that patients avoid compounded products "due to uncertainty about their content, safety, quality, and effectiveness."[7]

Federal regulators, 37 State Attorneys General, and State Drug Task Forces have all warned the public about the dangers of these unsafe and unapproved products, including compounders using "non-sterile ingredients" and taking "no steps to sterilize them."[8] FDA recently warned a tirzepatide mass compounder for violating federal law by producing drugs in unsanitary conditions and using active ingredients from an unregistered entity.[9] And Lilly continues to discover compounded tirzepatide with critical safety, sterility, and efficacy problems, including products infected with dangerous bacteria and endotoxins.[10]

Continued Prescriptions of Unlawfully Compounded Drugs

We are concerned that even with tirzepatide out of shortage and fully available to meet patients' needs, some physicians are continuing to prescribe compounded tirzepatide that is illegally compounded and risky for patients. We are similarly concerned that decisions to compound, market, sell, and prescribe these compounded drugs are driven by financial considerations in a way that may not be in the best interests of patient health.

---

5 https://jamanetwork.com/journals/jama-health-forum/fullarticle/2829225.

6 https://www.obesityaction.org/why-compounded-glp-1-medications-arent-the-answer/.

7 https://nclnet.org/the-national-consumers-league-urges-the-public-to-heed-warnings-about-unregulated-versions-of-glp-1-weight-loss-drugs/; https://diabetes.org/sites/default/files/2024-12/24.11.8%20compounding%20statement%20press%20release_FINAL.pdf.

8 https://www.naag.org/policy-letter/state-and-territory-attorneys-general-urge-fda-to-take-action-against-counterfeit-and-illegally-sold-glp-1-drugs/; https://www.nbcnews.com/health/health-news/tennessee-woman-accused-selling-fake-weight-loss-drugs-counterfeit-con-rcna184154; https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-compounded-drugs-fullerton-wellness.

9 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/prorx-llc-696742-12202024.

10 *Complaint for False Advertising and Deceptive Trade Practices, Eli Lilly v. Thrive Health*, Case No. 25-cv-00104, Dkt. No. 1 (D. Colo. January 13, 2025).

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

When an FDA-approved product is not in shortage, federal law permits compounding a drug only when it differs from the FDA-approved medicine in a way that makes a "significant difference" for a specific patient. A classic example is when a patient is allergic to an inactive ingredient in an FDA-approved medicine, such as gluten; a compounded product without the inactive ingredient—e.g., a gluten-free version—is permitted because it produces a "significant difference" for that specific patient.

Tirzepatide does not contain any common allergen. Yet under the pretext of offering "personalized care," certain telehealth providers and drug compounders are mass-producing and mass-marketing tirzepatide with manipulated ingredients, doses, or route of administration, and providers are prescribing them without regard to patient need. These manipulated products have never been clinically tested or proven to be safe and effective, and a product that is mass produced and prescribed in the same manipulated formulation to many patients clearly is not designed to meet any specific patient's individual needs. None of these schemes is allowed, and all of them put patients at risk.

- *Additives.* Some physicians are prescribing compounded tirzepatide with added ingredients like B-3, B-6, B-12, or glycine. Compounders cannot simply add an ingredient to avoid legal restrictions against knockoff FDA-approved medicines that are not in shortage. There is no clinical evidence that adding these other ingredients to tirzepatide works better than tirzepatide alone or that there is a clinical need for any particular patient.

- *Altered Doses.* The FDA-approved labels for Mounjaro® and Zepbound® recommend 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg, and 15mg doses with a four-week titration schedule (for slowly increasing dosage). Some physicians are prescribing new, different doses under the pretext of providing "personalized" care. There is no clinical evidence that would support adjusting the FDA-approved dosing regimen—and certainly not routinely prescribing an unapproved dosing regime for all patients.

- *Oral Versions.* Some physicians are prescribing what compounders claim are pill, under-the-tongue, or other oral versions of tirzepatide. There are no clinical trials or other human studies involving any oral tirzepatide product, meaning these physicians are experimenting on unsuspecting patients. Anyone claiming that oral tirzepatide products are safe or effective is doing so without clinical support.

We are also concerned about the troubling relationship between certain prescribing physicians, telehealth companies, and compounding pharmacies, which appear to work hand in glove to direct patients exclusively to untested, unapproved, illegally mass-produced compounded drugs. The routine—sometimes exclusive—prescribing of compounded tirzepatide, including tirzepatide with altered formulas, manipulated doses, or untested and unapproved routes of administration, when Lilly's FDA-approved products are available suggests that some physicians are not prioritizing patient health when prescribing tirzepatide products. Not only does this practice risk patient health, it may also put a physician malpractice insurance in jeopardy. As one senior risk consultant for a medical

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

malpractice insurer recently observed: "Some compounders . . . may believe the FDA enforcement manpower is so weak that the FDA won't be enforcing the prohibition that closely. . . . Physicians need to be aware of that. From a risk standpoint, I don't think they'd want to be associated with a compounder that's in violation of the law."[11]

Preventing Prescriptions of Unlawfully Compounded Tirzepatide

In light of the above, Lilly requests the Commission's continued help to protect Washington patients from the risks of unlawfully compounded prescription drugs. Specifically, Lilly requests that the Commission:

- Inform Washington physicians of FDA's December 19, 2024 Declaratory Order and the Texas federal court's ruling, attached to this letter, upholding FDA's removal of Lilly's medicines from the drug shortage list and confirming that compounding of tirzepatide must stop; and FDA's confirmation that it will immediately "take action against compounders for violations of the FD&C Act" related to tirzepatide as of March 19[12];

- Issue guidance to Washington physicians concerning compounded tirzepatide, making clear that prescribing tirzepatide with added substances (like vitamin B-6 or B-12), in untested and unapproved oral formulations, or with altered doses intended to create the appearance of "personalization" is unlawful; and

- Work with your state board of pharmacy and board of medicine, together with any relevant state health and consumer protection regulators, and the FDA, in any investigation or enforcement action related to improper compounding of tirzepatide or improper prescriptions.

We appreciate your attention to these issues.

Sincerely,

Jillian V. Fuhs

Jillian V. Fuhs, JD, PharmD
Associate Vice President, Global Regulatory Affairs - Americas
Eli Lilly and Company

---

11 https://www.medscape.com/viewarticle/end-compounded-glp-1s-what-physicians-need-know-2025a100063o?form=fpf.

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

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

OUTSOURCING FACILITIES ASSOCIATION, ET AL.,

Plaintiffs,

v. **No. 4:24-cv-0953-P**

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,

Defendants.

OPINION & ORDER

Before the Court is Plaintiffs Outsourcing Facilities Association's and North American Custom Laboratories LLC Partners' (collectively "Plaintiffs") Motion for Preliminary Injunction and Stay (ECF No. 64). Having considered the briefing and applicable legal authorities, the Court will **DENY** Plaintiffs' Motion.

BACKGROUND

A. Regulatory Background

The Federal Food, Drug, and Cosmetic Act ("FDCA") generally prohibits the introduction of a "new drug" into interstate commerce without the United States Food and Drug Administration's (the "FDA") approval. 21 U.S.C. § 355(a). To obtain FDA approval, a manufacturer generally must submit a new drug application ("NDA"). *Id.* § 355(b)(1). The FDA adjudicates such applications and approves them only if it finds, based on the evidence before it, that the drug is safe and effective for its intended use under the conditions of use described in the drug's labeling. *Id.* § 355(c)(1)(A), (d). Once an NDA is approved, facilities producing the new drug generally must comply with "current good manufacturing practice[s]" ("cGMP"), which "assure[s] that such drug meets the requirements of this chapter as to safety and has the identity

and strength, and meets the quality and purity characteristics, which it purports . . . to possess." *Id.* § 351(a)(2)(B); *see* 21 C.F.R. Pts. 210, 211.

In order to protect patients and ensure efficacy, the FDA's approval process is demanding. Each drug seeking the FDA's approval must be evaluated through three increasingly complex phases of studies, typically culminating in double-blind, multi-center, placebo-controlled clinical trials. The sponsor must detail every ingredient and component in its application to the FDA. 21 U.S.C. § 355(b)(1)(A)(i)–(viii). The FDA conducts inspections to ensure compliance with cGMP, *id.* § 351(a)(2)(B), reviews the drug's labeling to ensure appropriate disclosure of side effects, warnings and contraindications, *id.* § 352(f)(1)–(2), and monitors advertising and promotion to ensure it is not misleading, *id.* §§ 321(n), 352(a)(1), 352(n). The FDA also requires manufacturers to track and trace each finished product, *id.* § 360eee-1, to promptly report all adverse events, *id.* § 355(k), and to conduct further post-approval studies, *id.* § 355(o). Because of the FDA's rigorous requirements, "[o]n average, it takes 10-15 years and costs $2.6 billion to develop one new medicine."[1]

Despite the difficulties in getting new drugs approved, companies regularly invest in the research and development of new drugs due to the incentives created by Congress. Relevant here, new chemical entity exclusivity is earned whenever the FDA approves a new medicine for the first time. 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii). This statutory exclusivity means that for five years the FDA is prohibited from approving another manufacturer's application for any drug using the same active moiety. *Id.*

In addition to subjecting all new drugs to the NDA process, the FDCA regulates when drug compounding is permitted. Drug compounding is "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication," is "a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools." *Thompson v. W. States*

[1]PhRMA, *Research and Development Policy Framework* (Sept. 2024), https://tinyurl.com/5eecdtm9.

Med. Ctr., 535 U.S. 357, 360–61 (2002) (internal citation omitted). For example, the FDCA allows licensed pharmacists and physicians to compound a version of an FDA-approved product to address patient-specific needs, such as creating a liquid version of a medication for a patient who has trouble swallowing solids. *See* 21 U.S.C. § 353a.

Compounding pharmacies and physicians whose drugs meet the conditions of 21 U.S.C. § 353a (hereinafter "503A compounders") are not required, *inter alia*, to follow cGMP. On the other hand, outsourcing facilities (hereinafter "503B compounders") are subject to cGMP, registration, and product reporting requirements. *Id.* § 353b. Regardless of who produces them, compounded drugs are not subject to the safety requirements that apply to FDA-approved drugs because they do not undergo the FDA's premarket review for safety, effectiveness, and quality. Due to this reduced oversight, Congress has generally prohibited compounders from producing products that "are essentially copies of a commercially approved drug." *Id.* §§ 353a(b)(1)(D); 353b(a)(2)(A)(ii). Nonetheless, this prohibition is temporarily lifted when a drug is placed on the "shortage list."

The FDCA defines "shortage" as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." *Id.* § 356c. Further, the FDCA requires the FDA to "maintain an up-to-date list of drugs that are determined by the [FDA] to be in shortage in the United States." *Id.* § 356e(a). For every drug the FDA adds to its shortage list under this provision, it is required to identify "[t]he name of the drug in shortage," "[t]he name of each manufacturer of such drug," "[t]he reason for the shortage" from an enumerated list of seven categories, and "[t]he estimated duration of the shortage as determined by the [FDA]." *Id.* § 356e(b)(1)–(4). When a drug is placed on the FDA's shortage list, Congress permits 503A compounders to compound copies of the drug and 503B compounders to compound from that drug's active ingredient—which is otherwise prohibited—including by compounding drugs that are "essentially a copy" of an approved drug. *See Id.* §§ 353b(a)(2)(A)(ii), (a)(5), (d)(2)(A). Because, as discussed above, compounders are subject to less oversight

than drug manufactures, the FDCA permits this type of compounding only while a shortage persists.

B. Factual and Procedural Background

The drugs relevant to this case are Mounjaro® and Zepbound® (collectively the "Lilly Drugs"). The FDA approved the Lilly Drugs pursuant to Intervener Eli Lilly and Company's ("Lilly") marketing applications in 2022 and 2023, respectively. The Lilly Drugs contain a complex molecule called tirzepatide, which targets hormone receptors (called GIP and GLP-1). The FDA approved Mounjaro® for adults with type 2 diabetes mellitus seeking to improve their glycemic control. And the FDA approved Zepbound® for adults with obesity, weight-related medical problems, and moderate to severe obstructive sleep apnea. Given the groundbreaking nature of these drugs, Lilly experienced unprecedented demand, which it was unable to meet. As a result, the FDA placed the Lilly Drugs on its drug shortage list.

The Lilly Drugs remain protected by statutory exclusivity, meaning that the FDA is prohibited by law from accepting an NDA or abbreviated NDA for any tirzepatide product from any company other than Lilly until June 2027. *See* 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2), (b)(3). However, as discussed above, this exclusivity is suspended while the drugs remain on the FDA's shortage list. Thus, until the drugs are removed from the shortage list, compounders can legally produce similar products to help satisfy the demand not filled by Lilly.

In an effort to regain its exclusive right to produce and sell tirzepatide products—by having the Lilly Drugs removed from the FDA's shortage list—Lilly spent roughly $23 billion to build, expand, acquire, or obtain internal and external manufacturing facilities in the United States and Europe. Additionally, in August 2024, Lilly obtained supplemental FDA approvals authorizing the sale of the Lilly Drugs in single-use vials—on top of addition to the already approved auto-injector devices—allowing Lilly to more readily supply doses of the drugs. As a result of Lilly's efforts, the FDA updated the shortage list to reflect that "[a]ll doses of Mounjaro® and Zepbound® [were] available." Two

months after that announcement, on October 2, 2024, the FDA announced that the tirzepatide shortage was over and that the Lilly Drugs would be removed from the shortage list.

Five days later, on October 7, 2024, Plaintiffs filed this lawsuit. On October 11, 2024, the FDA filed an unopposed motion to remand and stay the case so that the FDA could "reevaluate the decision at issue in this case." The Court granted the motion, and the FDA reconsidered its decision. On December 19, 2024, the FDA issued a "Delisting Action" reaffirming its decision to remove the Lilly Drugs from the shortage list. The Delisting Action was memorialized in two documents. The first, titled the "Decision," presented the evidence considered by the FDA and its reasoning. The second, titled the "Order," summarized the FDA's rationale and provided that the FDA would exercise its enforcement discretion to delay the enforcement of its decision.

Thereafter, on January 1, 2025, Lilly filed its Motion to Intervene, which the Court granted on January 6, 2025. On January 2, 2025, Plaintiffs and the FDA filed a Joint Motion to Reopen the Case and Enter Scheduling Order. After holding a hearing on January 14, 2024, the Court reopened the case and set a briefing schedule for the present Motion. The Parties, and *Amici Curiae*, have filed their respective briefs and the Motion is ripe for determination.

LEGAL STANDARD

A preliminary injunction is an "extraordinary remedy" and will be granted only if the movants carry their burden on four requirements. *Nichols v. Alcatel USA, Inc.*, 532 F.3d 364, 372 (5th Cir. 2008). The movants must show: "(1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) the threatened injury to the movant outweighs the threatened harm to the party sought to be enjoined; and (4) granting the injunctive relief will not disserve the public interest." *City of Dall. v. Delta Air Lines, Inc.*, 847 F.3d 279, 285 (5th Cir. 2017) (cleaned up). "The decision to grant or deny a preliminary injunction is discretionary with the district court." *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985).

ANALYSIS

The Court begins with Plaintiffs' likelihood of success on the merits for their claims against Defendants. For the reasons stated *infra*, the Court finds that Plaintiffs have failed to demonstrate a likelihood of success on the merits of their claims, which is the most important (and usually decisive) factor. *See Tesfamichael v. Gonzales*, 411 F.3d 169, 176 (5th Cir. 2005); *Baird v. Bonta*, 81 F.4th 1036, 1041 (9th Cir. 2023). While the Court's analysis could end there, in an abundance of caution, the Court will briefly address the other preliminary injunction elements.

A. Likelihood of Success on the Merits

Plaintiffs' Amended Complaint raises six claims for why the FDA's Delisting Action should be set aside. *See generally* ECF No. 68. Plaintiffs, in their Motion for Preliminary Injunction, do not address their fifth cause of action—unlawful interpretation of the statute under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024). *Id.* at 22. Thus, because Plaintiffs did not raise it as a basis for injunctive relief, the Court's analysis focuses on the other five claims, which are addressed in Plaintiffs' Motion.

Those claims are: (1) rulemaking without conducting notice and comment; (2) failure to consider the statutory factors; (3) facially contradictory findings that undermine the basis of the agency action; (4) failure to consider countervailing evidence; and (5) failure to publish a rule in the federal registry. ECF No. 68 at 17–24. Because claims one and five are both predicated on the Delisting Action being a rule, the Court considers them together. Similarly, Plaintiffs' remaining three claims are considered together as they all involve whether the Delisting Action was arbitrary and capricious.

1. Notice-and-Comment and Failure to Publish Claims

For the Court to determine Plaintiffs' likelihood of success on the merits on their notice-and-comment and failure to publish claims, the Court must first determine how to categorize the Delisting Action. The Parties do not dispute that the Delisting Action is a final agency action subject to judicial review under the Administrative Procedures Act

("APA"). However, the Parties do dispute how to classify the FDA's Delisting Action. Plaintiffs assert that the Delisting Action is a substantive rule. ECF No. 64 at 8. On the other hand, Lilly and the FDA (collectively the "FDA Defendants") claim that the Delisting Action is an informal adjudication. ECF Nos. 83 at 16; 90 at 17–18. If the Delisting Action is a substantive rule, as Plaintiffs urge, then then the FDA was required to comply with the APA's stringent notice-and-comment requirements and that process is reviewed under the arbitrary and capricious standard. But if the Delisting Action is an informal adjudication, as the FDA Defendants urge, then the Court simply reviews the decision under the arbitrary and capricious standard.

As best the Court can tell, the question of how to classify the FDA's removal—or addition—of a drug from its shortage list has never been raised or answered. In fact, the regulatory scheme is seemingly silent as to what procedure the FDA must use to make its shortage determinations. Plaintiffs argue that the Delisting Action is a substantive rule under the APA because it "changed the law by establishing a new prohibition." ECF No. 64 at 8. Specifically, Plaintiffs assert that the Delisting Action "creates law by prohibiting all compounding of tirzepatide by Section 503B outsourcing facilities and compounding drugs that are essentially copies of branded tirzepatide products by Section 503A pharmacies" because "there is no difference between" the FDA explicitly declaring "that 'compounding of tirzepatide is prohibited' and removing it from the shortage list." *Id.*

In contrast, the FDA Defendants argue that the Delisting Action is not a substantive rule and was properly issued through adjudication for two reasons. *First*, the FDA simply resolved a factual dispute according to an established statute rather than promulgating a policy-like standard or new interpretation of a statute. *See* ECF No. 83 at 16. And *second*, the FDA has discretion to choose whether to proceed through adjudication or rulemaking because the statutory framework does not explicitly provide what procedure the FDA must use. *See* ECF No. 83 at 16–17.

In reviewing whether an agency action was a rulemaking or an adjudication, courts consider two things. "First, we consider the agency's

characterization of its own action. Second, we must examine the ultimate product of the agency action." *City of Arlington, Tex. v. FCC*, 668 F.3d 229, 240 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013). The Court will first address whether the FDA had the discretion to proceed through adjudication before turning to whether the Delisting Action is in effect an adjudication or substantive rule.

a. The FDA's discretion

When a statutory scheme is silent as to what procedure an agency must use to act, an agency has discretion to proceed through either rulemaking or adjudication. *McDonald v. Watt*, 653 F.2d 1035, 1042 (5th Cir. 1981) ("[T]he Supreme Court held that the decision to make new law through rulemaking or adjudication 'is one that lies primarily in the informed discretion of the administrative agency.'") (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947)). An agency's decision to proceed through rulemaking or adjudication is reviewed under an abuse of discretion standard, and the agency's judgment "is entitled to great weight." *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974); *see also Neustar, Inc. v. Fed. Commc'ns Comm'n*, 857 F.3d 886, 894 (D.C. Cir. 2017) (internal citations omitted) ("[A]s a general matter, '[i]n interpreting and administering its statutory obligations under [an] Act, [an agency] has very broad discretion to decide whether to proceed by adjudication or rulemaking."). Here, the FDA Defendants argue that the FDA did not abuse its discretion by choosing to proceed through an informal adjudication because: (1) Congress requires the shortage list to be "up-to-date" and rulemaking is incompatible with that mandate; (2) engaging in a meaningful notice-and-comment process was not possible given the confidential materials involved; and (3) Congress permits the FDA to withhold confidential information, including the very existence of a shortage. ECF No. 83 at 17–18.[2] Having reviewed the Parties' arguments and the applicable law, the Court finds that the FDA did not

[2]Because the Court finds that the FDA did not abuse its discretion to proceed through adjudication because of the requirement that the list be up-to-date and the issues presented by the confidential data, the Court declines to address the third argument—that the FDA is allowed to withhold information.

abuse its discretion by choosing to proceed through adjudication because notice-and-comment rulemaking is incompatible with Congress's mandate to keep an up-to-date list.[3]

Congress has tasked the FDA with "maintain[ing] an up-to-date list of drugs that are determined by the [FDA] to be in shortage in the United States." 21 U.S.C. § 356e(a). Merriam-Webster defines "up-to-date" as "extending up to the present time: including the latest information." *Up-to-date*, Merriam-Webster's Collegiate Dictionary (11th ed. 2003). If the FDA had chosen to proceed through rulemaking, as Plaintiffs urge, it would have been required by the APA to provide adequate "opportunity to participate in the rule making through submission of written data, views, or arguments. . . ." 5 U.S.C. § 553(c). Generally, for an agency to give adequate opportunity for notice and comment, the APA "requires . . . a minimum thirty-day comment period." *Chamber of Com. of U.S. v. SEC*, 85 F.4th 760, 779 (5th Cir. 2023). An agency is then required to review the comments, respond to "significant" comments, and make any appropriate changes before officially promulgating a rule. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). Thus, even if the FDA expeditiously participated in notice-and-comment rulemaking, the process would take well over a month. Given the constant fluctuation in national supply and demand numbers for a given drug, a rule based on data that is more than a

[3]Additionally, and in the alternative, the Court finds that the FDA did not abuse its discretion due to the issues presented in achieving meaningful notice and comment while maintaining Lilly's confidentiality. Plaintiffs argue that the Delisting Action is invalid because, *inter alia*, the FDA did not post it in the federal registry for notice and comment before issuing it. However, a simple review of the redacted version of Plaintiffs' Brief in Support of its Motion evidences the difficulty—if not the impossibility—of giving sufficient notice of the data that the FDA relied upon in drafting the proposed "rule," and allowing for meaningful comment on it. *See* ECF No. 66 at 14–19. The redacted data in the above reference section of Plaintiffs' Brief was not even made available to them through the issuance of the Delisting Action. Rather, Plaintiffs were not allowed to see the data until, as a part of this lawsuit, the Court signed and entered an agreed confidentiality agreement. Requiring the FDA to do the same with everyone who wishes to participate in the notice-and-comment process is unattainable and unenforceable.

month old cannot be said to be based on "the latest information" available.

Moreover, the APA "mandate[s] that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance." *Perez*, 575 U.S. at 101 (internal citation omitted); *Texas v. Biden*, 646 F. Supp. 3d 753, 771 (N.D. Tex. 2022); *Ctr. for Biological Diversity v. Regan*, 691 F. Supp. 3d 1, 8 (D.D.C. 2023). Consequently, if the FDA is required to participate in notice-and-comment rulemaking to remove a drug from its shortage list, then it is required to do the same to add a drug to the shortage list. Requiring the FDA to participate in a lengthy rule-making process to add and remove drugs from the shortage list—based on stale information—cannot be said to be congruent with Congress's mandate for the FDA to maintain an "up-to-date list of drugs . . . in shortage in the United States." 21 U.S.C. § 356e(a)

To emphasize this point, the Court proposes the following scenario. Company A creates a breakthrough drug and is unable to supply enough of the drug to meet an unprecedented national demand. Company A reports its inability to meet demand, as required, and a couple months later the FDA, after going through notice-and-comment rulemaking, places the drug on the shortage list. Company A, understanding the value of its drug, invests tens-of-billions of dollars to ramp up production in order to meet demand. Company A's investment pays off, and it is able to supply enough of the drug to meet the national demand. The FDA, based on the data provided by Company A, engages in notice-and-comment rulemaking, and a couple of months later removes the drug from the shortage list. The day after the rule is final, the demand numbers for the preceding month come in, and due to an unexpected spike, Company A's supply capabilities no longer meet the national demand. Not only did the FDA remove a drug that is in a shortage based on stale information, but it must now once again participate in a lengthy rulemaking process to allow compounders to fill the unmet demand. In contrast, through informal adjudication the FDA can act in a matter of days not months. And while efficiency may not always be the benchmark for agency action, Congress's explicit

command to keep the shortage list up-to-date makes efficiency important here. This example demonstrates why the Court finds that the FDA did not abuse its discretion in choosing to proceed through an informal adjudication rather than notice-and-comment rulemaking.

Based on the foregoing, the Court agrees with the FDA Defendants that the FDA did not abuse its discretion by choosing to proceed through an informal adjudication. However, the label the FDA has attached to the Delisting Action is not dispositive of whether the action should be classified as such. *Safari Club Int'l v. Zinke*, 878 F.3d 316, 332 (D.C. Cir. 2017) ("An agency may not escape the requirements of § 553 by labeling its rule an 'adjudication'"). If the FDA properly exercised its discretion to proceed though adjudication, but the Delisting Action is a substantive rule in effect, then the APA requires that it be subject to notice-and-comment rulemaking. Therefore, the Court now turns to whether the Delisting Action is an adjudication or substantive rule in its effect.

b. Substantive rule or informal adjudication in effect

As a preliminary matter, it appears to the Court that this issue is a "lose-lose scenario" for Plaintiffs. As discussed above, the APA requires the FDA to use the same procedure to add a drug to the shortage list that it uses to remove a drug from the list. Thus, if the FDA's removal of the Lilly Drugs from the shortage list required notice and comment, then so did the FDA's addition of the Lilly Drugs to the list. It is undisputed that Plaintiffs are only able to compound their versions of the Lilly Drugs because of the FDA's placement of the Lilly Drugs on the shortage list. Consequently, if Plaintiffs are correct and the FDA's removal of the Lilly Drugs from the shortage list is invalid because it violated the APA's notice-and-comment requirements, then the FDA's listing of the Lilly Drugs without notice and comment is similarly invalid and Plaintiffs should not have been allowed to compound their versions of the drugs. But, if Plaintiffs are wrong, and the Delisting Action is an adjudication, then both the addition and removal of the Lilly Drugs were proper, and Plaintiffs can no longer compound their versions

of the drugs.[4] Nevertheless, the Court turns to the Parties' arguments regarding whether in effect the Delisting Action is a substantive rule or informal adjudication.

Plaintiffs assert that the Delisting Action is a substantive rule because it created law and is "no different in its force and effect than if Congress had enacted a statute prohibiting" the compounding of tirzepatide. ECF No. 65 at 7–11. Additionally, Plaintiffs argue that the Delisting Action cannot be an adjudication because it does not resolve a factual dispute between two parties, but, rather, is generally applicable to an entire industry. *Id.* The Court will begin with the latter before addressing the former.

i. Broad impact argument

Plaintiffs first argue that the Delisting Action cannot be an adjudication because of its broad impact. While "[a]djudications typically 'resolve disputes among specific individuals in specific cases, whereas rulemaking affects the rights of broad classes of unspecified individuals,'" "[i]t is true that an agency need not be presented with a specific dispute between two parties in order to" proceed through adjudication "because § 554 does not limit an agency's use of declaratory rulings to terminating controversies between parties." *City of Arlington, Tex.*, 668 F.3d at 242–43. This is the case because "[j]ust as a class action can encompass the claims of a large group of plaintiffs without thereby becoming a legislative proceeding, an adjudication can affect a large group of individuals without becoming a rulemaking." *Goodman v. F.C.C.*, 182 F.3d 987, 994 (D.C. Cir. 1999) (citing *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 292 (1974) (explaining that an agency may "promulgate a new standard that would govern future conduct" of non-parties in an adjudication)); *see also Neustar, Inc.*, 857 F.3d at 894 ("The fact that an order rendered in an adjudication 'may affect agency policy and have general prospective application,' does not make it rulemaking

[4]Plaintiffs argue that the FDA adding a drug to the shortage list is less legally consequential than removing a drug from the list. The Court finds the opposite to be true. An agency action that suspends statutory exclusivity and allows for a statutorily prohibited action to be temporarily performed is a greater "change" in law than restoring the statutory norms.

subject to APA section 553 notice and comment."); *Nat'l Biodiesel Bd. v. Env't Prot. Agency*, 843 F.3d 1010, 1018 (D.C. Cir. 2016) (internal citation omitted) ("[T]he fact that an agency action applies to a 'large number of [parties]' 'carr[ies] [little] weight' in [the Court's] analysis.").

As pointed out by the FDA Defendants, the FDA routinely conducts adjudications that affect large numbers of third parties: the new drug approval process. *See* 21 U.S.C. §§ 355(d)–(g). The FDA's approval of an NDA triggers numerous effects on potential competitors, such as: (1) prohibiting the FDA from approving a competitor's NDA for any drug containing the same active moiety; and (2) triggering statutory restrictions on compounding drugs that are essentially copies of the approved drug. *Id.* §§ 353b(a)(5), (d)(2)(A); *id.* § 355(c)(3)(E)(ii).[5] The Supreme Court has endorsed the FDA's use of informal adjudications to approve NDAs and remove unsafe drugs from the market, despite those adjudications triggering broad sweeping effects on "several persons or manufacturers." *See, e.g., Weinberger v. Hynson, Westcott & Dunning Inc.*, 412 U.S. 609, 624–26 (1973). Consequently, the Court is unpersuaded by Plaintiffs' broad impact argument.

ii. Creates new law argument

Turning now to Plaintiffs' argument that the Delisting Action is a substantive rule in effect because it creates law, Plaintiffs rely on a series of cases in which an agency listing action was considered a rule.

---

[5]In their Reply, Plaintiffs attempt to distinguish the FDA's approval of an NDA from an FDA's shortage determination by arguing that an NDA application involves a specific party while a shortage determination does not. *See* ECF No. 98 at 3–4. The Court is unpersuaded by this argument. To approve an NDA, the FDA reviews data submitted by a company and determines whether it satisfies a set of requirements. If the FDA approves an NDA, it triggers statutory exclusivity for the submitting company as well as a statutory prohibition against compounding the drug. Similarly, to make a shortage determination, addition or removal, the FDA reviews data submitted by a company to determine whether supply is greater than demand over a period of time. If, for example, the FDA finds that a shortage no longer exists, it reinstates the same statutory exclusivity and prohibitions that the FDA's approval of that drug's NDA put into place. And those statutory provisions apply to the same company and compounders that were affected by the NDA adjudication. Thus, Plaintiffs argument that one affects specific parties and the other does not, is unpersuasive.

ECF No. 65 at 8–10. Of the cases cited by Plaintiffs, they rely most heavily on *Safari Club*. 878 F.3d 316. Because that case is demonstrative and dispositive of Plaintiffs' other cited authorities, the Court will focus its analysis on *Safari Club*.

The "basic distinction between" an adjudication and rulemaking is that adjudications are "proceedings designed to adjudicate disputed facts in particular cases," whereas rulemakings are "proceedings for the purpose of promulgating policy-type rules or standards." *See United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224, 244–45 (1973); *see also* 5 U.S.C. §§ 551(4) (defining "rule"), 551(6) ("order"), 551(7) ("adjudication"). The "line between" adjudication and rulemaking "is frequently a thin one. . . ." *Gen. Am. Transp. Corp. v. Interstate Com. Comm'n*, 883 F.2d 1029, 1030 n.2 (D.C. Cir. 1989). While it can be difficult to decipher where courts draw the thin line between adjudication and rulemaking, courts generally find that an agency action is an adjudication when it involves "concrete and narrow questions of law the resolutions of which would have an immediate and determinable impact on specific factual scenarios." *City of Arlington, Tex.*, 668 F.3d at 243. Rulemaking, on the other hand, is identifiable when the application of the action "will only become clear after adjudication of the dispute in a court of competent jurisdiction." *Id.*

This distinction can be seen in *Safari Club*. In *Safari Club*, the United States Fish and Wildlife Service (hereinafter the "Service") issued findings providing that it lacked sufficient information to make a positive finding that the sport-hunting of elephants would enhance the survival of the species. 878 F.3d at 323. The Service's findings also "temporarily banned imports of sport-hunted trophies of elephants." *Id.* The plaintiffs filed a lawsuit challenging the findings and argued, *inter alia*, that the findings were substantive rules despite the Service's insistence that they were adjudications. *Id.* at 331–34. The United States Court of Appeals for the District of Columbia agreed and held that the Service's findings could not be adjudications because, unlike the denial of "an application for an import permit," they had "no immediate legal consequences for any specific parties." *Id.* at 334–35. Rather, the D.C. Circuit held that the findings were substantive rules because they

"established a standard binding on the agency . . . to be applied to future requests" and were "only meant to bind hunters in future permitting adjudications and enforcement actions." *Id.* at 334.

Applying the principle that "adjudications immediately bind parties" while rules have "only future effect" to this case, the Court finds that the Delisting Action is an adjudication for two reasons. *First*, the Delisting Action undoubtably has immediate legal consequences for specific parties. The immediate consequences of the Lilly Drugs being removed from the shortage list are, *inter alia*, that Lilly regains its statutory exclusivity over tirzepatide products, and that 503A and 503B Compounders, like Plaintiffs, must cease production of their versions of the drugs. Plaintiffs seemingly concede the immediate effect the Delisting Action has on them as they argue that the removal of the Lilly Drugs from the shortage list will force their tirzepatide products "off the market," causing them irreparable harm. ECF No. 65 at 2, 23. In contrast, the Service's findings in *Safari Club*, did not cancel any prior but unfulfilled importation approvals, they only served to govern the Service's consideration of future applications. *See Safari Club*, 878 F.3d at 333 ("[T]he Service's ban on imports was only meant to bind hunters in future permitting adjudications and enforcement actions . . . ."). Thus, unlike *Safari Club*, where the findings had no immediate impact on a specific party, the Delisting Action triggered statutory provisions, immediately restoring Lilly's exclusivity and requiring compounders to stop compounding tirzepatide.

And *second*, the Delisting Action does not promulgate a new policy-type rule or standard that will govern the FDA's future actions. Instead, it made a specific factual determination based on the statutory definition of shortage. The Delisting Action did not change or interpret the statutory definition of shortage. It simply fulfilled the FDA's mandate to determine whether tirzepatide products are in shortage. Put another way, unlike *Safari Club*, where the Service's findings "implement[ed] and interpret[ed] [a rule's] enhancement requirement" to make a policy like judgment about what level of protection elephants needed to be afforded to enhance their chance of survival; the FDA's Delisting Action simply looked at the evidence presented and made a

factual determination on whether one number was bigger than another. 878 F.3d at 334 (internal quotations omitted). While it is true that the FDA's numerical determination had the immediate effect of prohibiting Plaintiffs from continuing to compound tirzepatide products, that prohibition did not come by way of a new agency interpretation, but rather by operation of an existing statute.

This distinction is further evidenced by the difference in the prospective effect of the respective agency actions. In *Safari Club*, the Service's findings determined that a ban on the future importation of elephant parts was appropriate until further notice to protect the species. This new standard served as a guide for the Service's consideration of future importation applications. In contrast, rather than creating a standard by which the FDA will consider future compounding applications,[6] the Delisting Action immediately reinstated, as discussed above, statutory protections and prohibitions. In fact, the Delisting Action provides no guidance for any future shortage determination the FDA must make, as every shortage determination—even potentially one involving tirzepatide—must be made on a case-by-case basis. Such case-by-case factual determinations have been found by courts to be adjudications. *See, e.g., Vanda Pharms., Inc. v. FDA*, 436 F. Supp. 3d 256, 270 n.4 (D.D.C. 2020) (rejecting the argument that the FDA's analysis of scientific literature in an adjudication applied to future cases such that it was a legislative rule, and noting that, unlike in *Safari Club*, the agency's analysis was "in the context of 'adjudicating a particular set of disputed facts'").

The FDA's Delisting Action made a factual determination about whether from [redacted] to [redacted], and projecting forward through [redacted], the supply of the Lilly Drugs was equal to or greater than the demand. It did not make a policy-like determination. Therefore, the Court finds that the Delisting Action was an informal adjudication—not a rule. And as a result, the FDA was not required to submit the Delisting Action to notice and comment or publish it in the

[6]In fact, the statutory exclusivity that Lilly immediately regained upon the issuance of the Delisting Action explicitly prohibits the FDA from even considering an application. 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii).

Federal Registry. Accordingly, Plaintiffs are unlikely to succeed on their notice-and-comment and failure to publish claims.

2. Arbitrary and Capricious Claims

The Court now turns to whether Plaintiffs demonstrate a likelihood of success on the merits because the FDA's actions were arbitrary and capricious. Agency decisions are "presumptively valid; the [plaintiff] bears the burden of showing otherwise." *Barr v. SEC*, 114 F.4th 441, 447 (5th Cir. 2024); *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 120 F.4th 494, 504 (5th Cir. 2024) (citing *Medina Cnty. Env't Action Ass'n v. Surface Transp. Bd.*, 602 F.3d 687, 699 (5th Cir. 2010). "If the agency articulates a rational relationship between the facts found and the choice made it does not act arbitrarily or capriciously." *Joseph v. Dir. of Texas Serv. Ctr., U.S. Citizenship & Immigr. Servs.*, No. 24-40249, 2025 WL 458001, at *3 (5th Cir. Feb. 11, 2025) (internal quotation and citation omitted). The "focal point" of that review "should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). And "[j]udicial review under that standard is deferential, a[s] a court may not substitute its own policy judgment for that of the agency." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). While courts "may not supply a reasoned basis for the agency's action that the agency itself has not given," courts are to "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Tex. Med. Ass'n*, 120 F.4th at 504 (citing *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983) (quotations omitted)).

Here, Plaintiffs assert that the Delisting Action is arbitrary and capricious because: (1) it does not sufficiently identify or analyze the key parameters of the shortage determination; (2) it is facially incoherent and inconsistent; and (3) it improperly ignored countervailing evidence. *See* ECF No. 68 at 19–22; *see also* ECF No. 65 at 13–23. The Court will address each in turn.

a. Identification of key parameters[7]

Plaintiffs first argue that the Delisting Action is arbitrary and capricious because it fails to identify what time period the FDA looked at to make its shortage determination. ECF No. 68 at 19–20; ECF No. 65 at 14–19. Plaintiffs assert that the Delisting Action's failure to state a specific time frame is fatal because it is inconsistent with the statutory language and it "blinded [the] FDA to Lilly's inconsistent temporal presentations that concealed shortages." ECF No. 65 at 14. The Court need not spill much ink on this argument as it plainly fails.

Even assuming without deciding that the FDA was required to explicitly provide what period of time on which it based its shortage determination, the FDA satisfied that burden. On multiple occasions, the Delisting Action clarifies that it considered the previously produced supply and demand numbers for [redacted] to [redacted], as well as the recently released [redacted] numbers and the projected numbers through [redacted]. *See* ECF No. 65-1 at 1, 7, 8, 9, 10, 14, 15. This time period was seemingly evident to Plaintiffs as, in the same section of their brief, they take issue with the specific period of time used and argue that the Delisting Action is arbitrary because it failed to consider evidence from outside that time period. ECF No. 65 at 15–16 (asserting that the FDA erred because it did not consider past deficits or surplusages in its analysis as it started [redacted]" and looked at the numbers through [redacted]). Thus, in one breath, Plaintiffs assert that the FDA failed to identify a specific time frame and in another that the FDA's time frame was erroneous. While the Delisting Action occasionally references narrower time frames, the decision as a whole focuses on a set of data and projected data from a specific time frame—[redacted] to [redacted].

Thus, the Court finds that the FDA sufficiently identified what time period it considered in making the shortage determination. Further, the Court finds that because it is tasked to determine whether a shortage

[7]The Court does its best to separate out Plaintiffs' first two arbitrary and capricious claims as they intermingle them in their brief. *See* ECF No. 65 at 14–19.

exists over a specific period of time, the FDA did not err in failing to consider evidence from outside that time frame. Therefore, the Court finds that Plaintiffs have failed to demonstrate a likelihood of success on the merits of this claim.

b. Facially incoherent and inconsistent

Before turning its attention to Plaintiffs arguments for why the Delisting Action is facially incoherent and inconsistent, the Court finds it prudent to begin by briefly summarizing the FDA's decision.

i. Summary of the Delisting Action

The Delisting Action concluded that the tirzepatide shortage was over because the data demonstrated "that Lilly's supply is currently meeting or exceeding demand for these drug products, and that Lilly has developed reserves that it now holds in its finished product inventory, plus significant units of semi-finished product." ECF No. 65-1 at 1. Additionally, the FDA noted that Lilly received approval to produce doses in vials, and that it has scheduled substantial additional production over the coming months. *Id.* [redacted]

In making its determination, the FDA reviewed:

> [D]etailed information and data regarding its production and inventory of these drug products at various points in time, including stock reports that show quantities supplied and demanded, and inventory held in stock, for all strengths of these drug products; cumulative quantities supplied to and demanded by its customers in the year 2024; projected demand and supply in future months; and wholesaler inventory data, among other information.

Id.[8]

The data reviewed by the FDA is best summarized by two tables contained within the Delisting Action, as shown below:

[8]"[A]mong other information" includes numerous information submitted by Plaintiffs and others to demonstrate the existence of a shortage. Because that is the basis for Plaintiffs' third arbitrary and capricious claim, the Court does not discuss that information in this section.

Table 4. Lilly-reported cumulative demand and cumulative supply of tirzepatide single-dose pens for [redacted] (thousands of doses)[51]

Cum. demand	[redacted]
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Cum. supply	
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Net (cum. supply – cum. demand)	
2.5	
5	
7.5	
10	
12.5	
15	
Total	

Table 6. Lilly-reported projected cumulative demand and cumulative supply of tirzepatide single-dose pens [redacted] (thousands of doses)[58]

Cum. demand	[redacted]
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Cum. supply	
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Net (cum. supply – cum. demand)	
2.5	
5	
7.5	
10	
12.5	
15	
Total	

Id. at 10, 15.

These tables summarize Lilly's reported and projected supply and demand numbers beginning in [redacted] and concluding in [redacted]. The tables are constructed in a cumulative fashion with each month building on the previous month(s). This means that each month's column shows the total supply and demand numbers from [redacted] to the specified month. As a consequence, the numbers for [redacted] appear astronomically larger than those for [redacted].

The FDA determined that the shortage had concluded based on the fact that: (1) from [redacted] to [redacted], Lilly's total supply

( ) outpaced total demand ( ); (2) at least through , the shortage would not return based on the projections that Lilly's total supply ( ) would continue to outpace total demand ; and (3) the information provided by wholesalers "further indicate[d] that nationwide supply for [Lilly's] products is exceeding demand." ECF No. 65-1 at 10–15. Furthermore, the FDA noted that its determination was bolstered by: (1) the months-long production of data by Lilly to the FDA; (2) Lilly's supply of over units of semi-finished syringe products (products that have already completed sterile manufacturing and are awaiting labeling and packaging); (3) the recent approval of Lilly's vial versions of the drugs, which allows Lilly to supply more product than currently projected; and (4) Lilly's investment into additional production facilities that will soon be in operation. *Id.* After reviewing the other evidence provided by Plaintiffs, and others, the FDA determined that the nationwide shortage had ended and reaffirmed its decision to remove the Lilly Drugs from the shortage list. *Id.* at 16–23.

ii. Plaintiffs' arguments

Plaintiffs seemingly insist that the Delisting Action needed to be perfect. It did not. Rather, it needed only to "articulate[] a rational relationship between the facts found and the choice made." *Joseph*, 2025 WL 458001, at *3. Thus, the Court need not confuse the trees for the leaves. The question before the FDA was, for "a period of time" did "the demand or projected demand for the [Lilly] drug[s] within the United States exceed the supply of the [Lilly] drug[s]." 21 U.S.C. § 356c(h)(2). The FDA answered that question in the negative and therefore found that the shortage had ended. Consequently, the question before the Court is whether the FDA's decision, that supply of the Lilly drugs outpaced demand for a period of time, was reasonable in light of the evidence before it. For the reasons set out *infra*, the Court answers that question in the affirmative.

The crux of Plaintiffs' argument that the Delisting Action is incoherent and inconsistent is that "Lilly's use of cumulative figures misled or at least confused [the] FDA." ECF No. 65 at 15. Plaintiffs claim that this confusion obfuscated the fact that the shortage still persists

and created an unreasonable reliance on Lilly's statements. *Id.* at 15–19. Specifically, Plaintiffs argue that the Delisting Action is facially incoherent and inconsistent because: (1) the FDA looked at the total supply and demand data for the relevant period rather than at "monthly snapshots;" (2) the FDA [redacted], but then did not [redacted]; (3) the "FDA made no finding of demand under any consistently defined time period" as "[o]nly cumulative tables report demand, and each month has a different baseline;" and (4) the Delisting Action "turns on" Lilly's unsupported statement that it can supply over [redacted] a month. *Id.*

Plaintiffs' first argument, that the Delisting Action should not have considered cumulative data, fails. It is axiomatic that to consider something for a period of time requires considering it for the entire period of time. Yet, Plaintiffs argue that the FDA's decision is without reason because there were data points from shorter periods of time, within the overall time frame, that could lead to a different result. The real and "detailed data" considered by the FDA shows that for the period of [redacted] to [redacted], Lilly supplied some [redacted] more than were demanded ([redacted] supplied - [redacted] demanded). The FDA, relying on projected data,[9] found that for the period of [redacted] to [redacted], Lilly would be capable of supplying at least [redacted] more than would be demanded [redacted] supplied - [redacted] demanded).

Plaintiffs insist that the FDA should have considered the data on a month-to-month basis, rather than through cumulative numbers, and point out that there was more demand than supply produced for individual months. However, this argument ignores the fact that even if

[9]There is no evidence to show that the FDA's reliance on the projections was unreasonable as they provided that Lilly's [redacted] " ECF No. 65-1 at 14. Further, [redacted]

the charts were based on each individual month's numbers, the FDA would have had to add them together to get the total numbers for the relevant period of time. Thus, the result would have been the same as surplus carries over[10] and every month [redacted] ended with a net total surplus. *See* ECF No. 65-1 at 10, 15. Consequently, Plaintiffs are unlikely to succeed on the basis that the FDA fatally erred by considering cumulative numbers.

Plaintiffs next argue that the Delisting Action is arbitrary because the FDA [redacted]. In addition, Plaintiffs argue that the FDA erred by [redacted]. Plaintiffs claim that the FDA had no reason to [redacted], because doing so ignores the fact that surpluses/shortages carry over. While true, it ignores the fact that a period of time requires a starting and ending point. Thus, it was not unreasonable for the FDA to [redacted], as it was the beginning of the relevant time period.[11] Additionally, for the same reason Plaintiffs' cumulative numbers argument fails so does their assertion that the FDA should have [redacted]. In evaluating data for a period of time, one looks at the whole not just part. Therefore, Plaintiffs are unlikely to succeed on the basis that the FDA arbitrarily started [redacted], and [redacted].

Plaintiffs third argument, that the FDA "made no finding of demand under any consistently defined time period" fails for the same reasons. The FDA considered total demand for the relevant time period based on actual and projected data. The argument that the cumulative demand numbers were based on different lengths of time ignores the fact that the supply numbers were based on the same lengths of time. Additionally, just as above, even if they were broken down by month, the FDA would have still been required to total the months up to

[10]Each dose can be stored for up to 24 months. ECF No. 90 at 12.

[11]Plaintiffs do not, and cannot, argue that the FDA was required to look at numbers all the way back to the approval of the Lilly drugs. As Plaintiffs do argue, the FDA was required to choose a time period for its analysis. The FDA did and it looked at the actual and projected numbers for that time frame. The statute does not require more of the FDA and neither does this Court.

evaluate if the total demand outpaced total supply for the time period being considered. Thus, Plaintiffs are unlikely to prevail on their demand calculation argument.

Finally, Plaintiffs assert that the Delisting Action is arbitrary because it "turns on" Lilly's unsupported representation that it can now supply over [redacted] a month. This argument also fails. Even assuming without deciding that Lilly's [redacted] a month estimate is unsupportable, Plaintiffs cannot show that the FDA's determination has no reasonable relationship to the facts presented for two reasons. *First*, Plaintiffs statement is a mischaracterization, as the FDA considered significantly more information than Lilly's explicit [redacted] estimate. *See* ECF No. 35-1 at 1. And *second*, even if the monthly estimate is unsupportable by the data, that does not negate the fact that the actual numbers show that total supply outpaced demand for the relevant period. *Id.* at 10, 15. Thus, even if the FDA was never presented with Lilly's estimate, the actual supply and demand numbers provide the FDA with a reasonable basis for determining that the Lilly Drugs are no longer in shortage. Accordingly, because the FDA was not required to be perfect, Plaintiffs are unlikely to succeed on their claim that the Delisting Action is incoherent and inconsistent.

c. Countervailing evidence

Finally, Plaintiffs assert that the Delisting Action "arbitrarily waved away all evidence of shortage." ECF No. 65 at 19–23. Specifically, Plaintiffs claim that the FDA reviewed all of the evidence provided by them, and others, with "hyper-skepticism."[12] *Id.* Plaintiffs, and others, provided four categories of evidence to the FDA: (1) screenshots of pharmacy wholesalers websites; (2) patient reports; (3) news reports; and (4) compounding numbers. *Id.* Plaintiffs argue that all of this evidence shows that the FDA unreasonably relied on Lilly's assertions and should not have been waved away. *Id.* The Court will address each

[12]As a preliminary matter, the Court notes that the FDA also scrutinized and rejected some of Lilly's evidence based on the same standards it applied to the countervailing evidence. *See, e.g.*, ECF No. 65-1 at 13 n.44., 13–14 n.53. If nothing else, this shows that the FDA did not blindly rely on Lilly's assertions and evidence.

set of evidence to determine if the FDA's finding that it did not outweigh or undermine the evidence provided by Lilly was reasonable in light of the facts before it.

First, Plaintiffs point to the screenshots of wholesalers' webpages showing that on certain days some tirzepatide products were unavailable. *Id.* at 19–20. The FDA reviewed the screenshots and found that the evidence did not "undermine[] or outweigh[] the information provided by Lilly . . . with respect to availability of product to wholesalers and retailers" because: (1) Lilly provided data from the wholesalers showing that Lilly is meeting or exceeding wholesaler demand for the Lilly Drugs; (2) of supply chain dynamics; (3) most of the screenshots were undated; (4) Lilly [redacted] and (5) some localized and temporary supply issues do not demonstrate a national shortage. ECF No. 65-1 at 19–21.

Plaintiffs take issue with all of the FDA's explanations, but most notably argue that "[d]elay in shipping of the drug" is a statutory indicator of a shortage. ECF No. 65 at 20 (citing 21 U.S.C. § 356e(b)(3)(F)). While a significant delay in shipping could affect supply on a national level, it was reasonable for the FDA to conclude that a "[redacted]" delay for a specific dose of tirzepatide on a specific retailer's website does not rise to the level of a national shortage. Similarly, the Court finds that the FDA's review and explanation of the data related to screenshots of wholesalers' websites was not unreasonable in light of the additional data provided and supply chain dynamics.

Second, Plaintiffs claim that the FDA unreasonably found that Lilly's evidence was not outweighed by the "tens of thousands" of "reports of patients" not being able to obtain tirzepatide. ECF No. 65 at 20. Plaintiffs, and others, submitted website "survey data" where people responded in the affirmative to a question asking if they have had "an inability to access name brand GLP-1s." *Id.* at 20; ECF No 65-1 at 17. The FDA reviewed the submissions and found that they did not undermine Lilly's evidence that the shortage was over because: (1) there is no way to verify how many individuals actually filled out the reports,

when they filled out the reports, or when their inability to obtain the drugs occurred; (2) the prompt does not define "inability to access" so some may be reporting that a pharmacy was out of stock and others that their doctor did not prescribe them the medication; (3) of business decisions made by pharmacies as well as their limited storage capacities; and (4) some localized and temporary supply issues do not demonstrate a national shortage. ECF No 65-1 at 16–19. Given the issues with the evidence as articulated by the FDA, the Court finds that the FDA did not unreasonably determine that Lilly's evidence is not outweighed by the patient survey reports.[13]

Third, Plaintiffs assert that the FDA "ignored" news coverage of the shortage situation. ECF No. 65 at 21. With regard to this evidence, the FDA stated:

> FDA reviewed various articles and blog posts submitted by various groups, as well as other news coverage. While these pieces discussed various aspects of the shortage situation, FDA did not find them to contain probative evidence relevant to the analysis FDA must conduct to determine whether a shortage has resolved. While some of these sources contained personal accounts of inability to get a particular product at a particular time, like the evidence discussed in sections II.B.1.i and ii above, those individual accounts do not undermine or outweigh the more specific, reliable, comprehensive, and current information that has been provided by Lilly demonstrating its ability to supply enough product to meet demand.

ECF No. 65-1 at 21.

The Court finds that it was not unreasonable for the FDA to give more weight to specific, reliable, comprehensive, and current information from Lilly, than news reports and blog posts from sources who may have had ulterior motives and lacked the same detailed data presented to the FDA. Consequently, the Court finds that the FDA did not arbitrarily wave away the news coverage of the shortage situation.

---

[13]As previously noted, the FDA found some of Lilly's evidence to be unpersuasive [redacted]. *See, e.g.*, ECF No. 65-1 at 13 n.44., 13–14 n.53.

Fourth, and finally, Plaintiffs argue that the "FDA erred" by "disregarding the '[] sales volume of compounded tirzepatide' as evidence of demand." ECF No. 65 at 21–23. Specifically, Plaintiffs claim that FDA "erroneously deemed compounded products irrelevant," "disregard[ed] demand for compounded products because they beat Lilly's on price," failed to take into account the correct volume of compounding, and incorrectly assumed that some patients were using compounded tirzepatide for off-label uses. *Id.*

Plaintiffs' first point, that the FDA deemed compounded products irrelevant, fails. The FDA stated that the number of compounded products has "minimal relevance" on the current demand of the Lilly Drugs, but that it is relevant to projected demand—after the compounded drugs are removed from the market. ECF No. 65-1 at 22–23. On that basis, the FDA considered whether Lilly would be able to fill the demand hole that would be left after the compounded drugs were removed. *Id.* at 23–28. After a lengthy discussion, the FDA found that based on the projections Lilly would be able to meet the projected demand. *Id.*

Plaintiffs' second and fourth arguments similarly fail. In essence, Plaintiffs take issue with the FDA's statements that demand for compounded drugs does not translate one-for-one to demand for the Lilly Drugs because of price considerations and patients' current off-label use. ECF No. 65 at 21–23. Lilly did not zero out the projections of demand based on these principles, it simply found these were factors to consider in projecting the demand of the Lilly Drugs. ECF No. 65-1 at 26–27. It is not unreasonable to consider missuses or price differences in attempting to calculate a projected national demand.

Finally, Plaintiffs assert that the FDA improperly evaluated how much compounding was occurring. ECF No. 65 at 22. Plaintiffs claim that the FDA erred in considering only the "first six months of 2024" while considering [redacted] for Lilly's data. But the data from the first six months of 2024, was "the most recent complete reporting period" that was available to them. ECF No. 65-1 at 24–25. Plaintiffs also assert that the FDA overcalculated how much Plaintiffs were producing. ECF No. 65 at 22. Even if true, this does not show error as the FDA conducted its

analysis based on inflated compounding numbers, which would only have helped Plaintiffs' position on the shortage. Lastly, Plaintiffs argue that the FDA should have investigated more based on the evidence provided that thirty-seven pharmacies produced roughly 500,000 doses per month. ECF No. 65 at 22. The FDA considered this evidence and found that "[e]ven assuming that all of these doses have been supplied to the market and, upon the curtailing of compounding, would translate to demand for Lilly's products, this would represent a very small amount relative to Lilly's production and inventory." ECF No. 65-1 at 24. Furthermore, the FDA had no obligation "to conduct or commission [its] own empirical or statistical studies." *Prometheus Radio Project*, 592 U.S. at 427. Accordingly, the Court finds that the FDA's treatment of the evidence submitted by Plaintiffs, and others, was reasonable based on the evidence it had before it. *Id.* Thus, Plaintiffs are not likely to succeed on this claim.

B. Irreparable Injury

Parties frequently confuse the magnitude of a harm with the irreparability of a harm. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 18–20 (2008); *Rest. Law Ctr. v. U.S. Dep't of Lab.*, 66 F.4th 593, 597 (5th Cir. 2023) (citing *Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016) ("In determining whether costs are irreparable, the key inquiry is 'not so much the magnitude but the irreparability.'")). Yet even enormous harms can be compensable by money damages, thus failing to justify injunctive relief. *See Sampson v. Murray*, 415 U.S. 61, 90 (1974) ("The key word in this consideration is irreparable. Mere injuries, however substantial . . . are not enough. The possibility that adequate compensatory or other relief will be available at a later date . . . weighs heavily against a claim of irreparable harm.") (internal quotations omitted). That's off the table here, as Plaintiffs sue the federal government and cannot recover monetary compensation. *See Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1136 (5th Cir. 2021). And "complying with a regulation later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs." *Louisiana v. Biden*, 55 F.4th 1017, 1034 (5th Cir. 2022) (internal citation omitted); *see generally Rest. Law Ctr.*, 66 F.4th at 433. Here, without a

preliminary injunction, Plaintiffs will suffer unrecoverable financial losses, which constitutes irreparable harm.[14] *White Lion Invs., LLC*, 16 F.4th at 1136.

C. Public and Private Interests

Finally, Plaintiffs must show that, if the injunction is denied, the threatened injury outweighs any harm that will result if the injunction is granted, and that the granting of an injunction will not disserve the public interest. *See Mock v. Garland*, 75 F.4th 563, 577 (2023). These factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). On one hand, if the Department is enjoined, it "suffers the irreparable harm of denying the public interest in enforcement of its laws." *Veasey v. Abbott*, 870 F.3d 387, 391 (5th Cir. 2017). On the other, "it is always in the public interest" to stop enforcement of unconstitutional or invalid laws. *See Jackson Women's Health Org. v. Currier*, 760 F.3d 448, 458 n.9 (5th Cir. 2014) (internal citations omitted). The Parties' arguments for both interests are the same.

Plaintiffs argue that if the Court denies an injunction, patients will be deprived of their medications. ECF No. 65 at 24. In contrast, the FDA Defendants claim that if the Court grants an injunction, patients will continue to be subject to dangerous compounded versions. ECF Nos. 83 at 24; 90 at 22–25. Congress considered both of these interests in crafting the relevant regulatory scheme. As discussed above, compounding is generally prohibited due to the reduced oversight and the potential harms associated with the practice. However, Congress chose to allow for compounding when a drug is on the FDA's shortage list so that patients can receive their medications. If Congress thought it prudent to account for both of the asserted public interests at issue here, it is not for this Court to make a policy determination on which is

[14]Lilly argues that Plaintiffs are compounding in violation of the relevant statutes. However, the FDA does not contest this element. The Court agrees with Plaintiffs that this argument has no place in this case and must be decided, if at all, in a different lawsuit. Thus, for the purposes of this Motion, the Court does not consider that argument.

greater.[15] Thus, the Court finds that the public and private interests at issue in this case are a wash and do not weig in favor of or against the granting of an injunction.

CONCLUSION

For the reasons set out above, Plaintiffs' Motion for Preliminary Injunction and Stay is **DENIED.**

Given the agreed confidentiality agreement that was entered into by the Parties, and enforced by the Court, the undersigned finds it appropriate to file this unredacted opinion under seal. Shortly after the opinion is filed, the Parties will be provided, via email, an unsigned PDF version of the order. It is **ORDERED** that, **on or before 4:00 p.m., March 7, 2025**, the Parties shall submit, via response to the email, an agreed upon version of the order containing any appropriate redactions. After receiving and reviewing the Parties' version, the Court will issue the redacted order.

SO ORDERED on this **5th day of March 2025.**

Mark T. Pittman

MARK T. PITTMAN
UNITED STATES DISTRICT JUDGE

[15]The Court agrees with John Adams's sentiment that the judiciary should avoid exercising the powers of the legislative and executive branches, so that this Nation may remain "a government of laws and not men." Mass. Const. art. 30; *John Adams, Architect of American Government*, https://www.mass.gov/guides/john-adams-architect-of-american-government.

Committee/Workgroup Reports
May 9, 2025

High Reliability Organizations Workgroup – Chair: Dr. Chung Staff: Mike Farrell
The workgroup met on Friday, March 14 and adopted a revised charter.

Healthcare Disparities Workgroup – Chair: Dr. Currie Staff: Kyle Karinen
We have received partial funding to establish and run a Health Equity Advisory Group in the budget as passed by the Legislature. We are awaiting the Governor's review.

IV Hydration Treatment Workgroup – Chair: Dr. Murphy Staff: Mike Farrell/Jimi Bush
The workgroup developed a draft IV hydration policy and sent it to the Board of Osteopathic Medicine & Surgery, the Washington Board of Nursing, and the Pharmacy Commission. We received feedback from Osteo and Nursing. We are waiting for feedback from Pharmacy.

Finance Workgroup – Chair: Dr. Domino Staff: Kyle Karinen
The Finance Workgroup will meet on May 9 to discuss the Commission's budget for the 25-27 biennium.

Psychedelics in Behavioral Health Treatment Workgroup – Chair: Dr. Domino Staff: Kyle Karinen
Dr. Fino discussed ketamine clinics and their regulation at the medical director forum at the recent FSMB meeting. She hopes to connect with her counterpart in Oregon after the meeting to discuss further specific to our region. She received additional resources from community practitioners here and continues to draft a best practices document.

Committees & Workgroups

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Executive Committee
Chair: Dr. Domino
Chair Elect: Dr. Murphy
Officer-at-Large: Ed Lopez, PA-C
Policy Chair: Chris Blake, PM
Immediate Past Chair: Dr. Chung
Ex Officio Member: Dr. Gallinger
Kyle Karinen
Micah Matthews
Heather Carter, AAG

Policy Committee
Chris Blake, PM, Chair (B)
Dr. Domino (B)
Ed Lopez, PA-C (B)
Dr. Lyle (A)
Scott Rodgers, PM (A)
Dr. Trescott (B)
Heather Carter, AAG
Kyle Karinen
Micah Matthews
Amelia Boyd

Newsletter Editorial Board
Dr. Currie
Dr. Chung
Dr. Wohns
Jimi Bush, Managing Editor
Micah Matthews

Legislative Subcommittee
Chris Blake, PM
Dr. Gallinger
Dr. Jaeger
Dr. D'Souza
Dr. Chang
Scott Rodgers
Micah Matthews
Stephanie Mason

Finance Workgroup
Dr. Domino, WMC Chair, Workgroup Chair
Dr. Murphy, WMC Chair Elect
Kyle Karinen
Micah Matthews
Jimi Bush

Health Equity Advisory Committee
Dr. Currie, Chair
Dr. Browne
Dr. Jaeger
Chris Blake, PM
Douglas Pullen, PM
Kyle Karinen
Mahi Zeru

Panel L
Dr. Chung, Chair
Chris Blake, PM
Arlene Dorrough, PA-C
Dr. Lyle
Dr. Wohns
Dr. Trescott
Dr. Browne, Pro Tem
John Maldon, PM, Pro Tem
Marisa Courtney,
Micah Matthews

High Reliability Workgroup
Dr. Chung, Chair
Dr. Domino
Chris Blake, PM
Dr. Jaeger
Scott Rodgers, PM
Dr. Chang
Ed Lopez, PA-C
Dr. Lyle
John Maldon, PM, Pro Tem
Kyle Karinen
Micah Matthews
Mike Farrell
Jimi Bush
Amelia Boyd

Updated: May 2, 2025

Committees & Workgroups

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Nominating Committee 2024
Dr. Chung
Arlene Dorrough, PA-C
Dr. Jaeger

IV Hydration Treatment Workgroup
Dr. Murphy, Workgroup Chair
Dr. Jaeger
Kyle Karinen
Freda Pace
Dr. Fino
Mike Farrell
Jimi Bush
Taylor Bachrach-Nixon

Psychedelics in Behavioral Health Treatment Workgroup
Dr. Domino, Workgroup Chair
Kyle Karinen
Rick Glein
Dr. Fino
Mike Farrell
Jimi Bush
Marne Nelson
Taylor Bachrach-Nixon
Ex Officio Member: Dr. Chris Bundy, WPHP

CDTA Workgroup
Dr. Chung
Dr. Lyle
Ed Lopez. PA-C
Kyle Karinen
Micah Matthews
Dr. Fino
Joel DeFazio, Staff Attorney
Amelia Boyd

Anesthesiologist Assistants Rules
Dr. Domino
Dr. Currie
Dr. Chung
Ed Lopez, PA-C
Micah Matthews
Marisa Courtney
Amelia Boyd
Heather Carter, AAG
Marlon Basco-Rodillas, DOH Policy Analyst

Opioid Prescribing General Provisions for MDs and PAs Rules
Commissioner TBD
Commissioner TBD
Commissioner TBD
Kyle Karinen
Amelia Boyd
Heather Carter, AAG
Marlon Basco-Rodillas, DOH Policy Analyst

Any committee or workgroup engaging with interested parties or gathering public input must conduct open public meetings.

PM = Public Member

WPHP = Washington Physicians Health Program

WMC Rules Progress Report						Projected filing dates			
Rule	**Status**	**Date**	**Next step**	**Complete By**	**Notes**	**CR-101**	**CR-102**	**CR-103**	**CR-105**
Collaborative Drug Therapy Agreements (CDTA)	CR-101 filed	7/22/2020	Waiting on the results of the Sunrise Review	NA	PQAC Sunrise Review	Complete	TBD	TBD	NA
OBS - Use of Nitrous Oxide, WAC 246-919-601	CR-102 approved	3/14/2025	File CR-102	June 2025	Keep BoMS updated. Need to file CR-102 by July 2. Don't file too early--CR102s have an expiration date of 180 days after filing. The current file date we have now is 5/28	Complete	TBD	TBD	NA
ESSB 5389 - Define Qualified Physician	CR-101 approved	10/20/2023	Wait until IS is filed	TBD	Board of Optometry approved proposed language 10/11/2024 Keep BoMS updated.	TBD	TBD	TBD	NA
SB 5184 - Anesthesia Assistants - New Profession	CR-102 filed	3/25/2025	Hearing	5/9/2025		Complete	Complete	TBD	NA

Updated: 5/2/2025

Opioid prescribing--General Provisions for MDs and PAs	CR-101 filed	4/30/2025	Schedule workshops	June 2025	Keep BoMS updated.	Complete	TBD	TBD	NA
chapter 246-919 WAC MD Physicians WAC 246-919-010 through WAC 246-919-520 WAC 246-919-602 through WAC 246-919-700	CR-101 submitted for pre-review	3/19/2025	File CR-101	July 2025		July 2025			

Washington State Department of Health

Washington Medical Commission

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

Interpretive Statement

Title:	"Qualified Physician" Under Optometry Law
Interpretive Statement Number:	INS2025-01
References:	Chapter 18.53 RCW; Chapter 18.71 RCW
Contact:	Washington Medical Commission
Phone:	(360) 236-2750
Email:	medical.policy@wmc.wa.gov
Effective Date:	May 9, 2025~~TBD~~
Supersedes:	N/A
Approved By:	Karen Domino, MD, Chair

The Washington Medical Commission (WMC) interprets the term "qualified physician under chapter 18.71 RCW" in Enrolled Substitute Senate Bill 5389, chapter 400, Laws of 2023, to mean a physician who meets each of the following criteria:

1. Holds a current license to practice as a physician and surgeon with the WMC;
2. Is not currently under an order or a stipulation to informal disposition with the WMC;
3. Holds a current and unrestricted certification from the American Board of Ophthalmology or is eligible to do so; and
4. Has a surgical suite on site or holds privileges at a local hospital.

On May 9, 2023, Governor Inslee signed Enrolled Substitute Senate Bill 5389, chapter 400, Laws of 2023, amending chapter 18.53 RCW, an act regulating the practice of optometry in Washington. This new law expanded the scope of optometry to include certain advanced procedures:

> RCW 18.53.010
> (2)(a) The practice of optometry may include the following advanced procedures:
> (i) Common complication of the lids, lashes, and lacrimal systems;
> (ii) Chalazion management, including injection and excision;
> (iii) Injections, including intramuscular injections of epinephrine and subconjunctival and subcutaneous injections of medications;
> (iv) Management of lid lesions, including intralesional injection of medications;
> (v) Preoperative and postoperative care related to these procedures;

(vi) Use of topical and injectable anesthetics; and
(vii) Eyelid surgery, excluding any cosmetic surgery or surgery requiring the use of general anesthesia.

The new law provides that an optometrist cannot perform these advanced procedures until the Board of Optometry has issued a license endorsement. The Board of Optometry will issue the license endorsement after the optometrist meets "the educational, training, and competence criteria" set forth in the new law.

To receive a license endorsement, the optometrist must successfully complete postgraduate courses as designated by the Board of Optometry, successfully complete a national examination for advanced procedures, and

(iii) Enter into an agreement with a qualified physician licensed under chapter 18.71 RCW or an osteopathic physician licensed under chapter 18.57 RCW for rapid response if complications occur during an advanced procedure.

The new law does not define the term "qualified physician licensed under chapter 18.71 RCW." Since the WMC licenses allopathic physicians under chapter 18.71 RCW, the WMC is putting forth its understanding of the term "qualified physician." It can be a challenge when laws create opportunities for collaboration between separately regulated professions. In putting forth its interpretation of the term, the WMC is undertaking its commitment to fulfill the Legislature's action and is not seeking to regulate another profession. This interpretation is intended to assist physicians who are contemplating entering into an agreement. Being able to respond rapidly to complications from the procedures listed in the new law requires a high level of competence.

Interpretive Statement

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

Title:	Opioid Prescribing & Monitoring for Allopathic Physicians and Physician Assistants
Interpretive Statement Number:	INS2025-02
Document Number:	
References:	RCW 18.71.800; RCW 18.71A.800; WAC 246-919-850 through WAC 246-919-985; WAC 246-918-800 through WAC 246-918-935
Contact:	Washington Medical Commission
Phone:	(360) 236-2750
Email:	medical.policy@wmc.wa.gov
Effective Date:	TBD
Supersedes:	INS2019-01, INS2023-03
Approved By:	,Chair

Description of the Issue

The Washington Medical Commission (Commission) is aware of concerns by practitioners that the Commission's opioid prescribing rules are inflexible and do not allow for variation based on patient presentation. The Commission is also aware that some practitioners are refusing to see or continue to treat patients who have taken or are currently using opioids. This interpretive statement clarifies that the Commission's opioid prescribing rules in WAC 246-919-850 and WAC 246-918-800 support flexible, patient-centered care. Practitioners should not deny treatment or force tapering based solely on opioid use. The 120 mg MED is a consultation threshold, not a limit. The rules allow clinical judgment, emphasize documentation, and aim to improve care, not restrict it.

The Commission encourages practitioners, especially those in primary care, to view pain management as a part of standard medical practice for all patients and to become knowledgeable about assessing pain and effective treatments.

Interpretive Statement

The Intent and Scope section of both the physician opioid prescribing rule, WAC 246-919-850, and the physician assistant opioid prescribing rule, WAC 246-918-800, states that appropriate pain management is the responsibility of the treating practitioner and the inappropriate treatment of pain, including lack of treatment, is a departure from the standard of care. ~~The Commission encourages practitioners, especially those in primary care, to view pain~~

~~management as a part of standard medical practice for all patients and to become knowledgeable about assessing pain and effective treatments.~~

Given the intent and scope of the opioid prescribing chapter, the Commission is also interpreting that practitioners should avoid rigid morphine equivalent dose (MED) requirements that may lead to the undertreatment of pain or the unnecessary tapering of patients who are stable in both pain levels and function. The Commission will evaluate a practitioner's treatment based on available documentation rather than solely on the quantity, duration, or MED of prescribed medication. The goal is to manage the patient's pain while also addressing their overall well-being, including physical, psychological, social, and work-related factors.

It is important to note that the rules are not inflexible and recognize the importance of sound clinical judgment. Those concerned about the use of the word "shall" within the rules are encouraged to review the Intent and Scope Section. This opening provision describes the purpose of the rules and sets the tone for interpretation and application of the entire opioid prescribing rule set by the Commission.

Background

In 2011, the Commission established rules for managing chronic, noncancer pain to alleviate practitioner uncertainty, encourage better pain management, and assist practitioners in providing appropriate medical care for patients. Since 2011, the Legislature and Commission have made changes on the management of chronic pain to improve patient care and safety.

In 2018, at the direction of the Legislature,[1] the Commission created new rules regarding opioid prescribing for acute nonoperative, acute perioperative, and subacute pain, including the use of multimodal pharmacologic and nonpharmacological therapies as possible alternatives to opioids. The Commission made minor modifications to the existing rules for managing chronic pain as well.

In 2020, at the direction of the Legislature, the Commission revised its rules to require a physician to inform a patient that the patient has the right to refuse an opioid prescription for any reason and to require documentation and clarification regarding honoring that refusal.[2]

Additionally, in 2022, the Commission amended the rules to state the rules do not apply to the treatment of patients in nursing homes, long-term acute care facilities, residential treatment facilities, and residential habilitation centers.[3]

Analysis

The opioid prescribing rules for physicians (WAC 246-919-850) and physician assistants (WAC 246-918-800) describe the Commission's intent and scope of the rules as follows:

[1] Engrossed Substitute House Bill 1427.
[2] RCW 18.71.810; WAC 246-919-865(1)(e); WAC 246-918-815(1)(d).
[3] WAC 246-919-851(5); WAC 246-918-801(5).

"The [commission] recognizes that principles of quality medical practice dictate that the people of the state of Washington have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity, mortality, and costs associated with untreated or inappropriately treated pain. For the purposes of these rules, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The commission encourages [practitioners] to view pain management as a part of quality medical practice for all patients with pain, including acute, perioperative, subacute, and chronic pain. All [practitioners] should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as become knowledgeable about the statutory requirements for prescribing opioids, including co-occurring prescriptions. Accordingly, these rules clarify the commission's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from a [practitioner's] lack of knowledge about pain management. Fears of investigation or sanction by federal, state, or local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the commission will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The commission recognizes that controlled substances including opioids may be essential in the treatment of acute, subacute, perioperative, or chronic pain due to disease, illness, trauma or surgery. The commission will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain.

The medical management of pain should consider current clinical knowledge, scientific research, and the use of pharmacologic and nonpharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration, impact of the pain, and treatment outcomes. [Practitioners] should recognize that tolerance and physical dependence are normal consequences of sustained use of opioids and are not the same as opioid use disorder.

The commission is obligated under the laws of the state of Washington to protect the public health and safety. The commission recognizes that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society. The inappropriate prescribing of controlled substances, including opioids, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the commission expects that [practitioners] incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

[Practitioners] should not fear disciplinary action from the commission for ordering, prescribing, dispensing or administering controlled substances, including opioids, for a

legitimate medical purpose and in the course of professional practice. The commission will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a [practitioner]-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The commission will judge the validity of the [practitioner's] treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

These rules are designed to assist [practitioners] in providing appropriate medical care for patients. The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these rules will not guarantee an accurate diagnosis or a successful outcome. The sole purpose of these rules is to assist [practitioners] in following a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care.

For more specific best practices, the [practitioner] may refer to clinical practice guidelines including, but not limited to, those produced by the agency medical directors' group, the Centers for Disease Control and Prevention, or the Bree Collaborative."

Examples

The following sections provide guidance on various scenarios related to opioid prescribing and management, including treatment for existing patients, new patients, and tapering considerations. They outline the expectations and standards of care for practitioners managing chronic pain and opioid therapy, emphasizing patient-centered approaches and clinical judgment. These sections also clarify the Commission's rules on the appropriate use of opioids, consultation thresholds, and tapering procedures, ensuring that practitioners understand their responsibilities in maintaining safe and effective pain management practices.

Existing Patient

A patient with a longstanding history in a medical practice develops an injury or condition that becomes a pain condition requiring chronic opioid therapy. Generally, a practitioner who refuses to treat the condition properly, including the appropriate utilization of opioids when opioids are clearly indicated, would be practicing below the standard of care. Similarly, a practitioner who refers the patient to a pain management specialist as defined by Commission rule but refuses to continue or support the pain management treatment plan designed by the specialist while responding to all other aspects of patient care, would generally be practicing below the standard of care. Finally, electing to terminate the patient from the practice because

their regular care involves pain management or opioid therapy would be generally be practicing below the standard of care.

New Patient

The Commission's opioid prescribing rules provide incentives for practitioners to take new patients into their practice who are on existing opioid therapy regimens.

WAC 246-919-955 and 246-918-905, provide specific guidance to the practitioner to do the following with new patients on high dose opioids:

- Maintain the patient's current opioid doses until an appropriate assessment suggests that a change is indicated (see second bullet point).
- Evaluate over time if any tapering can or should be done.
- Be aware that new patients on high dose opioids are exempt from mandatory pain specialist consultation requirements for the first three months of newly established care if:
    - The patient was previously being treated for the same condition(s);
    - The presenting dose is stable and nonescalating;
    - There is a history of compliance with written agreements and treatment plans; and
    - There is documented function improvements or stability at the presenting dose.

Tapering

A patient on opioid therapy, chronic or otherwise, is on a stable nonescalating dose. A practitioner has observed the patient's function and quality of life to be positive. However, citing reasons related to state or federal law or desire to have the patient below a certain MED per day, the practitioner initiates a tapering schedule without receiving the patient's consent or considering the patient's function or quality of life. This would be a clear violation of the Commission opioid prescribing rules.

WAC 246-919-950 clearly explains that tapering would be expected for chronic pain patients when one or more of the following occurs:

- The patient requests tapering;
- The patient experiences an improvement in function or pain;
- The patient is noncompliant with the written agreement;
- Other treatment modalities are indicated;
- There is evidence of misuse, abuse, substance use disorder, or diversion;
- The patient experiences a severe adverse event or overdose;
- There is an unauthorized escalation of doses; or
- The patient is receiving an authorized escalation of dose with no improvement in pain or function.

A practitioner treating a patient on a stable nonescalating dose with positive impact on function would not be required to seek additional consultation with a pain specialist. Additionally, there is no upper MED limit in Washington State or federal law. The Commission's opioid prescribing

rules represent the only legal requirement for licensed allopathic physicians and physician assistants in Washington state and set a 120 mg MED consultation threshold for practitioners who are not considered pain management specialists under the rule. The rules do not prohibit practitioners from referring a patient to a pain specialist before patients reach the "consultation threshold," nor do they prevent a practitioner from self-imposing a smaller MED limit for their patients.

The practitioner should document the outcomes, reasoning, and discussions with the patient as outlined in the rules and described in this interpretive statement in the patient's medical record as part of the normal course of medical practice.

Specific Guidance from the Rules

WAC 246-919-955 and 246-918-905 provide specific guidance to the practitioner to do the following with new patients on high dose opioids:

- Maintain the patient's current opioid doses until an appropriate assessment suggests that a change is indicated (see second bullet point).
- Evaluate over time if any tapering can or should be done.
- New patients on high dose opioids are exempt from mandatory pain specialist consultation requirements for the first three months of newly established care if:
    - The patient was previously being treated for the same conditions;
    - The patient's dose is stable and nonescalating;
    - The patient has a history of compliance with written agreements and treatment plans; and
    - The patient has documented function improvements or stability at the presenting dose.

WAC 246-919-950 clearly explains that tapering would be expected for chronic pain patients when:

- The patient requests tapering;
- The patient experiences an improvement in function or pain;
- The patient is noncompliant with the written agreement;
- Other treatment modalities are indicated;
- There is evidence of misuse, abuse, substance use disorder, or diversion;
- The patient experiences a severe adverse event or overdose;
- There is unauthorized escalation of doses;
- The patient is receiving an authorized escalation of dose with no improvement in pain or function.

A practitioner treating a patient on a stable, nonescalating dose with positive impact on function would not be required to seek additional consultation with a pain specialist. Additionally, there is no upper MED limit in Washington State or federal law. The Commission's opioid prescribing rules represent the only legal requirement and cite a 120 mg MED "consultation threshold" for allopathic physicians and physician assistants who are not considered pain management specialists under the rule. The rules do not prohibit practitioners

from referring a patient to a pain specialist before patients reach the "consultation threshold," nor do they prevent a practitioner from self-imposing a smaller MED limit for their patients.

For practitioners not considered pain management specialists treating patients over the 120 mg MED "consultation threshold," there are several options to satisfy the exemption to the consultation requirement, including but not limited to:

- Receiving a peer-to-peer consult with a pain management specialist;
- Participating in an electronic (audio/video) case consult with the University of Washington (UW) Telepain, the Washington Health Care Authority (HCA) Opioid Hotline, or other pain consulting service;
- Documenting in a chart note the attempt to get a consult but the lack of success in attaining one; and
- Successfully completing a minimum of twelve category I continuing education hours in chronic pain management within the previous four years with at least two of those hours dedicated to substance use disorders.

The practitioner should document the outcomes, reasoning, and discussions with the patient as outlined in the rules and described in this interpretive statement in the patient's medical record as part of the normal course of medical practice.

Commonly Asked Questions

1. What is episodic care and how does it apply to my practice?

For the purpose of these rules, episodic care usually includes patients seen in an emergency department or urgent care facility for chronic pain when complete medical records are not available. Additionally, patients seen in an ambulatory care setting with complaints associated with chronic pain whose complete medical records are not available would also be covered by this rule. However, some healthcare systems and clinics may have an associated urgent care facility with complete availability of medical records. These facilities would be excluded from the definition of episodic care for the purposes of these rules.

2. Does the rule define the entire standard of care for the management of pain?

No. The contents of the rules do address some important elements of the standard of care for pain management, but they do not define the entire standard of care. The rules are not exhaustive. The standard of care (current practice guidelines articulated by expert review) will continue to control circumstances and issues not addressed by the rule.

3. Is the 120 mg. MED "consultation threshold" a maximum dose under the rules?

No. The 120 mg morphine equivalent dose (MED) threshold is a triggering dose, intended to alert the practitioner to the fact that prescribing at this dose or higher significantly increases the potential for morbidity and mortality, and requires a consultation with a pain specialist unless the practitioner or circumstances are exempted under the rules. The articulation of this dose in the rules is consistent with the Legislature's requirement in RCW 18.71.450[4] to adopt

[4] ESHB 2876, effective June 10, 2010.

rules that contain a dosage amount that must not be exceeded without pain specialist consultation.

Some have referred to the 120 mg MED threshold (or "triggering") dose as a "maximum dose". The rules do not provide a maximum dose. They simply require, absent an exemption, that the practitioner obtain a pain specialist consultation before continuing to prescribe opioids at a level that is associated with significant increases in opioid-related overdoses and deaths.

4. Is the 120 mg. MED "consultation threshold" the minimum dosage at which a consultation should be obtained under the rules?

No. A practitioner should obtain a consultation when warranted. In WAC 246-919-930(2) and WAC 246-918-880(2), the threshold for mandatory consultation is set at 120 mg MED for adult patients. However, WAC 246-919-930(1) and WAC 246-918-880(1) reference, more generally, additional evaluation that *may* be needed to meet treatment objectives. This section makes specific reference to evaluation of patients under age 18 who are at risk, or who are potential high-risk patients. However, other circumstances may call for a consultation with a pain management specialist for patients who have not yet met the "consultation threshold" dose.

In summary, the Commission's opioid prescribing rules are designed to support practitioners in providing appropriate pain management while emphasizing clinical judgment and flexibility. The Commission encourages practitioners to manage pain as an integral part of medical practice, ensuring that patients receive the necessary care for their conditions. The rules are not intended to be rigid, but rather to guide practitioners in making informed decisions about opioid use, tapering, and consultations with pain specialists. Practitioners are expected to document their clinical decisions and maintain open communication with patients, focusing on overall patient well-being. By doing so, they can avoid undertreatment or unnecessary restrictions, thereby meeting the standard of care while addressing the complexities of pain management.

Interpretive Statement

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

Title:	Opioid Prescribing & Monitoring for Patients
Interpretive Statement Number:	INS2025-03
Document Number:	
References:	RCW 18.71.800; RCW 18.71A.800; WAC 246-919-850 through WAC 246-919-985; WAC 246-918-800 through WAC 246-918-935
Contact:	Washington Medical Commission
Phone:	(360) 236-2750
Email:	medical.policy@wmc.wa.gov
Effective Date:	TBD
Supersedes:	INS2019-02, INS2023-04
Approved By:	,Chair

The Commission interprets physician rules WAC 246-919-850 to 246-919-985 and corresponding physician assistant rules WAC 246-918-800 to WAC 246-918-935 as encouraging practitioners to not exclude, undertreat, or dismiss a patient from a practice solely because the patient has used or is currently using opioids in the course of normal medical care. Refusing to treat or discontinuing treatment of patients solely due to current or past opioid use is inappropriate and may violate the standard of care.

Description of the Issue

The Washington Medical Commission (Commission) is aware that some practitioners are refusing to see or continue to treat patients who have taken or are currently using opioids. To help underscore and clarify the need for patient access and the rights of patients for treatment, the Commission issues this interpretive statement for patient and practitioner use.

Interpretive Statement

The Intent and Scope section of both the physician opioid prescribing rule, WAC 246-919-850, and the physician assistant opioid prescribing rule, WAC 246-918-800, states that appropriate pain management is the responsibility of the treating practitioner and that the inappropriate treatment of pain, including lack of treatment, is a departure from the standard of care. The Commission encourages practitioners, especially those in primary care, to view pain management as a part of standard medical practice for all patients and to become knowledgeable about assessing pain and effective treatments.

The Commission interprets physician rules WAC 246-919-850 to 246-919-985 and corresponding physician assistant rules WAC 246-918-800 to WAC 246-918-935 as encouraging practitioners to not exclude, undertreat, or dismiss a patient from a practice solely because the patient has used or is currently using opioids in the course of normal medical care. While in most circumstances a practitioner is not legally required to treat a particular patient, the refusal to see or continue to treat a patient merely because the patient has taken or is currently using opioids is contrary to the clear intent of the Commission's rules governing opioid prescribing. Ending opioid therapy or initiating a forced tapering of opioids to a particular morphine equivalent dose (MED) level for reasons outside of abuse or clinical efficacy or improvement in quality of life or function would violate the intent of the rules.

Background

In 2011, the Commission established rules for managing chronic, noncancer pain to alleviate practitioner uncertainty, encourage better pain management, and assist practitioners in providing appropriate medical care for patients. Since 2011, the Legislature and Commission have made changes on the management of chronic pain to improve patient care and safety.

In 2018, at the direction of the Legislature, the Commission created new rules regarding opioid prescribing for acute nonoperative, acute perioperative, and subacute pain, including the use of multimodal pharmacologic and nonpharmacological therapies as possible alternatives to opioids.[1] The Commission made minor modifications to the existing rules for managing chronic pain as well.

In 2020, at the direction of the Legislature, the Commission revised its rules to require a practitioner to inform a patient that the patient has the right to refuse an opioid prescription for any reason.[2]

Additionally, in 2022, the Commission amended the rules to state the rules do not apply to the treatment of patients in nursing homes, long-term acute care facilities, residential treatment facilities, and residential habilitation centers.[3]

Analysis

The opioid prescribing rules for physicians (WAC 246-919-850) and physician assistants (WAC 246-918-800) describe the Commission's intent and scope of the rules as follows:

> *"The [commission] recognizes that principles of quality medical practice dictate that the people of the state of Washington have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity, mortality, and costs associated with untreated or inappropriately treated pain. For the purposes of these rules, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.*

[1] Engrossed Substitute House Bill 1427.
[2] RCW 18.71.810; WAC 246-919-865(1)(e); WAC 246-918-815(1)(d).
[3] WAC 246-919-851(5); WAC 246-918-801(5)

The diagnosis and treatment of pain is integral to the practice of medicine. The commission encourages [practitioners] to view pain management as a part of quality medical practice for all patients with pain, including acute, perioperative, subacute, and chronic pain. All [practitioners] should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as become knowledgeable about the statutory requirements for prescribing opioids, including co-occurring prescriptions. Accordingly, these rules clarify the commission's position on pain control, particularly as related to the use of controlled substances, to alleviate [practitioner] uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from a [practitioner's] lack of knowledge about pain management. Fears of investigation or sanction by federal, state, or local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating [practitioner's] responsibility. As such, the commission will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis. The commission recognizes that controlled substances including opioids may be essential in the treatment of acute, subacute, perioperative, or chronic pain due to disease, illness, trauma or surgery. The commission will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain.

The medical management of pain should consider current clinical knowledge, scientific research, and the use of pharmacologic and nonpharmacologic modalities according to the judgment of the [practitioner]. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration, impact of the pain, and treatment outcomes. [Practitioners} should recognize that tolerance and physical dependence are normal consequences of sustained use of opioids and are not the same as opioid use disorder.

The commission is obligated under the laws of the state of Washington to protect the public health and safety. The commission recognizes that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society. The inappropriate prescribing of controlled substances, including opioids, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the commission expects that [practitioners] incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

[Practitioners] should not fear disciplinary action from the commission for ordering, prescribing, dispensing or administering controlled substances, including opioids, for a legitimate medical purpose and in the course of professional practice. The commission will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a [practitioner]-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The commission will judge the validity of the [practitioner] treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

These rules are designed to assist [practitioners] in providing appropriate medical care for patients. The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these rules will not guarantee an accurate diagnosis or a successful outcome. The sole purpose of these rules is to assist [practitioners] in following a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care.

For more specific best practices, the [practitioner] may refer to clinical practice guidelines including, but not limited to, those produced by the agency medical directors' group, the Centers for Disease Control and Prevention, or the Bree Collaborative."

To further clarify the established intent and scope, the Commission directs practitioners to avoid rigid MED requirements that may lead to the undertreatment of pain or the unnecessary tapering of patients who are stable in both pain levels and function. The Commission will evaluate a practitioner's treatment based on available documentation rather than solely on the quantity, duration, or morphine equivalent dose (MED) of prescribed medication. The goal is to manage the patient's pain while also addressing their overall well-being, including physical, psychological, social, and work-related factors.

Examples

Here are real-life examples showing how the Commission's opioid prescribing rules apply in practice, including treating long-time patients with new pain conditions, accepting new patients already on opioids, and deciding when tapering is appropriate. These examples illustrate what good care looks like and what may fall below the standard of care.

Existing Patient

A patient with a longstanding history in a medical practice develops an injury or condition that becomes a pain condition requiring chronic opioid therapy. Generally, a practitioner who refuses to treat the condition properly, including the appropriate utilization of opioids when opioids are clearly indicated, would be practicing below the standard of care. Similarly, a practitioner who refers the patient to a pain management specialist as defined by Commission rule but refuses to continue or support the pain management treatment plan designed by the specialist while responding to all other aspects of patient care, would generally be practicing below the standard of care. Finally, electing to terminate the patient from the practice because their regular care involves pain management or opioid therapy would be generally be practicing below the standard of care.

New Patient

The Commission's opioid prescribing rules provide incentives for practitioners to take new patients into their practice who are on existing opioid therapy regimens.

WAC 246-919-955 and 246-918-905, and the corresponding physician assistant rules, provide specific guidance to the practitioner to do the following with new patients on high dose opioids:

- Maintain the patient's current opioid doses until an appropriate assessment suggests that a change is indicated (see second bullet point).
- Evaluate over time if any tapering can or should be done.
- Be aware that new patients on high dose opioids are exempt from mandatory pain specialist consultation requirements for the first three months of newly established care if:
    - The patient was previously being treated for the same condition(s);
    - The presenting dose is stable and nonescalating;
    - There is a history of compliance with written agreements and treatment plans; and
    - There is documented function improvements or stability at the presenting dose.

Tapering

A patient on opioid therapy, chronic or otherwise, is on a stable nonescalating dose. A practitioner has observed the patient's function and quality of life to be positive. However, citing reasons related to state or federal law or desire to have the patient below a certain MED per day, the practitioner initiates a tapering schedule without receiving the patient's consent or considering the patient's function or quality of life. This would be a clear violation of the Commission opioid prescribing rules.

WAC 246-919-950 clearly explains that tapering would be expected for chronic pain patients when one or more of the following occurs:

- The patient requests tapering;
- The patient experiences an improvement in function or pain;
- The patient is noncompliant with the written agreement;
- Other treatment modalities are indicated;
- There is evidence of misuse, abuse, substance use disorder, or diversion;
- The patient experiences a severe adverse event or overdose;
- There is an unauthorized escalation of doses; or
- The patient is receiving an authorized escalation of dose with no improvement in pain or function.

Additionally, this WAC section was updated in 2025 to include the statement: "Not all chronic pain patients will need their opioid prescriptions tapered." This revision was made in response to complaints received since the 2018 opioid rule updates, highlighting cases where chronic pain patients were tapered too quickly or had their opioid therapy discontinued entirely. The Department of Health released a statement on September 20, 2019 that spoke to this issue: "Neither the Washington State opioid prescribing rules nor the CDC opioid prescribing guideline

support rapidly tapering or discontinuing opioids for patients on existing opioid doses exceeding 90 mg MME per day under most circumstances. Abruptly tapering or discontinuing opioids in a patient who is physically dependent may cause serious patient harms including severe withdrawal symptoms, uncontrolled pain, psychological distress, and in rare instances, suicide."

A practitioner treating a patient on a stable nonescalating dose with positive impact on function would not be required to seek additional consultation with a pain specialist. Additionally, there is no upper MED limit in Washington State or federal law. The Commission's opioid prescribing rules represent the only legal requirement for licensed allopathic physicians and physician assistants in Washington state and set a 120 mg MED consultation threshold for practitioners who are not considered pain management specialists under the rule. The rules do not prohibit practitioners from referring a patient to a pain specialist before patients reach the "consultation threshold," nor do they prevent a practitioner from self-imposing a smaller MED limit for their patients.

The Commission directs the practitioner to document the outcomes, reasoning, and discussions with the patient as outlined in the rules and described in this interpretive statement in the patient's medical record as part of the normal course of medical practice.

In summary, the Commission issues this interpretive statement to clarify that refusing to treat or discontinuing treatment of patients solely due to current or past opioid use is inappropriate and may violate the standard of care. Pain management is a core responsibility of medical practitioners, and the Commission's opioid prescribing rules are designed to ensure patients have access to safe, effective treatment. Practitioners are encouraged to evaluate and manage pain based on individual needs, clinical judgment, and documented outcomes without rigid dose limits or unnecessary tapering. New patients on stable opioid regimens should be assessed and maintained appropriately, and decisions regarding tapering must consider patient function, quality of life, and consent. The Commission emphasizes documentation, adherence to clinical guidelines, and a commitment to compassionate, individualized care.

Policy

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

Title:	Visiting Student Learning Opportunity License Exemptions
Policy Statement Number:	POL2025-03
Document Number:	
References:	RCW 18.71.030(6) and (8), RCW 18.71.230, Chapter 18.130 RCW
Contact:	Washington Medical Commission
Phone:	(360) 236-2750
Email:	medical.policy@wmc.wa.gov
Effective Date:	TBD
Supersedes:	POL2020-01
Approved By:	,Chair

Policy

Medical students, residents, and fellows in post-graduate medical training who are completing an elective educational rotation in the state of Washington are exempt from licensure for the specific purpose of completing the rotation. These individuals are accountable to the Washington Medical Commission (commission) and may face disciplinary action if necessary.

RCW 18.71.030 lists exemptions to the requirement to have a license to practice medicine, and states, in part:

> Nothing in the chapter shall be construed to . . . prohibit:
> …
> (6) The practice of medicine by any practitioner licensed by another state or territory in which he or she resides, provided that such practitioner shall not open an office or appoint a place of meeting patients or receiving calls within this state;
> …
> (8) The practice of medicine by a person serving a period of postgraduate medical training in a program of clinical medical training sponsored by a college or university in this state or by a hospital accredited in this state, however, the performance of such services shall be only pursuant to his or her duties as a trainee.

The lack of a license requirement does not exempt those trainees covered by this policy from accountability by the Washington Medical Commission (commission). Per RCW 18.71.230, any person practicing in the state of Washington under exemptions in RCW 18.71.030(5) through

(1~~2~~3) is subject to disciplinary action by the commission. Any complaints received by the Commission on trainees, licensed or not, are processed according to the relevant procedure: Complaints against students, residents, fellows WMC

Therefore, medical students, residents, and fellows who are in post-graduate medical training who are completing an elective educational rotation in Washington State are exempt from licensure for the specific purpose of completing the rotation.

Medical Marijuana (Cannabis) Authorization Guidelines

April 2020

1.1 Purpose

To improve patient safety and maintain the dignity of healthcare practitioners, the regulating boards and commissions adopted professional practice standards expected of authorizing healthcare practitioners who recommend medical marijuana under Washington State law.

1.2 Definitions

Authorization. A form developed by the Department of Health that is completed and signed by a healthcare practitioner and printed on tamper-resistant paper containing the RCW 69.51A.030 logo. An authorization is not a prescription as defined in RCW 69.50.101. A patient with a valid authorization is allowed to grow up to four plants within their domicile under RCW 69.51A.210.

Authorizing healthcare practitioner. The following types of healthcare practitioners licensed in Washington State are allowed to authorize the use of marijuana to medical patients:

- Medical doctor (MD) – licensed under chapter 18.71 RCW
- Physician assistant (PA) – licensed under chapter 18.71A RCW
- Osteopathic physician (DO) – licensed under chapter 18.57 RCW
- Osteopathic physician assistant (OPA) – licensed under chapter 18.57A RCW
- Naturopathic physician (ND) – licensed under chapter 18.36A RCW
- Advanced registered nurse practitioner (ARNP)– licensed under chapter 18.79 RCW

Certified Medical Marijuana Consultant. A person who has completed a 20-hour state-approved Medical Marijuana Consultant Certification training program and holds a valid medical marijuana consultant certificate issued by the Department of Health - WAC 246-72-010. A certified consultant works in a licensed marijuana retail store that has a medical endorsement. A certified consultant's role is to assist a patient with registration into the medical marijuana authorization database, create and issue a recognition card to the patient and assist the patient with the selection of marijuana products that may benefit the patient's medical condition - WAC 246-72-030.

Designated provider. A person who is twenty-one years of age or older and is the parent or guardian of a qualifying patient who is under the age of eighteen; or has been designated by the qualifying patient to purchase, provide or grow marijuana for the patient and has an authorization from the patient's healthcare practitioner. A designated provider can only serve one patient at any one time – RCW 69.51A.010(4).

Medical marijuana authorization database. A secure and confidential database administered by the Department of Health and used by medically-endorsed marijuana retail stores to register, issue and verify recognition cards to qualifying patients and their designated providers (if any); and, used by healthcare practitioners to access health care information on their patients for the purpose of providing medical and pharmaceutical care as established under RCW 69.51A.230.

Medically-endorsed marijuana retail store. A marijuana retailer that has been issued a medical marijuana endorsement by the state liquor and cannabis board pursuant to RCW 69.50.375.

Qualifying patient. A person who is a patient of a healthcare practitioner; has been diagnosed by that practitioner as having a terminal or debilitating medical condition defined under RCW 69.51A.010(24); is a resident of Washington; has been advised by that practitioner about the risks and benefits of the medical use of marijuana; has been advised by that practitioner that they may benefit from the medical use of marijuana; and has an authorization from his or her healthcare practitioner to use marijuana for medical purposes – RCW 69.51A.010(17).

Recognition card. A card issued to qualifying patients and designated providers by a marijuana retailer with a medical marijuana endorsement that has entered them into the medical marijuana authorization database – RCW 69.51A.010(20). With a recognition card a patient can purchase up to three times the recreational amount of product, is allowed to grow up to six plants (or up to 15 plants upon their practitioner's additional plant recommendation), and can purchase sales tax free from a medically endorsed marijuana retail store – RCW 69.51A.210.

Tamper-resistant paper. Paper that meets industry-recognized security features to copying, erasure or modification of information on the paper, and to prevent the use of counterfeit authorization – RCW 69.51A.010(23).

Terminal or debilitating medical condition. Means a condition severe enough to significantly interfere with the patient's activities of daily living and ability to function, which can be objectively assessed and evaluated and limited to the conditions outlined under RCW 69.51A.010(24).

Compassionate Care Renewal. A renewal of an authorization by a health care practitioner through the use of telemedicine if the health care practitioner determines that requiring the qualifying patient to attend an in-person physical examination would likely result in severe hardship to the qualifying patient because of the qualifying patient's physical or emotional condition. A compassionate care renewal of a qualifying patient's registration and recognition card also allows the qualifying patient's designated provider to renew the qualifying patient's registration in the database and recognition card without the qualifying patient being physically present at a retailer and without a new photograph being taken per WAC 246-71-010(2).

Telemedicine. Has the same meaning as the definition of that term adopted by the authorizing health care practitioner's disciplining authority, whether defined in rule or policy per WAC 246-71-010(15).

1.3 Healthcare Practitioner Statutory Limitations

The healthcare practitioner shall not (RCW 69.51A.030):

a. Accept, solicit, or offer any form of pecuniary remuneration from or to a marijuana retailer, marijuana processor, or marijuana producer;

b. Offer a discount or any other thing of value to a qualifying patient who is a customer of, or agrees to be a customer of, a particular marijuana retailer;

c. Examine or offer to examine a patient for purposes of diagnosing a terminal or debilitating medical condition at a location where marijuana is produced, processed, or sold;

d. Have a business or practice which consists primarily of authorizing the medical use of marijuana or authorize the medical use of marijuana at any location other than his or her practice's permanent physical location;

e. Except as provided in RCW 69.51A.280, sell, or provide at no charge, marijuana concentrates, marijuana-infused products, or useable marijuana to a qualifying patient or designated provider; or

f. Hold an economic interest in an enterprise that produces, processes, or sells marijuana if the health care professional authorizes the medical use of marijuana.

1.4 Authorization Practice Guidelines

A healthcare practitioner may provide valid documentation to authorize medical marijuana (cannabis) to a qualifying patient under Chapter 69.51A RCW under the following conditions:

Section 1: Patient evaluation

A healthcare practitioner should obtain, evaluate, and document the patient's health history and physical examination in the health record prior to treating for a terminal or debilitating condition.

a. The patient's health history should include:

   i. Current and past treatments for the terminal or debilitating condition;

   ii. Comorbidities; and

   iii. Any history of substance misuse or abuse using a risk assessment tool.

b. The healthcare practitioner should:

   i. Complete an initial physical examination as appropriate based on the patient's condition and medical history; and

   ii. Check of the Prescription Drug Monitoring Program database for the patient's receipt of controlled substances

   iii. Review the patient's medications including indication(s), date, type, dosage, and quantity prescribed.

   iv. Provide the qualifying patient and their designated provider (if any) each with a medical marijuana authorization form printed on tamper-resistant paper containing the RCW 69.51A.030 logo as required under WAC 246-71-010.

Section 2: Treatment plan

A healthcare practitioner should document a written treatment plan that includes:

a. Review of other measures attempted to treat the terminal or debilitating medical condition that do not involve the medical use of marijuana;

b. Advice about other options for treating the terminal or debilitating medical condition;

c. Determination that the patient may benefit from treatment of the terminal or debilitating medical condition with medical use of marijuana

d. Advice about the potential risks of the medical use of marijuana to include: The variability of quality and concentration of medical marijuana;

   i. Adverse events, including falls or fractures;

   ii. The unknown short-term and long-term effects in minors, as more fully explained in Section 4, below;

   iii. Use of marijuana during pregnancy or breast feeding; and,

   iv. The need to safeguard all marijuana and marijuana-infused products from children and pets or domestic animals.

   v. Additional diagnostic evaluations or other planned treatments;

e. A specific duration for the medical marijuana authorization for a period no longer than 12 months for adults (age 18 and over) and 6 months for minors (under age 18); and,

f. A specific ongoing treatment plan as medically appropriate.

SECTION 3: ONGOING TREATMENT

A healthcare practitioner should conduct ongoing treatment and assessment as medically appropriate to review the course of the patient's treatment, to include:

a. Any change in the medical condition;

b. Any change in physical or psychosocial function;

c. Any new information about the patient's terminal or debilitating medical condition; and

d. An authorization may be renewed upon completion of an in-person physical examination.

e. Following an in-person physical examination, evaluate patient eligibility for a compassionate care renewal of their authorization per RCW 69.51A.030(2)(c)(iii).

SECTION 4: TREATING MINOR PATIENTS OR PATIENTS WITHOUT DECISION MAKING CAPACITY

The risks of marijuana use in minors are substantial, particularly given its well-documented adverse effects on the developing brain. [1] While research demonstrates that the use of marijuana can be helpful for adults with specific debilitating conditions, there are no published studies on the use of medical

[1] https://pediatrics.aappublications.org/content/135/3/584

marijuana for minors. A health care practitioner should strongly consider limiting the authorization of marijuana to minors in palliative pediatric care when short-term symptom relief outweighs long-term risks. The most common symptoms that may justify the use of medical marijuana for minors are pain, nausea, vomiting, seizures, and agitation. [2]

Under RCW 69.51A.220 and RCW 69.51A.230(4), a healthcare practitioner considering authorizing marijuana to a patient under the age of 18 or without decision making capacity must:

a. Ensure the patient's parent, guardian, or surrogate participates in the treatment and agrees to the medical use of marijuana;

b. Evaluate and document history of substance misuse or abuse using a risk assessment tool; [3]

c. Consult with other healthcare practitioners involved in the patient's treatment, as medically indicated and as agreed to by the patient's parent, guardian, or surrogate, before authorization or reauthorization of the medical use of marijuana; and

d. Include a follow-up discussion with the minor's parent or patient surrogate to ensure the parent or patient surrogate continues to participate in the treatment;

e. Ensure the patient's parent, guardian, or surrogate acts as the designated provider; and

f. Reexamine the minor at least once every six months or more frequently as medically indicated.

Additional requirements to note when treating minor patients:

a. Qualifying patients (adult or minor) can only have one designated provider under RCW 69.51A.010. This can be challenging for minor patients who live in divorced families.
   a. School districts must permit a designated provider (parent/legal guardian) to administer marijuana-infused product to a minor qualifying patient (under age 18) in accordance with school policy at the request of a parent – RCW 69.51A.225

   b. The minor may not grow plants or purchase marijuana (cannabis) - RCW 69.51A.220.

[2] The federal Food and Drug Administration (FDA) has approved medications related to marijuana that are available in pharmaceutical grade by prescription for rare conditions. One of the medications is approved for the treatment of seizures associated with Lennox-Gastut syndrome or Dravet syndrome in patients over two years of age. This medication is not considered medical marijuana and is not available at marijuana dispensaries. This medication is prescribed by subspecialists with expertise in these conditions.

[3] The use of a risk assessment tool is particularly important in the treatment of minors. The American Academy of Pediatrics developed a guide to help providers incorporate screening, brief intervention, and referral for the use of alcohol, tobacco, marijuana and other drugs among adolescent patients.
https://pediatrics.aappublications.org/content/138/1/e20161210

c. Both the minor and the minor's parent or guardian who is acting as the designated provider must be entered in the medical marijuana authorization database and hold a recognition card - RCW 69.51A.220.

SECTION 5: MAINTENANCE OF HEALTH RECORDS

A healthcare practitioner should maintain the patient's health record in an accessible manner, readily available for review, and include:

a. The diagnosis, treatment plan, and therapeutic objectives;

b. Documentation of the presence of one or more recognized terminal or debilitating medical conditions identified in RCW 69.51A.010(24).

c. Documentation of other measures attempted to treat the terminal or debilitating medical condition that do not involve the medical use of marijuana;

d. A copy of the signed authorization form for both the patient and their designated provider (if any);

e. Results of ongoing treatment; and

f. The healthcare practitioner's instructions to the patient.

SECTION 6: CONTINUING EDUCATION

A healthcare practitioner issuing authorizations or valid documentation for the medical use of marijuana on or after the effective date of these guidelines, should complete a minimum of three hours of continuing education related to medical marijuana.

Such program should explain the proper use of marijuana (cannabis), including the pharmacology and effects of marijuana (e.g., distinction between cannabidiol (CBD) and tetrahydrocannabinol (THC); methods of administration; and potential side effects or risks).

1.5 RESOURCES

Washington State Department of Health Medical Marijuana Program

Policy

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

Title:	Practitioners Exhibiting Disruptive Behavior
Policy Statement Number:	POL2025-XX
Document Number:	
References:	Chapter 18.130 RCW
Contact:	Washington Medical Commission
Phone:	(360) 236-2750
Email:	medical.policy@wmc.wa.gov
Effective Date:	TBD
Supersedes:	MD2021-01
Approved By:	,Chair

The Washington Medical Commission (Commission) considers disruptive behavior to be a threat to patient safety. If the Commission receives a complaint or report that a practitioner has engaged in disruptive behavior, the Commission may investigate a complaint and, if warranted, take disciplinary action against the practitioner to protect the public.

Disciplinary action may be based on the belief that the disruptive behavior constitutes unprofessional conduct under RCW 18.130.180(4) (negligence that creates an unreasonable risk of harm), RCW 18.130.180(1) (moral turpitude relating to the profession) or another subsection of RCW 18.130.180.

The Commission may also issue a statement of charges under RCW 18.130.170(1) if there is evidence that the practitioner is unable to practice with reasonable skill and safety due to a mental or physical condition. This statute does not require that the practitioner have a diagnosable mental condition under the DSM.[1]

If the Commission is unsure whether the practitioner has a mental or physical condition that may impact his or her ability to practice with reasonable skill and safety, the Commission may choose to order the practitioner undergo a mental or physical examination under RCW 18.130.170(2). The results of such an examination may provide evidence to support a statement of charges under RCW 18.130.170(1).

The Commission is aware that if a practitioner denies engaging in disruptive behavior, an evaluation under RCW 18.130.170(2) is particularly challenging, if not impossible, for the

[1] *Neravetla v. Department of Health*, 198 Wn. App. 647, 394 P.2d 1028 (2017).

evaluator. In most cases, the preferred option is to issue a statement of charges under RCW 18.130.180 on the theory that the disruptive behavior constituted unprofessional conduct.

The Commission may refer the practitioner to the Washington Physician Health Program at any point in the process, beginning with making a recommendation during the initial investigation up to imposing a requirement in a disciplinary order.

Background

Most physicians and physician assistants enter the field of medicine for altruistic reasons and have a strong interest in caring for and helping other human beings. The majority of practitioners carry out their duties with high levels of professionalism and recognize that quality care requires teamwork, communication and a collaborative work environment. However, several studies show that behavior that impedes teamwork and communication and interferes with patient care—often referred to as disruptive behavior—may be prevalent in somewhere between 1 and 5% of practitioners.[2]

Disruptive behavior has been defined as "an aberrant style of personal interaction with physicians, hospital personnel, patients, family members, or others that interferes with patient care or could reasonably be expected to interfere with the process of delivering good care."[3] Disruptive behavior comprises a wide variety of behaviors including overt actions such as verbal outbursts and physical threats, as well as passive activities such as failing to respond to repeated calls, not performing assigned tasks or quietly exhibiting uncooperative attitudes during routine activities.[4] A list of examples of disruptive behavior can be found in appendix A.

Disruptive behavior interferes with the ability to work with other members of the health care team, disrupts the effectiveness of team communication, and has been shown to be a root cause in a high percentage of anesthesia-related sentinel events.[5] The consequences of disruptive behavior include job dissatisfaction for physicians, nurses and other staff; voluntary turnover; increased stress; patient complaints; malpractice suits; medical errors; and compromised patient safety.

Disruptive behavior is not a diagnosis and should not be used to label a practitioner who has an occasional reaction out of character for that individual. The disruptive label should refer to a pattern of inappropriate behavior that is deep-seated, habitual, and pervasive.[6]

Disruptive behavior may be a sign of an illness or a condition that may affect clinical performance. Studies have shown that some physicians demonstrating disruptive behavior have subsequently been diagnosed with a range of psychiatric disorders and medical disorders

---

[2] Williams, B. W., and Williams M.V. The Disruptive Physician: A Conceptual Organization, *Journal of Medical Licensure and Discipline.* 2008; 94(3):13.
[3] Lang, D., and others. *The Disabled Physician: Problem-Solving Strategies for the Medical Staff.* Chicago, Ill.: American Hospital Publishing, Inc., 1989. *See also* Neff, K., Understanding and Managing Physicians with Disruptive Behaviors, pp. 45 – 72 (2000).
[4] The Joint Commission. Behaviors that undermine a culture of safety. *Joint Commission Sentinel Event Alert.* 2008; issue 40 (updated September 2016).
[5] *Id.*
[6] Reynolds, N., "Disruptive Physician Behavior: Use and Misuse of the Label, Journal of Medical Regulation, Vol. 98, No. 1, p. 9-10 (2012).

with significant psychiatric symptoms, most of which were treatable.[7] Referral for evaluation of impairment can identify health conditions, distress and other psychosocial factors that may be contributing to the disruptive behavior. If this is the case, an effective treatment and monitoring plan may resolve the disruptive behavior.[8] On the other hand, ruling-out impairment can provide reassurance in proceeding with progressive remediation. The Washington Physicians Health Program accepts referrals for disruptive behavior and will tailor its approach and recommendations based on the presence or absence of an impairing health condition.

When the practitioner exhibiting disruptive behavior is part of an organization where the behavior can be identified, the organization should take steps to address it early before the quality of care suffers, or complaints are lodged. The best outcome is frequently accomplished through a combination of organizational accountability, individual treatment, education, a systems approach and a strong aftercare program.[9] The Joint Commission has developed a leadership standard that requires leaders to develop a code of conduct that defines behaviors that undermine a culture of safety, and to create and implement a process for managing such behaviors.[10] Psychiatrist Norman Reynolds, MD, has developed a set of strategies to manage this behavior and provides advice on the construction of medical staff policies and a program of remediation.[11]

While organizations may be the best place to address disruptive behavior, state medical boards may also play a role when the behavior is brought to their attention. The Federation of State Medical Boards recommends that legislatures amend the practice acts of state medical boards to include disruptive behavior as a grounds for disciplinary action, explaining that it is imperative that state medical boards have the power to investigate complaints of disruptive behavior and to take action to protect the public.[12]

The Commission has taken disciplinary action against several practitioners who exhibited disruptive behavior. In some cases, the basis for the action is that the conduct constitutes unprofessional conduct under RCW 18.130.180(4) because it is negligence that creates an unreasonable risk that a patient may be harmed. The Commission has also taken action under RCW 18.130.180(1) when it deemed that the conduct amounted to acts of moral turpitude relating to the profession.

In one case, the Commission took action against a physician engaging in disruptive behavior under RCW 18.130.170(1) on the theory that the practitioner had a mental condition that prevented him from practicing with reasonable skill and safety. The Washington State Court of

[7] Williams and Williams, p. 14.
[8] Reynolds, p. 19.
[9] Williams and Williams, p. 17.
[10] The Joint Commission, Leadership Standard Clarified to Address Behaviors that Undermine a Safety Culture. *See also* Reynolds at pp. 14-17 for an excellent discussion of strategies for managing disruptive behavior.
[11] Reynolds, pp 14-19.
[12] Federation of State Medical Boards. *Report of Special Committee on Professional Conduct and Ethics.* 2000. https://www.fsmb.org/siteassets/advocacy/policies/report-of-the-special-committee-on-professional-conduct-and-ethics.pdf

Appeals, in a published opinion issued in 2017, upheld the Commission order imposing discipline for disruptive behavior, favorably citing the Commission's prior policy on disruptive behavior, and rejecting the respondent's argument that a diagnosable mental condition was required to proceed under RCW 18.130.170(1).[13]

[13] *Neravetla v. Department of Health*, 198 Wn. App. 647, 394 P.2d 1028 (2017).

Washington State Medical Association
Physician Driven, Patient Focused

April 25, 2025

Ms. Amelia Boyd
Washington Medical Commission
Department of Health

Re: Practitioners Exhibiting Disruptive Behavior Policy & Medical Professionalism Guidance Document

Delivered electronically

Dear Ameila,

On behalf of the Washington State Medical Association (WSMA) representing nearly 13,000 members, I am writing to provide comment on the Washington Medical Commission's policy, "Practitioners Exhibiting Disruptive Behavior" and "Medical Professionalism" guidance document. We understand that these documents are up for revision as part of the Washington Medical Commission's (WMC) standard four-year review cycle and welcome this opportunity to share our membership's thoughts on how these documents might be strengthened to help ensure physicians continue to be treated and evaluated equitably moving forward.

Our members are concerned that the definition of disruptive behavior is subjective and may be influenced by implicit bias. While we are glad to hear this has not appeared to be an issue in the past, we want to ensure this does not change in the future. Updating the "Practitioners Exhibiting Disruptive Behavior" policy will help ensure that changes in leadership do not result in unfair treatment. These concerns are not unfounded. For example, research has shown that women and people of color may be disproportionately targeted for allegations of "disruptive" behavior in medical organizations or hospitals due to biased expectations of what constitutes "appropriate" behavior.

One suggestion our membership offered was to add a step to WMCs process of review that requires that complaints be reviewed from a diversity, equity, inclusion, and belonging (DEIB) perspective to reduce the risk of disparate treatment. Another suggestion was to perhaps rename the policy to put more emphasis on concerns about professionalism and adherence to standards of care as opposed to more subjective personality issues that are susceptible to biased interpretation.

On the "Medical Professionalism" guidance document, our membership was pleased to see it largely aligned with the American Medical Association's (AMA) professionalism statement. The only suggested revisions were to include language stating that part of professionalism is being aware of conscious and unconscious bias and that physicians must make sure to treat all patients with respect and compassion. Retitling "Practitioners Exhibiting Disruptive Behavior," to put more focus on professionalism may help make the link between these two documents clearer for practitioners.

Thank you again for the opportunity to submit our thoughts on the WMC's "Practitioners Exhibiting Disruptive Behavior" policy and related guidance document on "Medical Professionalism," as they come up for their four-year review. Please contact WSMA policy analyst, Hillary Norris, JD, at hillary@wsma.org with any questions or to discuss further.

Sincerely,

Hillary Norris

Hillary Norris, JD
Policy Analyst
Washington State Medical Association

Seattle Office
1215 Fourth Avenue, Suite 1901
Seattle, WA 98161
o / 206.441.9762 *fax* / 206.441.5863
email / wsma@wsma.org

Olympia Office
1800 Cooper Point Road SW
Building 7, Suite A
Olympia, WA 98502
o / 206.441.9762 *fax* / 206.441.5863

Procedure

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Interactive and Transparent Development of Evidence-based Policies

Introduction

The Washington Medical Commission (Commission) develops policies[i] to encourage the medical profession to improve the delivery of medical care and enhance patient safety.[ii] The Commission wishes to better engage the public and the profession by creating an interactive, consistent, and transparent procedure to obtain input to develop evidence-based policies.[iii] This document describes the procedure the Commission uses to develop evidence-based policies.

Procedure

Step One: Determine the need for a policy

Any Commission member, member of the medical profession, organization, or member of the public may ask the Commission's Policy Committee to consider developing a policy in a particular area of medical practice. In general, the Policy Committee will consider developing a policy for an issue that has broad application to practitioners or the public, to respond to an emerging problem, and to fulfill its regulatory charge to protect the public. The Policy Committee may decide that a policy is not necessary, or that the subject is more appropriately addressed by adopting a rule, which has the force of law.

Step Two: Policy Committee

If the decision of the Policy Committee is to develop a policy, the Policy Committee Chair may assign members to a work group to analyze the research and evidence, and to draft the policy. The workgroup will include one or more Commission members and may include subject matter experts on staff. The workgroup may also include subject matter experts outside the Commission.

The Policy Committee also reviews existing policies to ensure that they remain useful and informative, and reflect the current state of medical practice and the current view of the Commission.

Step Three: Research and Obtain Evidence

If the Policy Committee decides to develop a policy or guideline, the next step is to research the topic and obtain evidence that will inform the Commission's decision-making. The research may include:

- Reviewing complaints or other patient experiences related to the topic of the proposed policy.
- Conducting a literature review of the latest journal articles and studies.
- Reviewing the positions of appropriate stakeholders.
- Reviewing the positions of other state medical boards and the Federation of State Medical Boards.

- Identifying and researching relevant legal issues, consulting with the Attorney General's Office as needed.

Step Four: Analysis and Drafting

The work group will analyze the research and evidence, relevant law, and draft the policy. For existing policies, the workgroup will review feedback submitted to the Commission via the Commission web site or otherwise. The workgroup will create a first draft of the proposed policy.

Step Five: Policy Committee Review

In a public meeting, the Policy Committee will review the draft policy and proposes revisions. The Policy Committee presents the draft to the full Commission. The Commission provides feedback and then may approve posting the draft policy for public dissemination, including posting the draft on the Commission web site.

Step Six: Solicit Feedback from Public and Profession

Upon approval by the Commission, staff posts the draft policy to the Commission web site and invites members of the public and the profession to post comments on the proposed draft policy. The Commission will notify the public and the profession of the proposed policy by:

- Sending out notice of the draft policy on social media;
- Sending out notice of the draft policy to the Commission listserv;
- Sending the draft policy to stakeholders and interested parties

The Commission accepts comments on the proposed policy for 28 days. The Commission will have discretion to remove comments that do not contribute to a constructive discussion of the relevant issues.

Step Seven: Policy Committee Review of Feedback

In a public meeting, the Policy Committee reviews the feedback and comments from the public and the profession. The Policy Committee considers the extent to which the comments represent the expectations of the profession and are consistent with the Commission's mission to promote patient safety and our vision of advancing the optimal level of medical care for the people of Washington. The draft policy is revised accordingly.

Step Eight: Secretary Review of Policy

The Commission staff sends the proposed policy to the Secretary of the Department of Health for review and comment. Following the Secretary's review, the Policy Committee reviews and discusses the comments from the Secretary in a public meeting. The Policy Committee brings its recommendations to the full Commission. The full Commission reviews the proposed policy in a public meeting and may revise the policy. If the Commission revises the policy, the Commission sends the proposed policy back to the Secretary for review. Once the Commission approves a policy, the policy is filed with the Washington State Code Reviser and it is published in the Washington State Register.

Step Nine: Final Review and Adoption

Once the Policy Committee is satisfied with the proposed policy, it refers the draft to the full Commission with a recommendation to adopt the policy. The full Commission, in a public meeting, discusses the policy

and decides whether to adopt the final version. When the policy is final, the Commission publicizes it through its web site, social media channels, listserv, and newsletter.

Emergency Exception

In case of an emergency in which the development of a policy is required in a short time period, one or more of these steps may be waived.

Date of Adoption: ~~May 19, 2017~~

Date of Revision: ~~August 20,2021~~

---

[i] RCW 34.05.010(15) defines "policy statement" as "a written description of the current approach of an agency, entitled a policy statement by the agency head or its designee, to implementation of a statute or other provision of law, of a court decision, or of an agency order, including where appropriate the agency's current practice, procedure, or method of action based upon that approach." A policy is advisory only. RCW 34.05.230. Examples of Commission policy statements are "Complainant Opportunity to be Heard Through and Impact Statement," and "Practitioners Exhibiting Disruptive Behavior."

[ii] This procedure does not apply to the development of procedures, which merely establish the proper steps the Commission and staff take to conduct Commission business. Examples include "Consent Agenda Procedure" and "Processing Completed Investigations More Efficiently."

[iii] This process is largely based on the "consultation process" developed by the College of Physicians and Surgeons of Ontario. http://www.cpso.on.ca/Footer-Pages/The-Consultation-Process-and-Posting-Guidelines

Guidance Document

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Medical Professionalism

Introduction

In 2002, the American Board of Internal Medicine Foundation, the American College of Physicians-American Society of Internal Medicine Foundation, and the European Federation of Internal Medicine developed a Charter on Medical Professionalism, and published it simultaneously in the Annals of Internal Medicine and The Lancet.[1] The Charter on Medical Professionalism is designed to reaffirm the medical profession's commitment to patients and to the health care system by setting forth fundamental and universal principles of medical professionalism.

The Washington Medical Commission (WMC) largely adopts the Charter on Medical Professionalism (Charter), as guidance for Washington physicians and physician assistants in fulfilling their professional responsibilities to their patients and to the public. [2]

Charter on Medical Professionalism

Preamble

Professionalism is the basis of medicine's contract with society. Professionalism demands placing the best interests of patients above those of the practitioner[3], setting and maintaining standards of competence and integrity, and providing scientifically accurate advice to society on matters of health. The principles and responsibilities of medical professionalism must be clearly understood by both the profession and the public. Public trust in practitioners depends on the integrity of both individual practitioners and the profession as a whole.

At present, the medical profession is confronted by an explosion of technology, evolving practice conditions, and heightened regulatory obligations. As a result, practitioners find it increasingly difficult to meet their responsibilities to patients and society. In these circumstances, reaffirming the fundamental and universal principles and values of medical professionalism, which remain ideals to be pursued by all practitioners, becomes all the more important.

The medical profession everywhere is embedded in diverse cultures and national traditions, but its members share the role of healer, which has roots extending back to Hippocrates. Indeed, the medical profession must contend with complicated political, legal, and market forces. Moreover, there are wide variations in medical delivery and practice through which any general principles may be expressed in both complex and subtle

[1] "Medical Professionalism in the New Millennium: A Practitioner Charter." Annals of Internal Medicine, 2002;136(3):243-246, *available at* http://annals.org/aim/article/474090/medical-professionalism-new-millennium-practitioner-charter

[2] This Guidance Document is not identical to the previous Charter on Medical Professionalism. The WMC has edited that previous document in order to conform to state laws and rules. For example, in many places in this document, the WMC has replaced the word "shall" with the word "should," so as not to create mandates outside of the rule-making process.

[3] In this guidance document, the WMC uses the term "practitioner" to refer to both allopathic physicians and physician assistants.

ways. Despite these differences, common themes emerge and form the basis of this Charter in the form of three fundamental principles, and as a set of definitive professional responsibilities.

Fundamental Principles

1. *Principle of primacy of patient welfare*. This principle is based on a dedication to serving the interest of the patient. Altruism contributes to the trust that is central to the practitioner–patient relationship. Market forces, societal pressures, and administrative exigencies must not compromise this principle.
2. *Principle of patient autonomy.* Practitioners should respect patient autonomy. Practitioners should be honest with their patients and empower them to make informed decisions about their treatment. Patients' decisions about their care must be paramount, as long as those decisions are in keeping with ethical principles and do not lead to demands for inappropriate care.
3. *Principle of social justice*. The medical profession should promote justice in the health care system, including the fair distribution of health care resources. Practitioners should work actively to eliminate discrimination in health care, whether based on race, gender, gender identity, sexual orientation, socioeconomic status, ethnicity, religion, or any other social category.

A Set of Professional Responsibilities

Commitment to professional competence. Practitioners should be committed to lifelong learning and to maintaining the medical knowledge and clinical and team skills necessary to deliver quality care. More broadly, the profession as a whole must strive to see that all of its members are competent[4] and must ensure that appropriate mechanisms are available for the profession to accomplish this goal.

Commitment to honesty with patients. Practitioners should ensure that patients are adequately and honestly informed before the patient has consented to treatment, and also after treatment has occurred. This expectation does not mean that patients should be involved in every minute decision about medical care; rather, they must be empowered to decide on their course of therapy. Practitioners should acknowledge that in health care, medical errors that injure patients do sometimes occur. Whenever patients are injured as a consequence of medical care, patients should be informed promptly because failure to do so seriously compromises patient and societal trust. Reporting and analyzing medical mistakes provide opportunities to develop and apply appropriate risk management strategies that should improve patient care, not only for patients who have been injured but also to prevent future harm moving forward.

Commitment to patient confidentiality. Earning the trust and confidence of patients requires that appropriate confidentiality safeguards be applied to prevent disclosure of patient information unless disclosure is legally necessary. This commitment extends to discussions with persons acting on a patient's behalf when obtaining a patient's own consent is not feasible. Fulfilling the commitment to confidentiality is more pressing now than

---

[4] Professional competence refers to "the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and community being served." Epstein RM, Hundert EM. Defining and assessing professional competence. *JAMA* 2002; 287(2):226-235), *available at* https://jamanetwork.com/journals/jama/article-abstract/194554?casa_token=nY5Pp29vutgAAAAA:fUtkGd2lVdq0e1p1T61lgKV1MYyhQNxUHoO4aEOxeZL21IchaFYoxgdHGC-nwjX0YNQJkhYTK9k6

ever given the increasing availability of genetic information and the widespread use of electronic information systems for compiling patient data. However, practitioners recognize that their commitment to patient confidentiality must occasionally yield to overriding legal requirements that protect public health and safety (for example, when patients endanger themselves or others).

Commitment to maintaining appropriate relations with patients. Given the inherent vulnerability and dependency of patients, certain relationships between practitioners and patients must be avoided. Practitioners should avoid exploiting patients for personal financial gain, or other private purpose. For example, state law prohibits practitioners from engaging in sexual or romantic relationships with current patients. This includes behaviors such as soliciting a date or kissing a patient in a romantic or sexual manner.[5] State law also prohibits romantic or sexual relationships with former patients if the practitioner uses or exploits the trust, knowledge, influence or emotions derived from the professional relationship, or uses or exploits privileged information to meet the practitioner's personal or sexual needs.[6] Practitioners should also abide by any ethical restrictions regarding romantic or sexual relationships with former patients that are applicable to their specialties.[7]

Commitment to improving quality of care. Practitioners should be dedicated to continuous improvement in the quality of health care. This commitment entails not only maintaining clinical competence but also working collaboratively with other professionals to reduce medical error, increase patient safety, minimize overuse of health care resources, and optimize the outcomes of care. Practitioners should actively participate in the development and application of better quality of care measures to assess routinely the performance of all individuals, institutions, and systems responsible for health care delivery. Practitioners, both individually and through their professional associations, should take responsibility for assisting in the creation and implementation of mechanisms designed to encourage continuous improvement in the quality of care.

Commitment to improving access to care. Medical professionalism demands that the objective of all health care systems is the availability of a reasonable and adequate standard of care that is accessible to all patients. Practitioners should individually and collectively strive to reduce barriers to equitable health care. Within each system, the practitioner should help eliminate barriers to access which are often based on education, laws, finances, geography, and social discrimination. A commitment to equity entails the promotion of public health and preventive medicine without concern for the self-interest of the practitioner or the profession.

Commitment to a just distribution of finite resources. While treating individual patients, practitioners should provide health care that is based on the standard of care which considers cost-effective management and limited resources. When medically necessary resources are scarce, such as during a pandemic, practitioners are encouraged to follow guidance from the Washington State Department of Health and local health departments to prioritize the needs of the public when there are not enough resources for all patients. Otherwise, practitioners should be committed to working with other practitioners, hospitals, and payers to develop and implement guidelines focused on the delivery of cost-effective care. While a practitioner, at times, may be tempted to "overtest" and "overtreat" to decrease their risk of medical malpractice claims, the

---

[5] WAC 246-919-630, 246-918-410. See also RCW 18.130.180(24).
[6] WAC 246-919-630(3). For additional guidance, see the WMC Guidance Document on "Sexual Misconduct and Abuse," GUI2017-03.
[7] For example, the American Psychiatric Association takes the position that sexual activity with a current or former patient is unethical. American Psychiatric Association: The principles of medical ethics (with annotations especially applicable to psychiatry), section 2. Arlington, VA: American Psychiatric Association, 2013. https://www.psychiatry.org/psychiatrists/practice/ethics. Accessed May 7, 2019.

practitioner's professional responsibility involving appropriate resource allocation requires scrupulous avoidance of superfluous tests and procedures. Providing unnecessary services not only exposes patients to avoidable harm and expense but also diminishes the resources available for others.

Commitment to scientific knowledge. Much of medicine's contract with society is based on integrity and the appropriate use of scientific knowledge, technology, and evidence-based medicine. Practitioners should uphold scientific standards, to promote research, and to create new knowledge and ensure its appropriate use. The profession is responsible for the integrity of this knowledge, which is based on scientific evidence, practitioner experience, and effective communication.

Commitment to maintaining trust by managing conflicts of interest. Medical professionals and their organizations have many opportunities to compromise their professional responsibilities by pursuing private gain or personal advantage. Such compromises are especially threatening in the pursuit of personal or organizational interactions with for-profit industries, including pharmaceuticals, laboratory services, medical equipment, and insurance companies. Practitioners should recognize, disclose to the public, and deal with conflicts of interest that arise in the course of their professional duties and activities. Relationships between industry and opinion leaders should be disclosed, especially when the latter determines the criteria for conducting and reporting clinical trials, writing editorials or therapeutic guidelines, or serving as editors of scientific journals.

Commitment to professional responsibilities. As members of a profession, practitioners are expected to work collaboratively to maximize patient care, be respectful of one another, and participate in the processes of self-regulation, including remediation and discipline of members who have failed to meet professional standards. The profession should define and organize the educational and standard-setting process for current and future members. Practitioners have both individual and collective obligations to participate in these processes. These obligations include engaging in internal assessment, offering constructive feedback to peers, and accepting external scrutiny of all aspects of their professional performance.

Summary

The practice of medicine in the modern era faces unprecedented challenges in virtually all cultures within our society. These challenges center on disparities in our health care system, an inability to meet the legitimate needs of patients due to insufficient resources, the increasing dependence on market forces to transform health care systems, and the temptation for practitioners to forsake their traditional commitment to the primacy of patient interests for their own personal gain. To maintain the fidelity of medicine's social contract, the WMC believes that practitioners must reaffirm their active dedication to the principles of professionalism, which entails not only their personal commitment to the welfare of their patients but also collective efforts to improve our health care system for the welfare of society. The WMC adopts this Charter on Medical Professionalism to encourage such dedication among practitioners and the profession in general, and to assure the public that the WMC upholds ideals of professionalism in the State of Washington.

Supersedes: N/A

Proposed Additions to “Medical Professionalism” Guidance to Address Pain Care Stigma and Ethical Responsibilities

April 30, 2025

To the Washington Medical Commission Policy Committee:

We appreciate the Commission’s efforts to regularly review and reaffirm the principles of medical professionalism. As an organization actively engaged in patient-centered advocacy and clinical policy reform, we respectfully submit for your consideration the following additions or clarifications to the Medical Professionalism Guidance Document (agenda item #4, May 1, 2025), specifically to support ethical, evidence-based care for patients experiencing pain.

Due to significant policy shifts over the last decade, more barriers than ever continue to impede appropriate pain care. While we recognize and appreciate all the Washington Medical Commission has done to address this, unfortunately many patients still report being dismissed, distrusted, or denied treatment solely due to their need for medication-based pain relief, particularly opioid therapy. This not only undermines patient welfare but contradicts core principles of professionalism and social justice.

To that end, we request the Commission consider integrating language into the existing document to make the following points clear:

Suggested Additions to the Guidance Document (Page 16–20):

1. Under “Principle of Primacy of Patient Welfare”:

> Practitioners should recognize untreated or undertreated pain as a legitimate and serious medical issue. The ethical duty to alleviate suffering includes

recognizing pain as a condition requiring compassionate, individualized care, free from stigma or bias.

2. Under “Commitment to Social Justice”:

Discrimination in healthcare can occur not only on the basis of race or identity, but also based on a patient’s medical condition or prescribed treatment. Patients who live with chronic pain must not be deprioritized, dismissed, or denied care due to assumptions about drug-seeking behavior.

3. Under “Commitment to Improving Quality of Care”:

Medical professionalism requires practitioners to stay current on the evolving science of pain management and to provide care that reflects individualized patient needs. Practitioners must ensure that external pressures … whether systemic, political, or rooted in misinformation … do not override their professional duty to relieve suffering..

4. Additionally: In the Summary Section

The WMC reaffirms that alleviating suffering is central to the role of a medical professional. Appropriately treating pain, including through use of controlled medications when warranted, is compatible with the highest standards of professionalism.

These additions are in alignment with the WMC’s past interim statements emphasizing that withholding appropriate pain care falls below the standard of care. Adding this language into the professionalism guidance ensures consistency, sets clear expectations, and reduces the chilling effect many patients and practitioners report.

Thank you for your continued leadership on this issue. We would welcome the opportunity to support or discuss these additions further.

Sincerely,

Tamera Lynn Stewart

Tamera Stewart

Policy Director / Founder

Maria Higginbotham

Maria Higginbotham

State Director

DRAFT

Joint Guidance for Retail Intravenous Therapy Clinics

WASHINGTON MEDICAL COMMISSION
WASHINGTON BOARD OF OSTEOPATHIC MEDICINE AND SURGERY
WASHINGTON BOARD OF NURSING
WASHINGTON PHARMACY QUALITY ASSURANCE COMMISSION

Purpose

The Washington State Department of Health has received reports that IV therapy clinics in our state are operating in contravention of Washington law and established standards of care and creating a risk of harm to the residents of the state of Washington. The Washington Medical Commission, the Board of Osteopathic Medicine & Surgery, the Washington Board of Nursing, and the Washington Pharmacy Quality Assurance Commission, issue this Joint Guidance to advise practitioners on the requirements for the safe and legal operation of intravenous (IV) therapy clinics in the state of Washington.

This guidance is based upon the existing laws and regulations of Washington and sets forth the relevant scopes of practice and standards of care implicated by retail IV therapy businesses.[1] We offer no opinion or evaluation concerning the efficacy of IV therapy offered by retail IV therapy businesses. As with all matters concerning the regulation of medical, nursing and pharmacy practice, we encourage and expect every licensee to practice within the applicable standard of care, the legal scope of practice, and with reasonable skill and safety for patients.

For the purpose of this document, the term "practitioner" refers to allopathic physicians, osteopathic physicians, physician assistants, and advanced practice registered nurses. These licensees have the legal authority to prescribe IV hydration therapy.

Legal Requirements and Best Practices

All practitioners should be aware of the legal requirements and best practices when offering IV therapy to patients in Washington, as follows:

1. The services provided in an IV therapy clinic—the diagnosis of the patient's condition and the recommendation of IV therapy--constitute the practice of medicine.[2]

[1] We acknowledge and appreciate the work done by other boards who have issued statements on this topic, in particular the West Virginia Boards of Medicine, Osteopathic Medicine, Pharmacy, and Registered Nurses; the Alabama Board of Medical Examiners; the South Carolina State Boards of Medical Examiners, Pharmacy, and Nursing; and the Mississippi State Board of Medical Licensure.

[2] Under RCW 18.71.011, one engages in the practice of medicine when one "offers or undertakes to diagnose, cure, advise, or prescribe for any human disease…or other condition"…or "administers or prescribes drugs or medicinal preparations…" Likewise, under RCW 18.57.001(4) defines "osteopathic medicine and surgery" as "the use of any and all methods in the treatment of disease…and all other physical and mental conditions." Advanced

2. IV therapy requires the insertion of a needle into a patient's vein for the intravenous administration of fluid into a patient's bloodstream, monitoring the patient during and at the conclusion of treatment, and removal of the IV catheter thereafter. This is a medical procedure that requires supervision by appropriately licensed health professionals.

3. A person who receives IV therapy is a patient, and an appropriate health care record for the patient must be created and maintained. The record should be available to the patient and other treating practitioners and should be maintained in a manner that fully complies with the health care record retention and confidentiality requirements of Washington law[3] and the HIPAA Privacy and Security Rules.[4]

4. To provide IV therapy, a practitioner must first establish a practitioner-patient relationship with the patient. A practitioner-patient relationship is formed when the practitioner agrees to advise, diagnose, or treat a patient and the patient agrees that the practitioner will advise, diagnose or treat the patient.[5] A practitioner-patient relationship may be established via telehealth, but not established through email, instant messaging, text messaging, or fax. Practitioners should be aware that the standard of care for telehealth care is the same as for in-person care.[6]

5. Practitioners may assess patients for IV therapy.[7] The practitioner assessment requires the practitioner to personally evaluate the patient, take an appropriate history, diagnose the patient, and make treatment recommendations. IV hydration therapy may not be appropriate for certain age groups, including children and the elderly.

6. A practitioner should obtain and document informed consent in the medical record prior to the delivery of care.[8]

7. IV saline and any after-market additives are drugs that require a prescription or order to administer. IV therapy cannot be administered without a valid prescription or order.

---

practice registered nurses may diagnose patients and recommend IV therapy. See RCW 18.79.050.

[3] Chapter 70.02 RCW. See also Washington Medical Commission Guidance Document: "Medical Records: Documentation, Access, Retention, Storage, Disposal, and Closing a Practice." GUI2024-02. Adopted April 26, 2024.

[4] See HIPAA Privacy Rule; HIPAA Security Rule.

[5] See Washington Medical Commission Policy Statement: Terminating the Practitioner-Patient Relationship, POL2022-03, adopted March 4, 2022.

[6] The newly enacted Uniform Telehealth Act provides, in part: "A health care practitioner may provide telehealth services to a patient located in this state if the services are consistent with the health care practitioner's scope of practice in this state, applicable professional practice standards in this state, and requirements and limitations of federal law and law of this state….A practitioner-patient relationship may be established through telehealth. A practitioner-patient relationship may not be established through email, instant messaging, text messaging, or fax. RCW 18.134.030.

[7] Physician assistants may assess patients for IV therapy if it is within their education, training, and experience, and is consistent with their collaboration agreement. RCW 18.71.A.030, WAC 246-918. Nurse practitioners may assess patients for IV therapy if they are practicing within their education, training, and experience. RCW 18.79.050, WAC 246-840-300.

[8] Washington Medical Commission Guidance Document: Informed Consent and Shared Decision-Making, GUI2022-01, adopted May 27, 2022.

8. Practitioners should only order IV therapy if they, as the assessing practitioner, determine it would be beneficial to the patient. The prescription or order must be part of a medically prescribed plan of care that includes a personal examination and a bona fide practitioner-patient relationship.
9. Practitioners should not issue "standing orders" for a retail IV therapy business, or its employees, to provide IV therapy to patients. A standing order does not create an independent practitioner-patient relationship between individual persons and the practitioner or the IV therapy business. IV therapy should not be administered based upon a standing order.[9]
10. The administering of IV therapy requires a professional license. A licensed person other than the physician (MD or DO), physician assistant, or nurse practitioner may administer IV therapy only if the administration of IVs is within that practitioner's scope of practice.
11. Registered nurses and licensed practical nurses may participate as part of the care team at an IV hydration clinic.[10]
12. Registered nurses and licensed practical nurses may insert and remove IV catheters and monitor patients before, during and after IV therapy is administered. The on-site presence of a physician, physician assistant, or nurse practitioner is not required for a nurse to administer the prescribed or ordered IV hydration; however, the nurse must have the knowledge, skill, and competency necessary to carry out the administration procedures and monitor the patient in a safe manner. The nurse should perform a nursing evaluation and monitor the patient for such things as side effects, toxic effects, allergic reactions, unusual and unexpected effects, changes in a patient's condition that contraindicate continued administration of the pharmaceutical or treatment regimen, and effects that may rapidly endanger a client's life or well-being. A nurse should be prepared to make judgments and decisions concerning actions to take in the event such effects occur and should document all nursing acts performed by the nurse in carrying out the IV administration and noted during the monitoring of the patient during administration.
13. Registered nurses and licensed practical nurses may not:
    a. Prescribe or order IV therapy.
    b. Independently recommend or approve the patient's "selection" of a specific IV hydration cocktail.
    c. Administer IV therapy without a valid prescription order for a prescribing practitioner who has established a practitioner-patient relationship with the patient and determined that a specific IV therapy would be beneficial to the patient.[11]
14. The term "compounding" means "the act of combining two or more ingredients in the

[9] See Washington Board of Nursing Advisory Opinion NCAO 28.00: Standing Orders, adopted November 12, 2021.
[10] See Washington Board of Nursing Advisory Opinion, *Infusion Therapy Management,* NCAO 24.00, adopted September 11, 2020.
[11] Id.

preparation of a prescription."[12] The FDA has cautioned that patients can be significantly harmed when drugs are compounded in a way that does not assure sterility and quality.[13]

15. IV therapy cocktails are compounded drugs. Adding vitamins, minerals, or prescription drugs to a bag of saline solution is compounding.
16. Drug compounding must follow specific safety and sterility guidelines, and may only be undertaken by licensed pharmacists and, in certain circumstances, legally qualified practitioners of medicine.[14]
17. Practitioners who order IV therapy and who do not receive compounded end-use cocktails from a licensed pharmacy may only compound IV therapy cocktails if they have the education, training, and experience to ensure the safety and sterility of the final product.
18. ~~Practitioners who elect to engage in the compounding of IV therapy cocktails should personally compound the cocktails they order for their patients~~. ~~Practitioners should not delegate the compounding of IV therapy cocktails to other members of the treatment team or other employees of the business.~~
19. Properly trained nurses may compound medication only for a specific patient and under the direction of an authorized health care practitioner with prescriptive authority.[15]
20. Treatment provided to a patient pursuant to a practitioner's order for IV therapy falls within the supervision and professional responsibility of the ordering practitioner. A physician who serves as a medical director for an IV hydration clinic is responsible for supervising all personnel in the clinic and is ultimately responsible for the safety of patients.[16]
21. Retail IV hydration clinics that are not owned by practitioners with prescriptive authority shall not exercise influence or control over the practitioner's independent exercise of medical judgment in the treatment of any patient.

~~If a licensed healthcare provider has~~ For questions concerning any of the guidelines set forth herein, please ~~the licensee should~~ contact the~~ir~~ appropriate licensing board for additional information. ~~If a non-licensed retail IV therapy business owner has questions concerning these guidelines, the owner should contact any of the four Boards who are responsible for this Joint Advisory Opinion.~~

[12] RCW 18.64.011(6).
[13] FDA reminds compounders to use ingredients suitable for sterile compounding.
[14] RCW 18.64.270; WAC 246-945-100. See also Compounding and the FDA: Questions and Answers; Federation of State Medical Boards White Paper on Compounding of Medications by Physicians.
[15] See Washington Board of Nursing Advisory Opinion, *Registered Nurse and Licensed Practical Nurse: Compounding and Reconstituting Medications,* NCAO 11.01, adopted November 12, 2021.
[16] Washington Medical Commission Guidance Document: Medical Directors: Roles, Duties, and Responsibilities, GUI2020-02, adopted August 21, 2020.

Staff Reports: May 9, 2025

Kyle Karinen, Executive Director

Dr. Janet Barrall: Dr. Barrall finished her fourth and final term as a pro tem member of the Commission on April 30. She was a valued and reliable member of the Commission on all things ophthalmology. Public service on the Commission is one of those quiet acts that does not get a ton of public attention but means the world for patient safety and quality of care. The Commission is sending a plaque to Dr. Barrall in commemoration of her service.

Budget: As Micah indicated in his legislative wrap-up email sent on April 27, the state budget process is on-going. While the Legislature has sent a final budget to the Governor, as of today (May 1), he has not signed or vetoed any portion of it. So, while we remain hopeful the Commission will receive authority on several fronts, nothing is for certain. Contained in the budget as passed by the Legislature were the following:

a. authority to establish and fund a no-cost CME program for licensees;
b. authority to establish and facilitate a Health Equity Advisory Group;
c. authority to establish a second medical consultant position;
d. authority to establish an ombudsperson position;
e. authority to establish a lead position for customer service within the licensing unit; and
f. authority to establish an investigations unit support position.

In a general sense, the Commission remains in a solid fiscal position and there is nothing on the horizon that is concerning in that sense.

FSMB Annual Meeting: I want to highlight and express appreciation to both Micah Matthews and Mike Farrell for their respective presentations. Both presentations were well-received and Micah and Mike were wonderful representatives of the Commission.

Micah Matthews, Deputy Executive Director

Recurring: Please submit all Payroll and Travel Reimbursements within 30 days of the time worked or travelled to allow for processing. Request for reimbursement items older than 90 days will be denied. Per Department of Health policy, requests submitted after the cutoff cannot be paid out. For specific guidance on Commissioner compensation, please refer to the WMC guideline: Compensation and Reimbursement for Commission Duties (wa.gov)

Micah Matthews, Deputy Executive Director continued

Conferences and Presentations

I presented the concept of a practice registry creation at FSMB in Seattle. The presentation was with Dr. Helen Hughes of Johns Hopkins and was received with interest. I am speaking at a telehealth policy summit at Johns Hopkins in mid-May to present the regulatory perspective in their development of a national telemedicine approach.

I am attending the Center for Telehealth and e-Health Law Spring Summit in Washington, D.C. in June. On the agenda are telehealth flexibilities and making those permanent at the federal level. I am also presenting the medical regulatory perspective on a panel addressing the rise in proposals for A.I. practitioners, to include autonomous prescribing.

Recruitment

Kaddijatou Keita (pronounced Kah-dee-jah-two, Kay-tah) will be our new Policy Manager starting May 16. Her first several weeks will focus on orientation with the organization and mandated training. Expect to see her at Interested Parties and Policy meetings going forward.

Legislation

HB 1640, WMC request legislation, was signed b Governor Ferguson in April. This bill added the MD and PA Compacts to the authority of the Uniform Disciplinary Act.

SB 5118, IMG Workgroup proposed legislation, made changes to the Clinical Experience license issued by the WMC was the first bill signed by Governor Ferguson. Notable policy changes in this bill:

- Removal of 12 months of Washington residency
- Removal of USMLE step 3. Step 3 is still required for full licensure

Increased time validity of the license from four years to a maximum of eight years

Amelia Boyd, Program Manager

Change to AMDG Opioid Dose Calculator

In February 2024, the Agency Medical Directors' Group (AMDG) updated the Opioid Dose Calculator. The WMC released a statement for prescribers about this change: Important Updates to the Opioid Dose Calculator and Implications for Prescribers (govdelivery.com)

Recruitment

We are seeking MDs in the following specialties to serve as Pro Tem Members:

- Urology
- Radiology
- Neurosurgery/Neurology
- General surgery

Amelia Boyd, Program Manager continued

- Psychiatry
- Orthopedic surgery

If you know anyone who might be interested in serving as a Pro Tem, please have them email me directly at amelia.boyd@wmc.wa.gov.

The following position expired as of June 30, 2022, and we are awaiting word from the Governor's office staff on the new appointee:

- Public Member – Toni Borlas – not eligible for reappointment

The following positions expired as of June 30, 2023, and we are awaiting word from the Governor's office staff:

- Congressional District 10 – Richard Wohns, MD – eligible for reappointment
- Public Member – Scott Rodgers – eligible for reappointment

The following positions expired as of June 30, 2024:

- One physician representing Congressional District 6 – Claire Trescott, MD, not eligible for reappointment
- One physician representing Congressional District 8 – Harlan Gallinger, MD, eligible for reappointment
- One Physician-at-Large – Karen Domino, MD, eligible for reappointment

The application deadline for these three vacancies was March 22, 2024. The applications, along with the Commissioners' recommendations, are with the Governor.

We will have the following vacancies as of June 30, 2025:

- One physician representing Congressional District 1 – Jimmy Chung, MD, not eligible for reappointment
- One physician representing Congressional District 7 – Anjali D'Souza, MD, eligible for reappointment
- One Physician Assistant – Arlene Dorrough, PA-C, eligible for reappointment
- One Public Member – Christine Blake, eligible for reappointment

The application deadline for these four vacancies was March 31, 2025. The applications, for all but the Congressional District 7 position, are with the WMC's Executive Committee for review.

If you have questions about serving as a member of the WMC, please contact me at amelia.boyd@wmc.wa.gov.

Mike Hively, Director of Operations and Informatics

Between March 1 and April 23, 2025, the Operations and Informatics team received and began processing two compulsory records with a combined total of more than 12,000 pages, 21 CDs, and 16 DICOM files containing multiple images to review. Additionally, we continue to monitor 9 active litigation holds in addition to digital archiving and other daily operational tasks.

Mike Hively, Director of Operations and Informatics continued

Digital Archiving

The following digital archiving activities were completed:

- Complaints closed below threshold 359
- MD licensing applications 118
- PA licensing applications 308
- A Closure 149
- Verification of 564 PA applications for accuracy
- 2,523 Demographic Census forms

Additionally, approximately 3 boxes of hardcopy PA licenses containing 75 applications were scanned into digital format with disposition tickets submitted for the destruction of the paper-based records. Approximately 8 boxes of previously scanned records were destroyed in accordance with WA State Records Retention and WA State Scan & Toss guidelines.

Data Requests Process

The team processed approximately:
845 emails received containing approximately 923 open/closed inquiries
657 address changes

Demographic Activities

Demographic data management included:

- Entering 2,480 census forms into the Integrated Licensing and Regulatory System (ILRS)
- Conducting 1,140 secondary census contacts
- Built quarterly aggregate demographic census reports
- Census data entry quality checks (varies)

The team has begun cleaning up secondary Excel records retention tracking sheets used in lieu of the ILRS data-based entries. This resulted in accurately documenting the locations and/or disposition of approximately 503 additional application files from the previous reporting period.

Lastly, staff continue to process mail and varying I.T. related inquiries for both staff and Commissioners.

Gina Fino, MD, Medical Consultant, Director of Compliance

The March personal appearances went well, and Compliance will schedule several mini appearances after the May meeting. Anthony Elders and I attended the Federation of State Medical Boards in Seattle in April. We enjoyed interacting with many of you in attendance and found the keynote speakers engaging and informative. Mike Kramer kept the compliance unit running in Tumwater. We are happy to announce Mike will graduate from San Jose State University on May 22, 2025, with a master's degree in archives and

Gina Fino, MD, Medical Consultant, Director of Compliance continued

records administration. In other achievements, Amara Elders, honorary compliance officer (Anthony's daughter) enjoys her preschool gymnastics program and has recently started soccer. She loves the game and moves the ball out of beehive formation. Kudos to Mike and Amara!

Rick Glein, Director of Legal Services

Items of Interest:

On March 24, Rick presented to a panel of physicians and staff at the Health Care Authority's monthly meeting. Rick explained the basic operations of the Commission and the disciplinary process. WABON and OILS also sent leaders to discuss their operations.

From April 24 through April 26, the Federation of State Medical Boards held its 2025 Annual Meeting (FSMB AM25) in Seattle. FSMB AM25 brought together experts in healthcare policy and oversight to explore current trends in medical licensure, professional discipline, and patient safety in an effort to help shape the future of regulatory standards. With the meeting being held in the Commission's own backyard, Rick, Mike Farrell, and Gina were excited to experience the networking opportunities, inspiring keynotes, and insightful seminars with a record number of Legal & Compliance staff. Our own Mike Farrell, along with Elizabeth Huntley, JD, CMBE, Executive Director of the Minnesota Board of Medical Practice, presented a Lunch and Learn session titled *Surveying the Diverse Structures and Operations of State Medical Boards,* which discussed differences in state medical boards across the country. Mike Farrell also co-moderated with Frank Meyers, JD, FSMB Deputy Legal Counsel, a breakout forum titled *Role Specific Forums-Board Attorneys*, which considered the roles and responsibilities of board attorneys. Other presentation topics of Legal interest included: *Fostering Critical Thinking in an Age of Information Overload*; *Physician Competency and Capacity to Practice Medicine*; *Building Influence in State and Federal Policy*; *Mitigating Sexual Misconduct through Legislation, Regulation and Education*; *The Evolving Definition of the Practice of Medicine;* and *A.I.'s Transformation of Medicin*e. On Thursday evening, Dr. Domino graciously hosted a gathering of Commissioners and Commission staff with delicious food and spirted chats. The evening fostered a sense of unity and camaraderie, capping the day perfectly.

Freda Pace, Director of Investigations

CMT Sign-up in 2025

We have plenty of CMT vacancies beginning in June 2025. Visit our SharePoint schedule or email Chris Waterman at chris.waterman@wmc.wa.gov for more information. We appreciate your continued participation in this very important process. We could not be able to do this work without you and your support!

Remember, if you sign up for a CMT slot and you have a last-minute scheduling conflict,

Freda Pace, Director of Investigations continued

at your earliest opportunity, please promptly notify Chris or Alex Bielaski at alexander.bielaski@wmc.wa.gov. This courtesy cancellation notice will allow Complaint Intake the opportunity to fill any last-minute vacancy needs.

If you have any CMT process or procedural questions, please do not hesitate to reach out to me directly – freda.pace@wmc.wa.gov.

Jimi Bush, Director of Quality and Engagement

HELMS Update

The Licensing system within HELMS was deployed on 4/29/2025. As of the writing of this report – we have not received major complaints from licensees about the new system. Most issues are connected to logging into HELMS and are resolved immediately. The new system will allow a licensee to check the status of their application / renewal without needing to contact the licensing department. They will also be able to update their own contact information and submit documentation related to their application without the wait times associated with traditional mail and email correspondence.

The enforcement section of the new system will not be available until (at least) the end of the year.

WMC Picture Day

At the May meeting I will be photographing our proceedings so that we can update the website with more recent photos. Please plan accordingly. If you would like your photo taken for your Teams profile or ID badge, just pull me aside.

FSMB Posters

Thank you to all of the volunteers the contributed to the development and editing of our posters: Analyzing Reports of Discrimination in Healthcare and The Practitioner Support Program – an alternative to discipline. The posters were very well received.

Mahi Zeru, Strategy Manager

Reasonable Accommodation Update

Complainants with a documented disability have reported challenges in accessing WMC's complaint intake forms specifically due to physical barriers that prevents them from typing or writing their complaints. Currently, WMC does not allow complaints to be received over the phone and lacks accommodation tools, such as speech-to-text transcription, contributing to this accessibility issue. WMC has contracted with a captioning service agency to provide speech-to-text accommodation service and is ready to assist individuals who need these accommodations. Since its launch in January, we have fulfilled **13** reasonable accommodation requests.

Marisa Courtney, Licensing Manager

Total licenses issued from 03/05/2025-05/01/2025 = 790

Credential Type	Total Workflow Count
Physician And Surgeon Clinical Experience License	2
Physician And Surgeon Fellowship License	3
Physician And Surgeon Institution License	0
Physician And Surgeon License	459
Physician and Surgeon License Interstate Medical Licensure Compact	155
Physician And Surgeon Residency License	74
Physician And Surgeon Teaching Research License	5
Physician And Surgeon Temporary Permit	1
Physician Assistant Interim Permit	3
Physician Assistant License	88
Physician Assistant Temporary Permit	0
Totals:	**790**

Information on Renewals: March Renewals-76.45% online renewals

Credential Type	# of Online Renewals	# of Manual Renewals	Total # of Renewals
IMLC	0	137	137
MD	1167	269	1436
MDRE	2	0	2
MDTR	4	2	6
PA	220	21	241
	76.45%	**23.55%**	**100.00%**

The Opioid Analgesic REMS Program Companies

PDR®

PO Box 1730 • West Caldwell, NJ 07007

Dear Professional Society/Licensing Board Letter #2

March 2025

FDA-Required REMS for Serious Drug Risks

Risk Evaluation and Mitigation Strategy (REMS) for opioid analgesic drug products[1] used in the outpatient setting to address their risks of addiction, abuse, and misuse, which can lead to overdose and death.

Dear **Professional Society/Licensing Board**:

The purpose of this letter is to inform you about the Opioid Analgesic REMS that is required by the U.S. Food and Drug Administration (FDA) for opioid analgesic drug products used in the outpatient setting. We ask you to consider the development and/or distribution of training materials for your healthcare providers (HCPs) and encourage them to utilize the below resources and to successfully complete REMS-compliant training to improve their ability to prescribe and dispense these medications more safely. Under the conditions of the REMS, the following resources are available:

1. Safe Disposal of Unused Opioid Analgesics—Pre-Paid Drug Mail-Back Envelopes

Counseling patients on the options for safe disposal of unused opioid analgesics is a critical component of the Opioid Analgesic REMS to avoid nonmedical use, opioid use disorder (OUD), and overdose. To support the availability of safe disposal systems, opioid analgesic manufacturers are providing pre-paid drug mail-back envelopes that can be given to patients with their opioid analgesic prescriptions upon request to pharmacies and other dispensers that dispense opioid analgesics for outpatient use.

Pharmacies and other opioid dispensing sites can now order pre-paid drug mail-back envelopes via the REMS website, www.opioidanalgesicrems.com, or by calling 1-800-503-0784 starting March 31, 2025.

Disposal options include drug take-back sites or programs and pre-paid drug mail-back envelopes. If these options are not available, the next best option is for patients to immediately flush their opioid analgesics down the toilet. More information on safe disposal methods is available at: www.fda.gov/safe-disposal-medicines.

2. REMS-Compliant Accredited Continuing Education (CE)

REMS-compliant training is a critical component of the Opioid Analgesic REMS and focuses on pain management and creating a pain treatment plan. The FDA developed specific core concepts to be communicated to a broad range of HCPs in the **Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain** ("FDA Blueprint"). This "**FDA Blueprint**" is being used to develop training that includes accredited CE courses or training offered by academic institutions/learned societies. The "**FDA Blueprint**" is available at: https://www.fda.gov/media/173774/download?attachment

Following completion of educational activities under the Opioid Analgesic REMS, HCPs should be knowledgeable about the following.

- The fundamental concepts of pain management, including definitions and mechanisms of pain
- How to assess patients in pain, and identify risk factors for substance use disorders
- The range of therapeutic options for managing pain, including nonpharmacologic approaches and pharmacologic (non-opioid and opioid analgesics) therapies

- How to integrate opioid analgesics into a pain treatment plan individualized to the needs of the patient and evaluate for functional improvement
- How to safely and effectively manage patients on opioid analgesics in the acute and chronic pain settings, including initiating therapy, titrating, and discontinuing use of opioid analgesics
- How to counsel patients and caregivers about the safe use of opioid analgesics, including proper storage and disposal (e.g., drug take-back sites or programs and mail-back envelopes)
- How to counsel patients and caregivers about the use of naloxone for opioid overdose
- When referral to a pain specialist is appropriate
- The fundamental elements of addiction medicine
- How to identify and manage patients with OUD

REMS-compliant accredited CE is available. Visit www.opioidanalgesicrems.com for a listing of available REMS-compliant training.

3. The Opioid Analgesic REMS Patient Guide & Medication Guide

Enclosed with this letter is the **Patient Guide** that was developed under the REMS. It was specifically designed to assist **you** with conducting important conversations about safety with patients for whom an opioid analgesic may be prescribed. It contains important safety information common to the drug products subject to this REMS and options for safe disposal of opioid medicines. The **Patient Guide** should be provided to the patient or their caregiver at the time of prescribing. The **Patient Guide** is also available on the REMS website, www.opioidanalgesicrems.com, or ordered by calling the REMS Call Center at 1-800-503-0784.

Adverse Event Reporting

To report all suspected adverse reactions associated with the use of the opioid analgesics, contact:

- the FDA MedWatch program:
  - — by phone at 1-800-FDA-1088 (1-800-332-1088) or
  - — online at www.fda.gov/medwatch, or
- the pharmaceutical company that markets the specific product

More information about this REMS can be obtained at: www.opioidanalgesicrems.com or by calling the Opioid Analgesic REMS Call Center at 1-800-503-0784.

Sincerely,
The Opioid Analgesic REMS Program Companies

[1] **The branded and generic drug products subject to this REMS include *all*:** a) oral dosage forms of extended-release and immediate-release opioids containing: codeine and codeine analogs, hydrocodone, hydromorphone, levorphanol, meperidine, morphine, oxycodone, oxymorphone, pentazocine, tapentadol and tramadol; b) fentanyl, butorphanol and buprenorphine-containing intranasal, buccal and transdermal delivery systems; and c) methadone tablets and solutions that are indicated for use as analgesics.

What You Need to Know About Opioid Pain Medicines

This guide is for you! Keep this guide and the Medication Guide that comes with your medicine so you can better understand what you need to know about your opioid pain medicine. Go over this information with your healthcare provider. Then, ask your healthcare provider about anything that you do not understand.

What are opioids?

Opioids are strong prescription medicines that are used to manage severe pain.

What are the serious risks of using opioids?

- Opioids have serious risks of addiction, abuse, and misuse, which can lead to overdose.
- **Too much opioid medicine in your body can cause your breathing to stop – which could lead to death.** This risk is greater if you are taking other medicines that make you feel sleepy or people with sleep apnea.
- **Addiction** is when you crave drugs (like opioid pain medicines) because they make you feel good in some way. You keep taking the drug even though you know it is not a good idea and bad things are happening to you. Addiction is a brain disease that may require ongoing treatment.

Risk Factors for Opioid Abuse:

- You have:
  - » a history of addiction
  - » a family history of addiction
- You take medicines to treat mental health problems
- You are under the age of 65 (although anyone can abuse opioid medicines)

- **You can get addicted to opioids even though you take them exactly as prescribed, especially if taken for a long time.**
- If you think you might be addicted, talk to your healthcare provider right away.
- If you take an opioid medicine for more than a few days, your body becomes physically "dependent." This is normal and it means your body has gotten used to the medicine. You must taper off the opioid medicine (slowly take less medicine) when you no longer need it to avoid withdrawal symptoms.

How can I take opioid pain medicine safely?

- Tell your healthcare provider about **all** the medicines you are taking, including vitamins, herbal supplements, and other over-the-counter medicines.
- Read the Medication Guide that comes with your prescription.
- Take your opioid medicine exactly as prescribed.
- Do not cut, break, chew, crush, or dissolve your medicine. If you cannot swallow your medicine whole, talk to your healthcare provider.
- When your healthcare provider gives you the prescription, ask:
  - How long should I take it?
  - What should I do if I need to taper off the opioid medicine (slowly take less medicine)?
- Call your healthcare provider if the opioid medicine is not controlling your pain. Do not increase the dose on your own.
- **Do not share or give your opioid medicine to anyone else**. Your healthcare provider selected this opioid and the dose just for **you**. A dose that is okay for you could cause an overdose and death for someone else. Also, it is against the law.
- Store your opioid medicine in a safe place where it cannot be reached by children or stolen by family or visitors to your home. Many teenagers like to experiment with pain medicines. Use a lock- box to keep your opioid medicine safe. Keep track of the amount of medicine you have.
- Do not operate heavy machinery until you know how your opioid medicine affects you. Your opioid medicine can make you sleepy, dizzy, or lightheaded.

What should I avoid taking while I am taking opioids?

Unless prescribed by your healthcare provider, you should avoid taking alcohol or any of the following medicines with an opioid because it may cause you to stop breathing, which can lead to death:

- Alcohol: Do not drink any kind of alcohol while you are taking opioid medicines.
- Benzodiazepines (like Valium or Xanax)
- Muscle relaxants (like Soma or Flexeril)
- Sleep medicines (like Ambien or Lunesta)
- Other prescription opioid medicines

What other options are there to help with my pain?

Opioids are not the only thing that can help you control your pain. Ask your healthcare provider if your pain might be helped with a non-opioid medication, physical therapy, exercise, rest, acupuncture, types of behavioral therapy, or patient self-help techniques.

What is naloxone?

- Naloxone is a medicine that treats opioid overdose. It is sprayed inside your nose or injected into your body.
- Use naloxone if you have it and call 911 or go to the emergency room right away if:
  - You or someone else has taken an opioid medicine and is having trouble breathing, is short of breath, or is unusually sleepy
  - A child has accidentally taken the opioid medicine or you think they might have
- Giving naloxone to a person, even a child, who has not taken an opioid medicine will not hurt them.

Where can I get naloxone?

- There are some naloxone products that are designed for people to use in their home.
- Naloxone is available in pharmacies. Ask your healthcare provider about how you can get naloxone. In some states, you may not need a prescription.
- When you get your naloxone from the pharmacy, **read the Patient Information** on how to use naloxone and ask the pharmacist if anything is unclear.
- Tell your family about your naloxone and keep it in a place where you or your family can get to it in an emergency.

How should I dispose of the opioid medicine?

When you no longer need your opioid medicine, dispose of it as quickly as possible to avoid any possibility of abuse or misuse by anyone else. The Food and Drug Administration recommends that you drop off your medicine at a drug take-back site or program or mail your medicine using a pre-paid drug mail-back envelope. If you cannot get to a drug take-back location or if a mail-back envelope is not available to you, your next best option is to immediately flush your medicine down the toilet. Find more information about disposal methods here: https://www.fda.gov/drugdisposal

Naloxone is never a substitute for emergency medical care. Always call 911 or go to the emergency room if you've used or given naloxone.

What things should I know about the specific opioid medicine that I am taking?

- Your healthcare provider has prescribed _____ for you. Read the Medication Guide for this medicine, which is information provided by your pharmacy.
- Remember this other important information about your opioid medicine:

Dosing instructions: _____

Any specific interactions with your medicines: _____

_____

What if I have more questions?

- Read the Medication Guide that comes with your opioid medicine prescription for more specific information about your medicine.
- Talk to your healthcare provider or pharmacist and ask them any questions you may have.
- Visit: www.fda.gov/opioids for more information about opioid medicines.

From: Thomas M Green <tomortho@aol.com>
Sent: Tuesday, April 1, 2025 4:15 PM
To: WMC <Medical.Commission@wmc.wa.gov>
Subject: PA News - Medice, Cura Te Ipsum

External Email

Ladies and Gentlemen of the WMC

I would like to commend Ed Lopez, PA-C for his excellent article PA News - Medice, Cura Te Ipsum in your recent publication. It is well written and expresses age old principles of medical professional care. They need to be emphasized repeatedly as increasing forces of regulation, corporate management and financial pressure seem to over ride the fundamental primacy of the patient in medical professionalism. These forces clearly adversely impact the health and welfare of those providing medical care often for the detriment of the patient. Often this manifests itself in poor communication with patients.

This is not a new problem but one that is aggravated by current political and social matters affecting medical practice.
As a past member of the WMC, it was quite clear years ago that the main factor provoking the overwhelming majority of complaints by patients against physicians and PAs was poor communication and unprofessional interaction with the patient. The patient may present the complaint as having to do with some deficiency or error in medical practice when something went wrong. If you are going to practice medicine, things are going to go awry at times through no fault of the physician or PA. That is the most critical time for there to be compassionate caring and effective communication with a patient.

It is good to be reminded of this by Mr. Lopez. Physicians and PAs need to be mindful of this in the face of forces that are making it more difficult. It is important to take care of oneself and continue to seek ways of reforming our health care system that is unduly burdensome and detracting from providing such professional care.

I commend Mr. Lopez on a well written article on a vital subject.

Sincerely,

Tom Green

Thomas M Green MD
Emeritus Physician, Virginia Mason
425-614-5298

www.movementislifecaucus.com

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

April 3, 2025

Sherry Thomas
Policy Coordinator
Health Systems Quality Assurance

Subject: Proposed Expansion of Pharmacist Prescribing Authority Sunrise Review 2025

Dear Ms. Thomas,

Please accept the following written comments regarding the Department of Health (DOH) Sunrise Review process that will examine expanding prescribing by pharmacists.

The Commission regularly works with the Pharmacy Quality Assurance Commission (PQAC). As its colleagues, we value our working partnership. The Commission regularly consults with the PQAC investigators on cases involving medication therapy. The Commission has taken part in a roundtable group within the Department of Health (Department) regarding intravenous hydration therapy with PQAC and their participation is invaluable. There are many other examples of this valued partnership. So, as I voice concerns, please accept the following comments with that background in mind.

In general, pharmacists make immense contributions to public healthcare, but as detailed below, they lack sufficient education and clinical experience in diagnostic reasoning. Also, PQAC lacks the requisite regulatory knowledge and experience to protect the public with the requested expanded prescribing rules.

Authority over scope of practice

The applicant seeks to vest authority over when, how, and under what circumstances a pharmacist could prescribe, which raises significant concerns. In the recent past, the Department has weighed in against sunrise proposals, such as the 2021 Optometry Scope of Practice and the 2024 Naturopathic Physician Scope of Practice where the scope of practice is delegated wholesale by the Legislature to the regulatory body.

Education

Without the multi-modal education from other professions, a far reduced residency and no universal requirements between schools offering pharmacological degrees, their training cannot be considered equivalent to medical doctors. It is not at all clear there are universal standards taught in pharmacy schools with regard to direct patient contact or training in clinical settings. This is in direct contrast with the clear and published accreditation standards for medical schools and residency training programs accredited by the Accreditation Council on Graduate Medical Education. A few examples from the Family Medicine training program, which is the shortest route to full scope licensed practice:

- No fewer than 1,600 unique patient encounters over three years, none of whom may be fellow students or trainees,
- Must be on call seven days per week/24 hours per day for 50 weeks of the year for the three-year duration of the training,
- Demonstration of observed and documented competence on a standardized entrustment scale in solo practice, group practice, and system settings.

A Doctor of Medicine degree (M.D.) includes several aspects that a Doctor of Pharmacy (Pharm.D.) does not. Including but not limited to:

- A highly regulated curriculum on the human body and its systems,
- Didactic courses and clinical training in pharmacology,
- Two years of patient care rotations through different specialties,
- Passage of a standardized, three-part licensing exam,
- Three to five years of accredited residency treating the acutely ill or injured in an emergency room setting,
- Demonstration of competence at the end of the residency, and
- Continued professional oversight that ensures physicians stay current with professional standards and safely incorporate new treatments and medications into their practice.

While the applicant provides examples of courses available at the two Washington schools of pharmacy, there are no examples of standardized curricula. In other words, the state of the modern healthcare workforce draws clinicians from all fifty states and around the globe. There is no information indicating whether the UW and WSU courses are at all universal in nature.

Clinical Experience

Being recognized as a prescriber does not equate to being qualified to provide the full scope of diagnostic services, nor justify scope expansion. Despite the attainment of professional degrees, pharmacists are not front-line providers of direct clinical care, primary or specialized. While overlaps may exist, there are necessary limitations to ensure patient safety. For example, pharmacists do not perform a comprehensive evaluation of a patient's medical history and a physical examination to assess their current health status which can lead to dangerous outcomes if more medication is given without this insight. We already see the dangers of this with lifestyle drug platforms and the patient harm that occurs when fully trained physicians neglect their duty to perform an adequate examination. We do not have any confidence that practitioners with less training, most likely in retail settings not designed for patient care, are used as a supplement for whole person care.

Doctors are responsible for the diagnosis of serious health conditions that may require use of controlled substances while pharmacists cannot diagnose patients. Notably, there is still a prevalence of overdose deaths from prescription opioids. Recent data from the Drug Enforcement Administration (DEA) have indicated a substantial increase in the prescription of amphetamines for adult ADHD, as well as notable misuse of ketamine. Having more non-physicians prescribe medications that have substantial harms including addiction and diversion is a significant public safety concern that goes against the clear intent of the elected leadership of Washington State. While pharmacists have made the argument that more primary care is needed, this expansion will not address that gap. In this era of addiction epidemics, the issue lies not in access to medications, but in the lack of access to knowledgeable care regarding their safe use.

The underlying conditions have evolved in recent years, but the fundamental issues remain regarding training and the significant public health challenges with mitigating addiction and abuse of opioids. Therefore, this request to expand the pharmacist scope of practice does not meet the first criteria for expansion: protecting the public from harm.

Regulatory Knowledge

The applicant was asked to “explain how the proposal ensures practitioners can safely perform the new skill or service.” Their answer was PQAC can regulate independent prescribing by pharmacists outside of collaborative drug therapy agreements (CDTAs). This creates a regulatory issue. PQAC will have to regulate new complaints in areas which they have not practiced, do not have experience reviewing such cases, and have no directly

relevant case law upon which to base even their most basic decisions. They further compare the "lack of state law detailing that a family practice physician should not perform a craniotomy in their clinic" as grounds to have pharmacists self-regulate. This completely ignores the entire medical practice framework in which a surgeon must be given hospital credentialing privileges, board certification, proof of residency and continuing medical education. Additionally, it ignores the clear regulatory history of the WMC taking regulatory action against practitioners performing functions outside of their scope and training. The applicants' lack of awareness regarding the basic function of the health care delivery system itself should raise concerns.

The applicant report implies that the complete removal CDTAs can help to fill the primary care shortages, and that legislation aimed at restrictions on participation in CDTAs would not work. However, this isn't accurate. A more balanced approach would involve refining these agreements, leveraging technological advancements, and ensuring that pharmacists continue to work within a framework that prioritizes patient safety while enhancing their ability to contribute to healthcare delivery. Additionally, the applicant report does not include any data on how many CDTAs exist present or compared to prior years. Absent data, it's difficult to ascertain whether the trend cited in the applicant report exists.

Furthermore, the applicant states that, "pharmacists have pursued a diverse range of physicians to address the shortage of providers willing to sign collaborative agreements. This has led to situations where out-of-state physicians, licensed in Washington, have signed agreements with numerous pharmacies, often turning this practice into a business. In many of these situations, the physicians provide little to no oversight or guidance." The applicant is correct that many CDTAs, especially those used by large chain stores, have turned signing the documents into a business and one that is not in keeping with the intent of the statute. The applicant statement ignores the clear history of CDTAs and the absolute lack of oversight of that tool both by the regulator, employer, and the signatories. Further, past attempts by the WMC to engage with the members of the pharmacy profession to explore avenues of making the CDTA process more meaningful have been met with, at best, skepticism. CDTAs are not simply bureaucratic tools but are essential in defining the scope of pharmacist practice in a way that ensures patient safety and promotes accountability. They should be used as the statute describes: clear scope guidance, appropriate scope expansion, and a quality assurance tool for both the signatories and the public that relies on those expanded services.

Expanding the role of pharmacists in prescribing medications must be done with great caution, ensuring that any changes prioritize patient safety, comprehensive care, and regulatory accountability. The current proposal does not adequately address the gaps in

education, training, and oversight necessary to ensure that pharmacists can safely expand their scope of practice without compromising public health.

Sincerely,

Kyle Karinen, Executive Director
Washington Medical Commission