WASHINGTON

Medical Commission

Licensing. Accountability. Leadership.

Business Meeting

July 19, 2024

Business Meeting Agenda
July 19, 2024

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 Business Meeting will begin at 9:00 am on July 19, 2024, until all agenda items are complete. The WMC will take public comment 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.

Virtual via Teams Webinar: Registration link can be found below.
Physical location: Department of Health, 111 Israel Rd SE, TC2 Rm 153, Tumwater, WA

Time	Friday – July 19, 2024
Open Session	
9:00 am	Business Meeting

To attend virtually, **register** for this meeting at: WMC Rules Hearings & Business Meeting

1.0 Chair Calls the Meeting to Order

2.0 Public Comment

The public will have an opportunity to provide comments. ***If you would like to comment, please limit your comments to two minutes. Please identify yourself and who you represent, if applicable, when the Chair opens the floor for public comment. If you would prefer to submit written comments, send them to amelia.boyd@wmc.wa.gov by April 25, 2024.***

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 be denied. The comment may still be submitted in writing for consideration and awareness.

2.1 The Chair will call for comments from the public.

3.0 Chair Report

4.0 Consent Agenda

Items listed under the Consent Agenda are considered routine agency matters and will be 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 July 19, 2024, Business Meeting agenda. — Pages 2-5

4.2 Minutes – Approval of the April 26, 2024, Business Meeting minutes. — Pages 10-15

5.0 Commissioner Training

5.1 **Open Public Meetings Act** (OPMA)
Heather Carter, AAG, will provide annual training on the OPMA.

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6.0 New Business

6.1 **Appointment to the Interstate Medical Licensure Compact Commission** — Action

Discussion and appointment of a representative to the Interstate Medical Licensure Compact Commission. This commission is responsible for streamlining the licensing process for physicians who wish to practice in multiple states.

6.2 **Appointment to the Physician Assistant Licensure Compact Commission** — Action

Discussion and appointment of a representative to the Physician Assistant Licensure Compact Commission. This commission is dedicated to creating a streamlined and efficient licensure process for physician assistants who wish to practice in multiple states.

6.3 **Grant funding Process for IMG Assistance Programs Process** — Action, Pages 16-17

Micah Matthews, Deputy Executive Director, will provide an overview of this process and request approval.

6.4 **2025 Legislation Request** — Action, Memo begins on page 18

Mr. Matthews will present and request approval on the following:

- Uniform Disciplinary Act Technical Amendment
- Non-Disciplinary License Yield
- Locums Limited License
- WMC Authority Related to Medical Examiners
- Public Records Act Exemption-Licensee Demographic Data

6.5 **2025 Meeting Dates** — Action, Pages (TBD)

Presentation of proposed 2025 meeting dates.
The documents for this item will be added to the packet by July 17, 2024.

7.0 Old Business

7.1 **Committee/Workgroup Reports** — Update

The Chair will call for reports from the Commission's committees and workgroups. Written reports begin on page 22. See page 23 for a list of committees and workgroups.

7.2 **Rulemaking Activities** — Update

Rules Progress Report provided on page 25.

Amelia Boyd, Program Manager, will request the following:

- **Initiate Standard Rulemaking – Opioid Prescribing** — Action, Memo on page 26

  Initiate standard rulemaking regarding the comments received as part of the Commission's current rulemaking regarding opioid prescribing: WSR #23-17-094.
  - The comments for consideration are on pages 27-34.
  - If the request to initiate rulemaking based on these comments is approved, Commissioners will need to discuss the appropriate scope of the rulemaking,

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determining whether its focus should be broad or narrow.

- **Initiate CR-102 – General Provisions for Opioid Prescribing and Tapering for Physicians and Physician Assistants** Initiate the next step in the rulemaking process, CR-102 Proposed Rulemaking, for Physician and Physician Assistant general provisions for opioid prescribing and tapering rules. The CR-101 was filed on August 16, 2023, as WSR #23-17-094. — Action — Memo on page 35 — Draft language on pages 36-45

8.0 Policy Committee Report

Christine Blake, Public Member, Chair, will report on items discussed at the Policy Committee meeting held on June 27, 2024. The agenda was as follows: — Report/Action

8.1 **Procedure: Processing Complaints Against Medical Students, Residents, and Fellows**
The Committee has deferred this document for additional revisions. The document as presented to the Committee is available in the June 27 packet. If you would like to provide feedback on this document, please email medical.policy@wmc.wa.gov.

8.2 **Proposed Policy: Commissioner and Pro Tem Recusal Policy to Address Conflicts of Interest**
The Committee has deferred this document for additional revisions. The document as presented to the Committee is available in the June 27 packet. If you would like to provide feedback on this document, please email medical.policy@wmc.wa.gov.

8.3 **Proposed Policy: Artificial/Assistive/Augmented Intelligence (AI)** — Pages 46-52
The Committee recommended approving this document for DOH Secretary review.

8.4 **Policy:** Telemedicine, POL2021-02 — Memo on page 53
The Committee recommended rescinding this policy.

8.5 **Proposed Policy: Clinical Experience Assessment** — Page 54
The Committee recommended approving this document for DOH Secretary review.
The Clinical Experience Assessment form begins on page 55.

9.0 Member Reports

The Chair will call for reports from Commission members.

10.0 Staff Member Reports

The Chair will call for further reports from staff. — Written reports on pages 60-82

11.0 AAG Report

Heather Carter, AAG, may provide a report.

12.0 Leadership Elections

12.1 Restatement of Nominating Committee Report — Report
Previously announced nominations for the following positions:

- Chair – Karen Domino, MD

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

12.2 Nominations from the floor — Nominations
The Chair will call for other nominations for all positions from the panel of Commissioners.

12.3 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.

13.0 Adjournment of Business Meeting

Informational

Hearing Schedule	Pages 6-7
2024 Meeting Schedule	Pages 8-9

Correspondence

1	Letter from Frank Madura	Page 83
2	Series of documents form Xiulu Ruan, MD	Pages 84-97

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FORMAL HEARING SCHEDULE

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DISCLAIMER: THE BELOW HEARING SCHEDULE IS SUBJECT TO CHANGE.

Hearing	Respondent	Case No.	Location
August 2024			
August 14-16	Siler, Thomas, MD	M2022-366	Virtual
August 19-21	Ilg, Ron, MD	M2022-712	Virtual
August 23	Washington, William, MD	M2021-755	Virtual
August 26-27	Nielson, Alex, MD	M2023-645	Virtual
September 2024			
September 3-4	Hanson, Jason L., MD	M2022-208	TBD
September 9-10	Schumer, David S., MD	M2022-991	TBD
September 20	O'Neill, Jay, PA	M2024-231	TBD
September 23	Olsson, Roger, MD	M2023-379	TBD
September 26-27	Johnson, Lisa, MD	M2023-802	TBD
October 2024			
October 1	Knox, David, MD	M2024-51	TBD
October 7-8	Crandall, Sarah, MD	M2023-887	TBD
October 23-25	Parvataneni, Kesav, MD	M2024-50	TBD

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

Hearing	Respondent	Case No.	Location
November 2024			
November 18-20	Hammel, James F., MD	M2023-493	TBD
November 21-22	Oliver, Richard T., PA-C	M2021-896	TBD

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

2024 Meeting Schedule

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Date & Time	Location	Meeting Type
January 4 **10 am – 11 am**	Virtual	Policy Committee
January 11 **8:30 am – 5 pm**	Virtual	Case Disposition Personal Appearances
January 19 **9am – 11 am**	Virtual	Business
March 7 **8:30 am – 5 pm**	Hilton Garden Inn Olympia 2101 Henderson Park Lane SE Olympia, WA 98501	Case Disposition Personal Appearances
March 21 **10 am – 11 am**	Virtual	Policy: Interested Parties
April 11 **10 am – 11 am**	Virtual	Policy Committee
April 26 **9 am – 11 am**	Virtual	Business
May 2, 2024 **8:30 am – 5 pm**	Hilton Garden Inn Olympia 2101 Henderson Park Lane SE Olympia, WA 98501	Case Disposition Personal Appearances
June 6 **10 am – 11 am**	Virtual	Policy: Interested Parties
June 13 **8:30 am – 5 pm**	Hilton Garden Inn Olympia 2101 Henderson Park Lane SE Olympia, WA 98501	Case Disposition Personal Appearances
June 27 **4 pm – 5 pm**	Virtual	Policy Committee
July 11 **8:30 am – 5 pm**	Virtual	Case Disposition Personal Appearances
July 19 **9 am – 11 am**	Virtual	Business
September 5 **10 am – 11 am**	Virtual	Policy: Interested Parties
September 12 **8:30 am – 5 pm**	Capital Event Center 6005 Tyee Drive SW Tumwater, WA 98512	Case Disposition Personal Appearances

Updated: June 5, 2024

Date & Time	Location	Meeting Type
September 26 **4 pm – 5 pm**	Virtual	Policy Committee
October 4 **8:00 am – 5 pm**	Radisson Seattle Airport 18118 International Blvd. Seattle, WA 98188	Commissioner Retreat
October 11 **9 am – 11 am**	Virtual	Business
November 14 **8 am – 5 pm**	Virtual	Case Disposition Personal Appearances
December 5 **10 am – 11 am**	Virtual	Policy: Interested Parties

Business Meeting Minutes
April 26, 2024

WASHINGTON Medical Commission
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Virtual Meeting via Teams Webinar
Link to recording: https://youtu.be/KlfGDgIlgEE?si=xuVYeggzXMaPm8X_

Commission Members

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

WMC Staff in Attendance

Colleen Balatbat, Staff Attorney
Jennifer Batey, Legal Support Staff Manager
Anjali Bhatt, Bus. Practices & Productivity Manager
Alexander Bielaski, Case Manager
Amelia Boyd, Program Manager
Renee Bruess, Investigator
Kayla Bryson, Executive Assistant
Jimi Bush, Director of Quality & Engagement
Adam Calica, Chief Investigator
Emily Cason, Licensing Specialist
Carmen Challender, Health Services Consultant
Marisa Courtney, Licensing Manager
Joel DeFazio, Staff Attorney
Sylke Dixon, IMLC Licensing Specialist
Kelly Elder, Staff Attorney
Anthony Elders, Compliance Officer
Mike Farrell, Supervising Staff Attorney
Gina Fino, Director of Compliance
Ryan Furbush, Paralegal
Rick Glein, Director of Legal Services
Mike Hively, Director of Operations & Informatics
Jenelle Houser, Investigator
Meghan Howell, Health Services Coordinator
Ken Imes, Information Liaison
Kyle Karinen, Executive Director
Shelley Kilmer-Ready, Legal Assistant
Pamela Kohlmeier, MD, JD, Staff Attorney
Mike Kramer, Compliance Officer
Lisa Krynicki, Staff Attorney
Joanna Mallard, Health Services Coordinator
Emma Marienthal, Licensing Lead
Stephanie Mason, PR & Legislative Liaison
Micah Matthews, Deputy Executive Director
Joe Mihelich, Health Services Coordinator
Lynne Miller, Paralegal
Fatima Mirza, Program Case Manager
Marne Nelson, Investigator
Taylor Bacharach-Nixon, Administrative Assistant
Freda Pace, Director of Investigations
Ariel Pierpoint, Renewal Specialist
Stormie Redden, Legal Assistant
Chris Waterman, Complaint Intake Manager
Mahi Zeru, Equity & Social Justice Manager

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Others in Attendance

Akanksha Arora
Amy Brackenbury
Angela Ross, ND, Executive Director, Washington Association of Naturopathic Physicians
Marlon Basco-Rodillas, Dept. of Health (DOH)
Heather Carter, Assistant Attorney General
Patrick Delaney, MD
Billie Dickinson
Chelsea Hager
Tessa Harvey, DOH
John Hebert, Dept. of Social & Health Services
Maria Higginbotham
Jason Hussey
Rommie Johnson
Shannon Klein
Susan Kvern
Dr. Nikzad
Susan Olson
Gina Robertshaw
Sjardo Steneker
Ledeane Stewart
Duane Whitaker

1.0 Call to Order

Karen Domino, MD, Chair, called the meeting of the Washington Medical Commission (WMC) to order at 9:03 a.m. on April 26, 2024.

2.0 Public Comment

Maria Higginbotham, thanked the WMC for their revisions to the opioid prescribing guidelines. She stated that adding patients with Sickle Cell Disease to the list of those that are excluded from the opioid prescribing rules is "awesome" and requested the WMC consider excluding patients with other rare diseases.

Susan Olsen, a chronic pain patient, asked that the WMC keep patients in mind when making changes to the opioid prescribing rules and guidelines.

3.0 Chair Report

Dr. Domino reported she recently attended the annual Federation of State Medical Boards meeting. She stated that one major issue that was presented was the demographic shift leading to a diminishing physician workforce over the next 10 years, prompting some states like Tennessee to allow internationally trained physicians to practice. There was also concern over unlicensed individuals providing IV therapies, with a reported death in Texas from a large dose of potassium. Additionally, there was a discussion on how to reduce stress for healthcare providers under investigation, with suggestions including providing perspective on the investigation process.

Rules Hearings

At 9:15 am the Business portion of the meeting was suspended to conduct the following rules hearings:

- General provisions for opioid prescribing – WSR #24-07-106
  - This hearing concluded without adopting any rules. Additional workshops to be held for this rulemaking.
- Postgraduate medical training for physicians – WSR #24-07-107
  - These rules were adopted. Permanent Rules, the next step in the rulemaking process, will be finalized shortly, and they will soon become effective.

At 10:24 am the Business meeting reconvened.

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4.0 Consent Agenda

The Consent Agenda contained the following items for approval:

4.1 Agenda for April 26, 2024.

This item was pulled from the consent agenda at the request of Amelia Boyd, Program Manager. Ms. Boyd requested the Outstanding Performance Awards be added to New Business as item 5.5.

***Motion**:* The Chair entertained a motion to approve this addition to the agenda. The motion was seconded and approved unanimously.

4.2 Minutes from the January 19, 2024, Business Meeting

***Motion**:* The Chair entertained a motion to approve the January 19, 2024, business meeting minutes. The motion was seconded and approved unanimously.

5.0 New Business

5.1 Joint Operating Agreement

Kyle Karinen, Executive Director, gave some background on the Joint Operating Agreement. In summary: The WMC, along with other disciplinary authorities, operates quasi-independently within the Department of Health (DOH), with authority over its budget and direct communication with the legislature. They rely on the department for support with administrative tasks. The joint operating agreement between the WMC and DOH defines their roles and expectations, with a major change regarding Public Records Act requests. The WMC has negotiated the ability to handle these requests ourselves, as we handle a significant portion of them and have had concerns about the DOH's handling of requests. This agreement has been heavily negotiated and has taken a long time to finalize, with the chair of the WMC and the Secretary of DOH signing off on it.

Dr. Domino opened the floor for the Commissioners to discuss this item.

***Motion**:* The Chair entertained a motion to accept the Joint Operating Agreement as presented. The motion was seconded and approved unanimously.

5.2 Bylaws

Mr. Karinen stated that the Executive Committee met virtually on April 1st to discuss amending the bylaws related to the election of WMC leadership. The current bylaws, based on an older version of the WMC's calendar, have become untenable since moving to quarterly business meetings. The Executive Committee recommended that the nominating committee make its recommendations at the second business meeting of each calendar year, and that the election of officers occur at the conclusion of the third business meeting of each year, with new officers assuming their roles immediately thereafter. These changes are being submitted for review and approval.

Dr. Domino opened the floor for the Commissioners to discuss this item.

***Motion**:* The Chair entertained a motion to approve the Bylaws as presented. The motion was seconded and approved unanimously.

5.3 Nominating Committee

Dr. Jimmy Chung, Committee Chair, announced the candidates for the following leadership positions:

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- Chair – Dr. Karen Domino
- Vice Chair – Dr. Terry Murphy
- Officer-at-Large – Ed Lopez, PA-C

The election of leadership will take place at the July 19, 2024, Business meeting.

5.4 Approved Entities for Accreditation or Certification of Facilities for Office-Based Procedures Under WAC 246-919-601 Requests

As directed by WAC 246-919-601, the WMC reviews requests from accrediting entities to accredit or certify facilities where physicians perform surgical procedures in office-based settings requiring moderate sedation or analgesia, deep sedation or analgesia, or major conduction anesthesia. The WMC then approves or denies these requests for inclusion on the list of approved accrediting entities. The following accrediting entity requested to be added to list:

The Accreditation Commission for Health Care (ACHC)

***Motion**:* The Chair entertained a motion to approve adding ACHC to the list of approved accrediting entities. The motion was seconded and approved unanimously.

The following approved accrediting entity is no longer in business. Amelia Boyd, Program Manager, requested the entity be removed from the list:

Institute for Medical Quality (IMQ)

***Motion**:* The Chair entertained a motion to remove IMQ from the list of approved accrediting entities. The motion was seconded and approved unanimously.

The following item was added to the agenda under item 4.1.

5.5 Outstanding Performance Awards

Mr. Karinen presented the awards as follows:

- Administrative/Licensing Staff – Emma Marienthal, Licensing Lead
- Investigative Staff – Marne Nelson, Investigator
- Legal Staff – Lynne Miller, Paralegal

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.

6.2 Rulemaking Activities

The rulemaking progress report was provided in the meeting packet. In addition to the written report the following requests were made:

- Initiate standard rulemaking in response to SB 5184 Concerning licensure of certified anesthesiologist assistants

  ***Motion**:* The Chair entertained a motion to initiate standard rulemaking. The motion was seconded and approved unanimously.

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- A committee be set up for certified anesthesiologist assistants rulemaking. The following Commissioners volunteered to be members of this committee:

  Dr. Domino
  Dr. Chung
  Dr. Diana Currie

- Initiate CR-105, expedited rulemaking, in response to ESHB 2041 Concerning physician assistant collaborative practice.

  ***Motion**:* The Chair entertained a motion to initiate expedited rulemaking. The motion was seconded and approved unanimously.

- Initiate CR-105, expedited rulemaking, to do some technical edits to WAC 246-919-945 and WAC 246-918-895.

  ***Motion**:* The Chair entertained a motion to initiate expedited rulemaking. The motion was seconded and approved unanimously.

- Initiate CR-102, proposed rules, regarding Second Substitute House Bill 1009 Concerning military spouse employment. Proposed revisions to WAC 246-918-076 (physician assistants) and WAC 246-919-397 (physicians).

  ***Motion**:* The Chair entertained a motion to initiate the CR-102, proposed rules. The motion was seconded and approved unanimously.

7.0 Policy Committee Report

Christine Blake, Public Member, Policy Committee Chair, reported on the items discussed at the Policy Committee meeting held on April 11, 2024. The agenda was as follows:

Guidance Document: Medical Records: Documentation, Access, Retention, Storage, Disposal, and Closing a Practice
Ms. Blake presented the amended document, stating that the Committee recommended its approval as amended. She then asked Dr. Kohlmeier to explain the amendments, which Dr. Kohlmeier proceeded to do. Dr. Kohlmeier also provided some history about the document.

> ***Motion**:* The Chair entertained a motion to approve the document as amended. The motion was seconded and approved unanimously.

Procedure: Compensation and Reimbursement for Commission Duties
Ms. Blake presented the amended document, stating that the Committee recommended its approval as amended. She then asked Dr. Kohlmeier to explain the amendments, which Dr. Kohlmeier proceeded to do. Mr. Matthews also spoke about the cut-off dates for reimbursement requests nearing the end of the fiscal year.

> ***Motion**:* The Chair entertained a motion to approve the document as amended. The motion was seconded and approved unanimously.

Procedure: Processing Complaints Against Medical Students, Residents, and Fellows
Ms. Blake stated this document has been deferred and will be presented at a future meeting.

Proposed Procedure: Approving Accrediting Entities to Accredit or Certify the Use of Anesthesia in Office-Based Surgical Settings
Ms. Blake

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Change to Policy Committee Meeting Day/Time
Ms. Blake stated the Committee has changed the time of their meetings from 10 am to 4 pm.

Policy Development Request: Recusal
Ms. Blake stated the Committee approved developing a policy regarding recusal.

Policy Development Request: Artificial Intelligence
Ms. Blake stated the Committee approved developing a policy regarding artificial intelligence.

8.0 Member Reports

No member reports were provided.

9.0 Staff Reports

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

Mr. Matthews gave an update to the Physician Assistant Compact and stated that Oklahoma has now joined the Compact.

10.0 AAG Report

Heather Carter, AAG, had nothing to report.

11.0 Adjournment

The Chair called the meeting adjourned at 11:37 am.

Submitted by

Amelia Boyd, Program Manager

Karen Domino, MD, Chair
Washington Medical Commission

Approved July 19, 2024

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Grant funding Process for IMG Assistance Programs

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Purpose

This process is used by the Washington Medical Commission (WMC) to award grants to entities that provide career guidance and support services to international medical graduates (IMG). Support services can include assistance with exam preparation for the United States medical licensing examination (USMLE) and clinical programs that provide supervised clinical training for IMG. For more information, please see *Section 3 of S.B. 6551, 66th Leg., 2020 Sess.*

Process Owner

Fatima Mirza, Program Case Manager

Process

Step	Description
1	The WMC advertises that grant funding is available for International Medical Graduate (IMG) support to organizations that are potentially eligible for a grant
2	An Applicant either: • Sends an email asking about grant funding for the IMG program, or • Submits an application for grant funding
3	The Program Contract Manager (PCM) checks this inbox each day and responds to inquiries within one business day
4	**Decision Point:** (Program Contract Manager) Did the Applicant submit a grant application? • If so, go to step 4 • If not, then the PCM asks the Applicant to submit an application via email. Go to step 2.
5	The PCM or the Program Case Manager takes the application to the DOH IMG Workforce Group for evaluation
6	The DOH IMG Workforce Group evaluates all the applications and makes a decision to award funding to an Applicant
7	**Decision Point:** (PCM) Is a new contract needed? • If so, go to step 8 • If not, go to step 10
8	The PCM sends a request for a new contract number to the DOH Contracts team • The subject line should read: New contract number The email must include the following information: • Contractor name • Brief purpose statement • General dollar amount • PCM's name • Division
9	The DOH Contracts team sends a new contract number to the PCM within three days • If a new contract number is not received within three days, the PCM sends a reminder email with the communication details listed in step 8 • The PCM should include the new contract number in all internal correspondence moving forward

10	The PCM prepares the Contracts Processing Action Request (CPAR) packet
	• Resources available
	  • Contracts link
	  • Grants management link
	  • Fiscal Monitoring link
	
	The CPAR packet should include:
	• A completed CPAR form
	• An SOW
	• Other office approvals and reviews, which should be attached to the email
	  • FMU determination email
	  • WMC leadership approval (email thread)
	  • Budget approval (email thread)
	• Other specific documentation as needed (i.e. FFATA, FGIS, etc.)

11	The Program Contracts Manager sends the SOW to the Fiscal Monitoring Unit for a determination of whether the Applicant is classified as a contractor or a subrecipient. • For more information, please see FMU contractors and subrecipients **Decision Point:** (FMU) Is the Applicant classified as a subrecipient? • If so, the PCM must send the entire CPAR packet for confirmation of determination via email. • If not, go to step 12
12	The PCM sends the CPAR packet to DOH Contracts
13	**Decision Point:** (PCM) Was the CPAR packet approved? • If so, go to step 14 • If not, the PCM would work with the DOH Contracts Unit to determine the next steps. **End of process.**
14	The PCM sends the CPAR packet to the Program Finance Operations Manager (PFOM) • The PFOM is Sheryl Hilt. She handles the WMC Budget at DOH
15	**Decision Point:** (PFOM staff) Is the CPAR packet approved? • If so, go to step 16 • If not, the PCM would work with the PFOM office to determine the next steps. **End of process.**
16	The PCM checks the status of the CPAR packet by using ECMS and the Contract log on SharePoint • If the PCM has any questions, they can submit their inquiries to the DOH Contracts Unit
17	The DOH Contracts Unit sends completed contracts out for signature via email • The contracts are sent using Adobe Sign and include specific instructions to the contractor • Those listed in 1A on the CPAR will be cc'd and receive an email when sent and fully executed
18	The PCM monitors the timeliness of signatures and full execution
19	The parties fully execute the contract
20	The PCM uploads the fully executed document and CPAR packet to ECMS and notifies the Office of Grants and Accounting

Last updated

July 2024

2025 Legislation Memo

WASHINGTON Medical Commission
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Request Legislation Authorization and Notification

In this package before you, there are two requests of you as commissioners.

1. Review and approve those policy efforts classified as request legislation;
2. Review for awareness policy efforts being put forward by the International Medical Graduate Workgroup.

As part of the legislative development process, the WMC is required to approve any legislation being requested in the name of the organization. These bills are called Agency Request Legislation and the WMC is the primary proponent behind their passage. Due to timelines established by the DOH, OFM, and the Governor's Office, the WMC must approve the legislative concepts to allow staff to move forward with development and stakeholder engagement. WMC approval at this juncture does not guarantee the proposals will be approved by the Governor's Office to move forward.

Items needing approval

- **Uniform Disciplinary Act Technical Amendment**
  - When the Medical License Compact was passed in 2017, an error occurred in the drafting where the new license type was not listed under the comprehensive list of professions in the Uniform Disciplinary Act RCW 18.130.040. We are requesting that all licenses issued by the WMC be listed explicitly to guarantee application of the UDA. This became more urgent with the passage of the PA Compact and Certified Anesthesiologist Assistants in 2024.

- **Non-Disciplinary License Yield**
  - The WMC has historically had a desire to create a pathway for a licensee to yield their license back to the Commission without the need for any kind of formal or informal administrative document (AO or STID). This proposal would grant the WMC rulemaking authority to create the pathway for yielding back the license and property right to the Commission so long as conditions were met. Examples of such conditions are no active complaints, investigations, or discipline and completion of a form to satisfy notice and due process for relinquishing the rights associated with the license.

- **Locums Limited License**
  - As mobility and workforce needs have intensified in recent years, the Licensing Unit has fielded requests to create a locums specific license type. This license, authorized in law but defined in rule, would provide an expedited limited license to practice that is a single use. We would expedite the process by specifying certain validations would be required for attestation and complete after the issuance of the license with the ability to rapidly

revoke the license should the new license fail to complete the requirements in the specified amount of time. This would also apply should the information attested to, such as out of state actions, not reflect accurately the information provided to the WMC. We currently provide this expediting feature for military spouse applicants.

- **WMC Authority Related to Medical Examiners**
  - The WMC has had several recent experiences in attempting to regulate Medical Examiners (MEs) licensed as MDs. Our authority is opaque in some ways due to lack of clear standards of accountability. However, the greater issue is the Medical Practice Act and the Uniform Disciplinary act assume there is a living patient under the care of the licensee. Obviously, that is never the case with an ME. To respond to this quirk of the law, the specifics of the specialty, and the needs of decedent families, this proposal would remove the WMC from responsibility of regulating the specialty in favor of the courts. The proposal would allow for families to challenge cause and manner of death determinations made by MEs through a court-based process and the appointment of a Special Master or subject matter expert, likely another ME. This would provide all parties equal footing to challenge findings while not relying on a judge without any substantive knowledge of the practice to make determinations.

- **Public Records Act Exemption-Licensee Demographic Data**
  - The Public Records Act in Washington State was originally instituted by public initiative in the 1970's and has been revised for clarification and adding exemptions to the act over the years. There is a standing "Sunshine Committee" that reviews all exemptions to the act in law to determine if they are still relevant. The result is Washington is considered a "sunshine state" where most records generated or held by the state are considered releasable with or without redaction. The point of this background is to explain the existing state policy relating to public records and to provide temporal awareness.

    Currently, personal information related to WMC licensees is almost entirely releasable to any requestor. The notable exemptions are certain elements of Personally Identifiable Information or PII which includes SSN, home phone number, and home address. While this would largely be a non-issue in the 1970's, the current state of having broad access to powerful computing platforms, algorithms to process large data sets, AI tools to merge disparate data sets, and the unrestricted access to licensee personal and demographic information necessitates reconsideration of what information regarding licensees should be broadly released. This risk to licensees is compounded by the increasingly savvy interest groups and out of state governmental actors who wish to impose their state policies and ideologies on Washington licensees and in some cases Washington patients.

    With these concerns and background, this proposal would establish two exemptions to the Public Records Act:
    - A wholesale prohibition on the WMC releasing any and all medical records, with the direction that record should be obtained from the person or entity who created them.

    - A prohibition on release of any demographic or personal information related to WMC licensees through the public records act. This includes practice information

such as location, specialty, race/ethnicity, or any other PII specified in the bill. While this proposal would restrict the release of this data through the public records act, I note that two other routes exist for access to this information: the Lists and Labels process and Data Sharing Agreements (DSAs). DSAs are crafted by staff as part of administrative oversight and management of the WMC owned information. Examples include state professional associations, state specialty associations, other state agencies, and ad hoc or legislative directed studies. The most recent example is the information we shared with the Latino Physician Health Coalition at UW which resulted in several successful legislative efforts over the past three years.

Items for notification

The following items are recommendations from the IMG Workgroup going forward in their current report for Legislative consideration for the 2025 session. Please submit any comments to Micah Matthews via email.

- **Clinical Experience License Revision**
    - The WMC Clinical Experience License was created by House Bill 1129 in 2021. At the time and presently, the approach is novel and has shown some success in its intent of getting IMGs recent clinical experience in preparation for residency application. Based on feedback from the IMG advocates, some modifications alignment is necessary to make the license type more applicable to the various pathways being developed for IMG integration in the Washington health care system. The proposed changes are to remove the twelve-month Washington residency requirement and remove the requirement for USMLE step 3 passage to better align with requirements of ECFMG certification. Additionally, and after consultation with stakeholders employing these license types, a request to extend the license duration from four to eight years to allow for flexibility of remediation and alignment with certain board eligibility programs being developed with IMGs in mind. Finally, language clarifying the role, scope, and appropriateness of this licensee to be credentialed, bill insurance, and covered by malpractice is proposed.

- **IMG Dedicated Residency Positions**
    - This proposal is dependent on a state-wide innovation waiver from the all-in policy required by the National Residency Matching Program. The waiver would allow the state to fund, at a level to be determined by the Legislature, residency positions that feature an IMG holding a Clinical Experience license conducting a transition year before successfully matriculating into the residency proper. NRMP has stated that before they will consider granting the state a waiver, that there must be statute for them to rely on. As such a null and void clause will be attached to this proposal should NRMP deny the request.

- **Apprenticeship Pathway for IMGs**
    - The IMG Workgroup has discussed, approved, and submitted as a policy recommendation to create a pathway to full and independent practice for IMGs that is not dependent on a residency specifically. Instead, the pathway would require satisfying all elements of the Clinical Experience license process (ECFMG, USMLE 1 and 2, background checks) and complete a minimum of four years of supervised clinical practice in a clinic setting with three or more full time physicians on site delivering patient care within the same

specialty. Upon completion of satisfactory clinical assessments by their supervisors and the curricula required, the IMG must pass USMLE step 3 and become board certified by the American Academy of General Practice or board eligible by any ABMS recognized board. Once these are completed the IMG will become eligible for a full MD license under 18.71. Of note, this proposal contains several other items of interest:

- Creation of a hardship waiver pathway for those applicants who may be refugee status or face persecution in their home country. The WMC retains sole discretion on authorizing an applicant for the process and determining appropriate pathways of skill evaluation.
- Creation of an evaluation process in rule for the exceptionally qualified IMG applicant who may only require an abbreviated assessment process to determine skill set. A similar program exists in certain provinces of Canada.
- Adds recognition of Canadian medical schools and exams as equivalent in advance of the cessation of accreditation of same by the LMCC on July 1, 2025.

Committee/Workgroup Reports:
July 19, 2024

High Reliability Organizations Workgroup – Chair: Dr. Chung Staff: Mike Farrell
No updates to report

Healthcare Disparities Workgroup – Chair: Dr. Currie Staff: Kyle Karinen
The New York Times published a piece several weeks ago about professionalism in medicine. ("The Unbearable Vagueness of Medical 'Professionalism'", March 19, 2024.) There were several aspects of this article that were concerning. Among those aspects, the following caught my attention: "In 2015-16, 20 percent of trainees dismissed from their residency were Black, although Black students make up only 5 percent of residents, according to unpublished data from the Accreditation Council for Graduate Medical Education, or A.C.G.M.E." I recommend this article to all of the Commission members. There has been some research into the impact of racial underrepresentation in the physician and physician assistant professions and the subsequent impact on access to medical care. On the staff side, we are convening a group of staff to discuss some of the implications raised by this piece and review the Commission's guidance document on medical professionalism. Medical Professionalism (wa.gov) The plan is to then bring staff feedback at least initially to this workgroup for an initial discussion. If revisions are recommended for the guidance document, then we will work through the Policy Committee.

Committees & Workgroups

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Amelia Boyd

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Christine Blake, PM
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Mahi Zeru, Equity & Social Justice Manager

Panel L
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Christine Blake, PM
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Dr. Lyle
Dr. Wohns
Dr. Trescott
Dr. Browne, Pro Tem
John Maldon, PM, Pro Tem
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Nominating Committee
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Arlene Dorrough, PA-C
Dr. Jaeger

Updated: May 2, 2024

Committees & Workgroups

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Joel DeFazio, Staff Attorney
Amelia Boyd
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Certified Anesthesiologist Assistants Rule
Dr. Domino
Dr. Currie
Dr. Chung
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Heather Carter, AAG
Marlon Basco-Rodillas, Policy Analyst

Please note, any committee or workgroup that is doing any interested parties work or getting public input must hold open public meetings.

PM = Public Member

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	CR-101 filed	7/22/2020	Waiting on the results of the workgroup	NA		Complete	TBD	TBD	NA
General provision for opioid prescribing and tapering	Present revised draft at business meeting for CR-102 approval	7/19/2024	Hearing	Tentative - 10/11/2024		Complete	TBD	TBD	NA
HB 1009 Military Spouse	CR-102 approved	4/26/2024	Submit CR-102 docs	July 2024	Keep BoMS updated	Complete	August 2024	TBD	NA
OBS - Use of Nitrous Oxide, WAC 246-919-601	CR-101 filed	5/17/2024	First workshop	7/31/2024	Keep BoMS updated	May 2024	TBD	TBD	NA
ESSB 5389 - Define Qualified Physician	CR-101 approved	10/20/2023	Submit CR-101 docs	TBD	Waiting on Board of Optometry rulemaking. Keep BoMS updated.	TBD	TBD	TBD	NA
SB 5184 - Anesthesia Assistants - New Profession	CR-101 approved	4/26/2024	Submit CR-101 docs	July 2024		TBD	TBD	TBD	NA
2041 PA Collaborative Practice	CR-105 signed	7/11/2024	File CR-105	July 2024		NA	NA	September 2024	July 2024
Technical edits to WAC 246-919-945 and WAC 246-918-895	CR-105 signed	7/11/2024	File CR-105	July 2024		NA	NA	September 2024	July 2024

Updated: 7/12/2024

Memo

WASHINGTON Medical Commission
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To: **WMC Commissioners**

From: **Amelia Boyd, Program Manager**

Subject: **Rulemaking Authorization Request-Opioid Prescribing**

During the rulemaking for "General provisions for opioid prescribing and tapering," CR-101 filed as WSR #23-17-094, the Commission received several comments. At the June 4, 2024, rules workshop, the panel of Commissioners decided to request initiating rulemaking to address these comments. The comments are available in this meeting packet and should be reviewed and discussed to determine whether the Commission should proceed with rulemaking.

If the request to initiate rulemaking based on these comments is approved, Commissioners will need to discuss the appropriate scope of the rulemaking, determining whether its focus should be broad or narrow. If a narrow focus is preferred, Commissioners will need to specify the specific elements that should be addressed as part of the rulemaking.

Public Comments

Pulled from this site on May 29, 2024:
https://wmc.wa.gov/rule_making_2023/physicians-and-physician-assistants-general-provision-opioid-prescribing-and

Savanna (not verified)-*Sep 10, 2023 08:53 AM*

Hello, thank you for taking the time to hopefully read my email. I have had chronic back pain for 4 years now. What I have experienced with trying to get answers and treatment through this process is beyond disturbing to me. The medical field discriminates and is down right abusive to chronic back pain. The first thing I would like to address is being forced to have procedures or refusal of treatment of any kind. If you go to a pain management in this state with chronic back pain you are automatically pushed to do spinal injections. I am going to paste below what the FDA has on the website and encourage you all to look it up for yourself. The U.S. Food and Drug Administration (FDA) is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. The injections are given to treat neck and back pain, and radiating pain in the arms and legs. We are requiring the addition of a Warning to the drug labels of injectable corticosteroids to describe these risks. Patients should discuss the benefits and risks of epidural corticosteroid injections with their health care professionals, along with the benefits and risks associated with other possible treatments. Injectable corticosteroids are commonly used to reduce swelling or inflammation. Injecting corticosteroids into the epidural space of the spine has been a widespread practice for many decades; however, the effectiveness and safety of the drugs for this use have not been established, and FDA has not approved corticosteroids for such use. We started investigating this safety issue when we became aware of medical professionals' concerns about epidural corticosteroid injections and the risk of serious neurologic adverse events.1 This concern prompted us to review cases in the FDA Adverse Event Reporting System (FAERS) database and in the medical literature (see Data Sum Now when I state this to doctors I am told this is a lie. That these injections are FDA approved. When I say we'll I don't feel comfortable and don't want to do them. I am met with aggression and am automatically treated like a drug seeker. First of all lieing to a patient is not right! I should be able to trust my providers and know the risks of procedures that are being pushed on me. Now let's get to the second thing that is pushed on back pain patients in this state. Cymbalta- if you do not know much about this medication I would again encourage you to do your research. It is being pushed by all your providers. Cymbalta has has hundreds of law suits filed against it. For severe withdrawal symptoms that last months. It literally causes brain zaps. There are literally rehabs to get off this medication and support groups. Again when I state this to the pain doctor I saw he got hostile. Told me that chronic pain support groups were for bitter people. Said he would never prescribe something that would cause such things. Again please do your research on this medication. Treatment for chronic back pain. When I started PT they spasmed and threw my back out so bad I was stuck hunched over couldn't move without severe pain. I called my primary care which was booking out over a month. So me not knowing what do do went to my normal urgent care where I have been taking my kids for years. The provider walked in and her exact words were why are you here what do you want me to do for you we don't give meds! I was confused I went here because I had no idea what was going on what the physical therapist

had done to me and was scared. She told me to go home and wait for my primary care appointment. Within 3 days the pain got worse I couldn't shower myself my left side was going numb so I then went to the ER. Again I got a lovely greetings from a provider that started to lecture me. He told me I was not allowed to go to the ER unless I was peeing myself or could not control my bowels. Said they won't do an MRI otherwise and they don't give meds. My mother who is a nurse case Manager in DC had to fly down to help me take care of my children and bathe me while I waited for my primary care appointment. I has a person had never felt so helpless in my entire life. I learned really quick that I was no longer treated as a person but a chronic pain patient. I learned to research everything that was being pushed on me. I am going to counseling for PTSD like symptoms now anytime my pain hits a level 6. I know I will be left bed ridden screaming in pain when my back goes out. Imagine having pain as bad as labor pains for a month and just having to lay like that knowing if you take all the strength you have left to try and see a provider you will get screamed at. I don't want to be on any medication daily all medications have side effects and withdrawals Nerve meds, antidepressants, steroids, anti- inflammatory, pain meds, muscle relaxers. I should be able to have pain medication for acute flare ups and severe back pain. I have had chronic pain for Four years now I have learned to live with it and except this is what life has thrown at me. I love my life even with the things I cannot do but I want to be able to live it. I need to work remotely as I cannot stand walk or sit for more then 1-3 hours at a time. Yet I cannot get pain control to even go do in-person training to get a remote position. If I'm in a bad flare up and my kiddos have a sport tournament or dance recital I should be able to have pain control to attend the event. Those are the little things that make the struggles worth it. Yet I have to either leave earlier or go to the bathroom and cry instead of injoy seeing my kids grow. If my back goes completely out I should not be left unable to move shower for days dress myself. It's unhuman and down right wrong. I understand that pain meds when taken long term can make you think your in more pain then you actually are. I understand when taken daily they cause withdrawal just like everyother med given for chronic pain. You guys set up the rules so we are forced to have monthly injections or have to take daily meds like Lyrica or cymbalta with dangerous withdrawal there even known to cause brain damage. Instead of being able to take 5 to 10 low dose pain meds a month to manage bad days and give a better quality of life. I have now lived on aleve and Tylenol daily for 4 years do you know what that is doing to my body my stomach my liver. How can you really promote what you are doing. You are causing depression, you are causing more health issues by restricting and taken away pain medication. Thank you for listening and I really hope you create a change. I fight as my son has identical back issues as I do. I hope to help change things before he hits 30s and has my issues. I could never imagine my child being left to suffer as I have and pray daily things will change. Kind Regards, Savanna

JEANNE A ROSNER (not verified)-*Sep 20, 2023 04:22 PM*

Sorry if I missed it... Do these rules for PAs and MDs exclude the prescribing of a long acting opiate e.g. methadone, or a schedule iii medicine such as buprenorphine, when used in the treatment of opiate addiction in an outpatient facility that complies with the SAMHSA regulations for distribution? Otherwise in agreement. Thanks.

Yvonne Helmick (not verified)-*Sep 22, 2023 04:24 PM*

Washington patients suffering from rare diseases and medical conditions that cause intractable pain have suffered tremendous harms because physicians fear legal retribution for treating pain patients. Patients have been abandoned or forced tapered and unable to find new practitioners willing to treat them. Many pain patients feel they only have few choices, to live suffering in pain with no quality of life, to move to countries that treat pain, go to the streets and obtain dangerous street drugs or commit suicide. Obviously the best choice is that patients are treated with empathy and compassion and remain under the watchful eye of physicians who treat them.

Anonymous (not verified)-*Sep 22, 2023 04:27 PM*
Why is it we have to suffer due to the ones choosing to take a medication not subscribed to them by their physician? Your cutting

Anonymous (not verified)-*Sep 22, 2023 04:33 PM*
Why is it we have to suffer due to the ones choosing to take a medication not subscribed to them by their physician? Your cutting off legit pain patients causing them to commit suicide because they have no quality of life left or forcing them to live in extreme pain! The 90MME is rediculious! The limit and milligram should be up to the physician that actually spent years upon years in college to learn how to safely prescribe. You try an go above an beyond protecting the criminal choosing to take things not prescribed at the expense of legit pain patients, when did their life become so much more valuable than ours?? Your sanctioning physicians for doing their jobs.

Maria (not verified)-*Sep 22, 2023 04:36 PM*
5 yrs ago The Human Rights Watch team did a year long investigation into how badly pain patients are being treated (mistreated) in this country. This mistreatment has only gotten worse since that report. This country's current overdose crisis is due to illicit and illegal drugs. Prescribing long ago stopped being the problem, yet politicians and the media keep feeding the false narrative. Physicians are afraid to treat patients, they face being arrested and prosecuted. Many have quit practicing, others have closed their clinics. Large health organizations forbid their "employees " (physicians) from doing their job, which is to "do no harm" So patients are left to suffer agonizing pain, facing limited choices, suffer, commit suicide, move to another country or go to the streets and likely die from laced illicit drugs. When do patients right's become important again? We definitely need to provide services to those suffering from addiction, but this can be done without causing harm to patients, who by no choice of their own, suffer from diseases and conditions that cause pain America is a great country, but it can do better, treat patients fairly

Isaac T Arnett Jr (not verified)-*Nov 22, 2023 09:06 AM*
Recently, my clinic had me sign a waiver agreeing that I am ok with being cut off from opioid meds, without notice and informed me that withdrawal is not life threatening. Frightening, that they would even mention such a thing. My pharmacy will not fill my full prescription and makes me pickup every 2 weeks instead every 28 days. 28 days is the standard, so I have the extra costs of transportation along with having to make the extra time. Even my Dr. askes me what is up with my pharmacist. The contract I am required to sign looks like something that a felony

prisoner being released on parole would have to sign. It includes that "I must get better". That is odd due to people my age don't get better with a degenerative disease. I don't think anyone gets better with degenerative spinal stenosis. In a nutshell, I am treated like a criminal and undertreated for pain and my treatment is not individualized. An example for that is take meds as needed with a daily limit. Instead, it is take 1 every 4 hours. a lot of the criminalizing of pain patients comes from NARX scoring. I recently had to purchase needles for intramuscular injection of hydrocortisone, due to having Addison's Disease. I did notice a difference in treatment at my pain clinic and at my pharmacy right after that. I had to go to a different pharmacy to get the meds and the needles and that because my regular pharmacy told me they couldn't get what I needed. Using more than one pharmacy goes against a person. The reason doesn't matter. Having injectables goes against a person. Living in pain 24/7/365 goes against a person. People living with chronic pain are treated like criminals..., and what looks to me like lab rats in some sci-fi experiment.

Kate Burton (not verified)-*May 24, 2024 04:22 PM*
For multiple years now, approximately 95% of opioid overdose deaths have been attributed to illegal, gang-manufactured fentanyl. Less than 3% of accidental overdoses have even included legally prescribed opioids. Imposing further limitations on legal pain medications - even incrementally - exacerbates the problems people with chronic pain (or surgery, or cancer) with medically documented conditions and diseases deal with while attempting to access their life-saving medications. Overall, these restrictions help little to none in reducing the supply of illegal opioids nor the rate of overdose death- but they do result in immense difficulties for patients and their families merely trina to survive their own sufferina. Sadly, suicide can be the result. The American Medical Society and the Medical Society of Interventional Pain Physicians both have made public statements about the misleading comments made by the CDC about opioid medications. Furthermore, nationwide news stories about international illicit fentanyl have made it very clear that we do not have a legal prescription opioid problem in our country, we have an illicit fentanyl problem invading our country. I urge you to not only abstain from further medication restrictions, but to also retract previous controls. Thank you for your consideration, Kate Burton

Rules Comment

Apr 19 2024 11:10AM

I do applaud the Commission adding sickle cell as exempt from opioid prescribing. The Commission has not gone far enough though. Not exempting long-term (2 year minimum) chronic pain patients needs to be addressed immediately, with this exemption protecting ALL prescribing medical professionals, especially pain management medical professionals. My husband is such a patient, with over 20 years of intractable, chronic pain, who had been forcibly tapered to an ineffective dose of opioid pain medication more than 6 years ago. The Commission needs to make it clear that all prescribing medical professionals should, and can use their best medical practices to prescribe opioid medications with the backing of the WA Medical Commission to protect those WA medical professionals from the US DEA combing the PMP for 'overprescribing' without any reason to do so. Please see: https://www.nytimes.com/2024/03/22/opinion/dea-opioids-restrictions-overdoses.html AND https://www.youtube.com/watch?v=wciQvg4EB5k&authuser=0 The Commission also needs to stop relying the fatally flawed 2016 & revised 2022 CDC Guidelines for Prescribing Opioids for Non-Cancer Pain. Please see: https://www.scivisionpub.com/pdfs/oversight-on-revision-of-us-cdc-opioid-guidelines-a-process-pre-destined-to-fail-2988.pdf AND https://reason.com/2024/04/15/government-data-refute-the-notion-that-overprescribing-caused-the-opioid-crisis/ Due to these CDC Guidelines, and the tactics used by the DEA, my husband has lost significant functionality and quality of life over the past 6+ years, and other medical issues have become worse, all due to that force-taper. His pain management doctor (supposedly not affected by the CDC Guidelines?) will not increase his dose to a more effective dose due to the fear of having his medical license revoked by the DEA for 'overprescribing' opioids pain medication. I would encourage all members of the Commission take a look at the literature available on the website of a patient advocate and subject matter expert on US public health policy for the treatment of pain, Richard Lawhern: http://www.face-facts.org/Lawhern Thank you for your time.

Apr 19 2024 9:41PM

I applaud the work the WMC has done to untangle the damage caused by the 2016 CDC Opioid Prescribing. Adding Sickle cell is a start BUT adding an Exemption for RARE DISEASE period would do more. RARE Diseases are causing so much pain Also Unless the WMC directly “touches” somehow every prescriber in Washington State patients will continue to suffer. Doctors are NOT getting the message, they are frightened that they will lose their license, their home their livelihood. Patients deserve to receive appropriate treatment and not be treated as if their lives don’t matter Patients are being abandoned, can’t find appropriate care, providers are refusing to treat chronic pain patients. Patients are suffering in agonizing pain due to RARE disease. Some are turning to the street, many are committing suicide. “this statement is well written and I applaud the efforts of the commission. Washington pain patients are dying -committing suicide or going to the streets because doctors refuse to treat pain. The statement cannot be effective if it is not read by physicians. Will the WMC-ensure that physicians read it by setting up some type of receipt verification or acknowledgment from medical practices and institutions that the interpretive statement will be shared with all practitioners? The direct issue is “touching” every physician in our state to ensure that they read the interpretive statements thereby noting they understand and acknowledge their responsibilities to all patients whether struggling with pain from a rare disease or suffering from addiction. All mankind deserves respect, compassion and empathy. Will

they include the statement in CME training? I have personally heard from dozens of legitimate pain patients who have been abandoned or forced tapered, many have filed complaints with the WMC but their complaints were discharged and physicians were not sanctioned. I respect the work done by WMC to untangle the issues brought forth by the 2016 cdc opioid guidelines but we have to find a way to reach these doctors and ensure patient pain treatment is no longer ignored and avoided Lastly ANY policies made based on the CDC Opioid prescribing guidelines should be removed and completely rewritten. Patients lives do matter

Apr 19 2024 9:57PM

My name is Sarah Tompkins, a Patient Advocate and Board Member of NW Rare Disease Coalition (501.c.4) and Connective Strength (501.c.3) a patient nonprofit for Ehlers-Danlos Syndrome, the genetic connective tissue disease I have. My symptoms began in high school, but it took 9 years before I would be properly diagnosed and treated. Due to having loose tissue and joints, I average 2-3 surgeries a year since 2011. In my experience as a chronic pain patient, tapering pain patients medications does not aid in preventing over or misuse, chronic pain patients need this medication to function and live our lives with quality of life. If I had to be tapered completely from my pain meds, I would be suicidal, and though we are lacking proper data, we know this is what happens to chronic pain patients who are inappropriately tapered from their pain medication. Only the patient can know how their pain feels and if they can tolerate tapering their pain medication, and physician and physician assistants do not listen to pain patients if they express that they cannot go down on their dosage. In 23', I had open abdominal surgery for median arcuate ligament syndrome and had to stay an additional 5 days in the hospital due to pain, but I was disrespected and unheard of by my pain management doctors and to this day have nightmares of that post op experience because they expected me to taper so much and so fast. Please don't punish patients for their pain by allowing doctors to manage their pain care without the patient's participation and permission.

Apr 19 2024 10:19PM

When the CDC issued its Opioid Prescribing Guidelines in 2016 many patients were forcibly tapered down on their pain medication. They have suffered more than any human should have to suffer due to untreated or under treated pain. Patients who have been in Chronic Pain and diagnosed with Rare Diseases or Medical Conditions that cannot be cured should be EXEMPTED from any Opioid Policies or rules as long as they are being cared for by a licensed physician Washington State needs to do more to reach the ears of the doctors in this state, to ensure that Pain Treatment becomes important again. Many physicians and practices REFUSE to prescribe opioids and or treat Chronic Pain, That should be a violation Physicians are afraid to treat pain. The WMC needs to do more to reach out to ALL prescribers and ensure that they understand that not treating pain is not an option. Patients are desperate, they need to know that their lives matter, that their pain matters. If a patient can't be fixed, then they deserve to receive treatment to relieve their suffering. Please do more to ensure chronic pain patients receive appropriate pain treatment and are not ignored and or treated with bias. This is a Human Rights Issue

Apr 19 2024 10:50PM

I agree that there should be more Exemptions added to the current opioid prescribing policy. I agree that Sickle Cell Patients should be Exempted but I don't understand why they are the only Rare Disease patients that are being added to the Exemption list? Add Rare Diseases Add Chronic Intractable pain (incurable conditions) From FDA " Over 7,000 rare diseases affect more than 30 million people in the United States. Many rare conditions are life-threatening and most do not have treatments" https://www.fda.gov/patients/rare-diseases-fda My 63 year old daughter has suffered in pain for over 20 years. She's had over 45 surgeries and at the age of 62 she was diagnosed with a Rare Disease that she's had all her life. It's what caused her body to deteriorate aggressively. She was receiving good pain treatment, never violated the rules, never ran out of meds, never didn't pass a drug test, but all of a sudden in 2017 her doctor said he had to start a taper. She found out that this was due to the 2016 CDC Opioid Prescribing Guidelines. She went from being able to do a few things around the house, to being bed bound and there's nothing worse than watching someone you love suffer. Your helpless. She lost her

doctor, couldn't find a new doctor, clinics refused to treat chronic pain, or prescribers refused to prescribe opioids or pharmacies refused to fill medications. It's bad enough to be sick, knowing there is no cure, to be in pain, but to be intentionally ignored and abandoned is heartbreaking. This state needs to reach out to every prescriber and ensure that they hear your words. Sending a memo, doesn't work. Hold a required virtual meeting, make sure that prescribers know that not treating pain, is not an option. I'm not talking about acute pain. I'm talking about Chronic Intractable Pain that has no cure. We need to do better. Patients are committing suicide Stop the suffering!!

Apr 19 2024 11:15PM

I'm writing to you today to request that all chronic pain and intractable pain patuents be given exemption from state opioid legislation. Because of state laws i was reduced 90% from the medication that allows me to lead a semi active life. People who suffer from severe pain that suffer from illness and injury that is not curable should be except from laws this state has passed. Drs know what works and as a intractable pain patient any farther reductions will be horrible for me. And the thousands of people Who are barely hanging on it will totally destroy any quality of life. I appreciate your reading this and thank you for your time

Apr 20 2024 10:45AM

To whom this may concern. I am writing in response to the Opioid Exemptions. While there are a few exemptions, there are many others that should be as well. I myself have incurable, and extremely painful diseases. I don't get any breaks from my pain, it's 24/7. My medication has given me quality of life, not quantity but quality. Without my pain medication I would be bed ridden, or worse dead. I'm so thankful for the drs I've had. I follow my contract, and I've never abused my medication for the 20 years I've been on it. I refuse to go to pain management clinics, and I never will. I have Drs that are perfectly competent, and I feel safe with them. There have been patients that have been cut off, and they took their lives. It shouldn't have ever happened, but it did. Those of us that are fortunate enough to have great drs are so thankful. Having incurable diseases has taken a lot from us. The majority of us can no longer work, drive, go out, or do just about anything. With our medication at least we can get out of bed, and have a small slice of life. That means the world to us. So cutting us off, or under treating us will be a no win situation. The suicide rate will skyrocket! Our lives are hard enough, to treat us like garbage is unacceptable!! We are human beings who need our medications. I'm 54, and I don't want my life cut short. Politicians, DEA, and CDC should NOT have any say in what my drs do. MY drs should be able to treat me accordingly without the fear of going to prison, losing their license, and their jobs. With the money that is being spent to take my medication away should be spent on busting the fentanyl problem. We are just easy targets. Please expand the chronic pain, and intractable exemption. I applaud the Sickle Cell exemption, but there are so many of us that have chronic intractable pain. I have a condition that has caused nerve damage throughout my body. My body turns on my joints that I have had so many surgeries for, and some of those I've had to have redone. The last surgery I had on my back was a huge surgery. They went in and found that my spine had collapsed. When I went home I got so sick, and I had ended up with a rare disease that damaged my nerves. Three years later I'm still struggling to get some kind of normalcy back. I'm literally in pain 24/7, and to be told that I' say. They all have their DEA numbers, which if a dr is abusing then it can be seen. We deserve to be treated with the treatments they give us, and humanly. If our medication is cutoff you will be seeing a lot of people turning to the dark web, or the streets, and they will most likely die.

Apr 20 2024 3:27PM

In researching this issue, I think these bullet points are useful and are reasons why I strongly belief opioid medications might be considered necessary or beneficial for such patients: 1. Pain Management: Opioids are potent analgesics that can effectively manage severe pain, which is often experienced by patients with chronic pain conditions or cancer. For these individuals, opioids can provide relief when other medications or therapies have been ineffective. 2. Improving Quality of Life: Chronic pain and cancer can significantly diminish a person's quality of life. Opioid medications can help alleviate pain, allowing patients to engage in daily activities, maintain social connections, and improve overall well-

being. 3. Individualized Treatment: Pain management is not a one-size-fits-all approach. Some patients may require opioid medications to effectively manage their pain due to factors such as the severity of their condition, their response to other treatments, or the presence of intolerable side effects from alternative medications. 4. End-of-Life Care: In cases of advanced cancer or terminal illness, opioid medications are often essential for providing comfort and dignity to patients in their final days. These medications can help alleviate the severe pain and discomfort associated with end-of-life care. 5. Access to Treatment: Restricting access to opioid medications can create barriers for patients who genuinely need them for pain management. Lack of access may force patients to endure unnecessary suffering or seek alternative, potentially unsafe methods of pain relief. Recently, at a public meeting in the Tri-Cities areas, Washington AG Ferguson stated that he made a mistake in the current Washington law so as to restrict pain medications, including Opioids, for patients in need. He used his mother's late-life suffering as an example for his regret. Other states (Colorado, California and others) have retracted and reformed their statutory language to be legal as a better fit for cancer and chronic pain patients. I believe Washington State can do this as well. I have a signed affidavit from an attendee to corroborate Mr. Ferguson's statement.

Apr 20 2024 6:21PM

I really thing people with cancer and people with fibromyalgia should be able to get opioid prescription I know they don't think opioid work for fibromyalgia but they do and without that medicine people are choosing to die , we have no quality of life with out the pain medicine to help most of us would be stuck in bed and hope to God we have someone to help us and again most of us don't, who wants to be around someone who can't move cuz they are in pain all the time .My last pain management doctor reduced my pain meds due to the new laws ,now I can't cook for myself I have a hard time taking a shower because I can't stand very long and I loose my balance . Fibromyalgia is not just chronic pain everyplace on your boady but also makes it hard to sleep which makes it hard to think with little sleep , we also get migraines ,balance issues , among other things that go with it . Please do not restrict opioid drugs for fibromyalgia patients . Cancer patients also go threw many issues I don't have it but I have friends that do

Apr 20 2024 10:20PM

My sister has had a lot of pain since she was 40, nows she’s 63. She lost her career, her ability to Live a normal life, plant flowers, play with grand children , walk her dogs. She has had surgeries on every part of her body. 7 years ago, after she had been on the same pain medications for over 16 years her doctor told her that she had to be tapered because the CDC made new rules. According to many reports, even a year long investigation into Pain Treatment in the US by Human Rights Watch International finding appalling treatment to vulnerable patients and even a report from the CDC stating their Guidelines were being misapplied. Misinterpreted and they had gotten their numbers wrong in the research they used to create the 2026 CDC Opioid Prescribing Guidelines. The CDC did not intend states, physicians nor insurance companies to make laws out of guidelines meant to only direct primary care doctors treated opioid naive patients! Now patients have been forced tapered, barely living, suffering in pain, can’t find doctors, can’t get prescriptions when they are living with Rare Disease and or long term Chronic Intractable Psin conditions that can’t be cured. Doctors are afraid They’ve abandoned the treatment of pain They’ve abandoned their patients Pharmacies won’t fill prescriptions Insurance companies won’t pay WMC needs to stop the loss of life of good people in the state who’s only wrong is living with a painful disease These are the most vulnerable patients and shouldn’t be treated this way

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Memo

WASHINGTON Medical Commission
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To: **WMC Commissioners**

From: **Amelia Boyd, Program Manager**

Subject: **Rulemaking Authorization Request-General Provisions for Opioid Prescribing and Tapering**

The CR-101 for Physician and Physician Assistant general provisions for opioid prescribing and tapering rules was filed on August 16, 2023, as WSR #23-17-094. At the WMC's business meeting on April 26, 2024, a rule hearing was conducted. During the hearing, concerns were raised about the draft language. As a result, the decision was made to revert to an earlier stage in the rulemaking process and hold another workshop to revise the draft language.

On June 4, 2024, a rule workshop was held where interested parties, staff, and Commissioners discussed and revised the draft language. The panel of Commissioners agreed that the draft language in this packet is ready to be approved for the next step in the rulemaking process, the CR-102 or Proposed Rules.

Physician Assistants

WAC 246-918-801 Exclusions. WAC 246-918-800 through 246-918-935 do not apply to:

(1) The treatment of patients with cancer-related pain;

(2) The treatment of patients with sickle cell disease;

(3) The provision of palliative, hospice, or other end-of-life care;

(43) The provision of procedural medications;

(54) The treatment of patients who have been admitted to any of the following facilities for more than 24 hours:

(a) Acute care hospitals licensed under chapter 70.41 RCW;

(b) Psychiatric hospitals licensed under chapter 71.12 RCW;

(c) Nursing homes licensed under chapter 18.51 RCW and nursing facilities as defined in WAC 388-97-0001;

(d) Long-term acute care hospitals as defined in RCW 74.60.010; or

(e) Residential treatment facilities as defined in RCW 71.12.455; or

(65) The treatment of patients in residential habilitation centers as defined in WAC 388-825-089 when the patient has been

transferred directly from a facility listed in subsection (54) of this section.

[Statutory Authority: RCW 18.71A.800, 18.71.017, and 18.130.050. WSR 22-22-039, § 246-918-801, filed 10/25/22, effective 11/25/22. Statutory Authority: RCW 18.71.017, 18.71.800, 18.71A.800 and 2017 c 297. WSR 18-23-061, filed 11/16/18, effective 1/1/19. Statutory Authority: RCW 18.71.450, 18.71A.100, 18.71.017, and 18.71A.020. WSR 11-12-025, § 246-918-801, filed 5/24/11, effective 1/2/12.]

WAC 246-918-870 Periodic review—Chronic pain. (1) The physician assistant shall periodically review the course of treatment for chronic pain. The frequency of visits, biological testing, and PMP queries in accordance with the provisions of WAC 246-918-935, must be determined based on the patient's risk category:

(a) For a high-risk patient, at least quarterly;

(b) For a moderate-risk patient, at least semiannually;

(c) For a low-risk patient, at least annually;

(d) Immediately upon indication of concerning aberrant behavior; and

(e) More frequently at the physician assistant's discretion.

(2) During the periodic review, the physician assistant shall determine:

(a) The patient's compliance with any medication treatment plan;

(b) If pain, function, and quality of life have improved, diminished, or are maintained; and

(c) If continuation or modification of medications for pain management treatment is necessary based on the physician assistant's evaluation of progress towards or maintenance of treatment objectives and compliance with the treatment plan.

(3) Periodic patient evaluations must also include:

(a) History and physical examination related to the pain;

(b) Use of validated tools or patient report from reliable patients to document either maintenance or change in function and pain control; and

(c) Review of the Washington state PMP at a frequency determined by the patient's risk category in accordance with the

provisions of WAC 246-918-935 and subsection (1) of this section.

(4) If the patient violates the terms of the agreement, the violation and the physician assistant's response to the violation will be documented, as well as the rationale for changes in the treatment plan.

(5) Biological specimen testing should not be used in a punitive manner but should be used in the context of other clinical information to inform and improve patient care. Physician assistants should not dismiss patients from care on the basis of a biological specimen test result alone.

[Statutory Authority: RCW 18.71.017, 18.71.800, 18.71A.800 and 2017 c 297. WSR 18-23-061, § 246-918-870, filed 11/16/18, effective 1/1/19.]

WAC 246-918-900 Tapering considerations—Chronic pain. Not all chronic pain patients will need their opioid prescriptions tapered. Relying on medical decision making and patient-centered treatment, ~~T~~the physician assistant shall consider tapering or referral for a substance use disorder evaluation when:

(1) The patient requests;

(2) The patient experiences a deterioration in function or pain;

(3) The patient is noncompliant with the written agreement;

(4) Other treatment modalities are indicated;

(5) There is evidence of misuse, abuse, substance use disorder, or diversion;

(6) The patient experiences a severe adverse event or overdose;

(7) There is unauthorized escalation of doses; or

(8) The patient is receiving an escalation in opioid dosage with no improvement in their pain or function.

[Statutory Authority: RCW 18.71.017, 18.71.800, 18.71A.800 and 2017 c 297. WSR 18-23-061, § 246-918-900, filed 11/16/18, effective 1/1/19.]

Physicians

WAC 246-919-851 Exclusions. WAC 246-919-850 through 246-919-985 do not apply to:

(1) The treatment of patients with cancer-related pain;

~~(1)~~ (2) The treatment of patients with sickle cell disease;

~~(2)~~ (3) The provision of palliative, hospice, or other end-of-life care;

~~(3)~~ (4) The provision of procedural medications;

~~(4)~~ (5) The treatment of patients who have been admitted to any of the following facilities for more than 24 hours:

(a) Acute care hospitals licensed under chapter 70.41 RCW;

(b) Psychiatric hospitals licensed under chapter 71.12 RCW;

(c) Nursing homes licensed under chapter 18.51 RCW and nursing facilities as defined in WAC 388-97-0001;

(d) Long-term acute care hospitals as defined in RCW 74.60.010; or

(e) Residential treatment facilities as defined in RCW 71.12.455; or

~~(5)~~ (6) The treatment of patients in residential habilitation centers as defined in WAC 388-825-089 when the patient has been transferred directly from a facility listed in subsection ~~(4)~~ (5) of this section.

[Statutory Authority: RCW 18.71A.800, 18.71.017, and 18.130.050. WSR 22-22-039, § 246-919-851, filed 10/25/22, effective 11/25/22. Statutory Authority: RCW 18.71.017, 18.71.800, 18.71A.800 and 2017 c 297. WSR 18-23-061, § 246-919-851, filed 11/16/18, effective 1/1/19. Statutory Authority: RCW 18.71.450, 18.71A.100, 18.71.017, and 18.71A.020. WSR 11-12-025, § 246-919-851, filed 5/24/11, effective 1/2/12.]

WAC 246-919-920 Periodic review—Chronic pain. (1) The physician shall periodically review the course of treatment for chronic pain. The frequency of visits, biological testing, and PMP queries in accordance with the provisions of WAC 246-919-985, must be determined based on the patient's risk category:

(a) For a high-risk patient, at least quarterly;

(b) For a moderate-risk patient, at least semiannually;

(c) For a low-risk patient, at least annually;

(d) Immediately upon indication of concerning aberrant behavior; and

(e) More frequently at the physician's discretion.

(2) During the periodic review, the physician shall determine:

(a) The patient's compliance with any medication treatment plan;

(b) If pain, function, and quality of life have improved, diminished, or are maintained; and

(c) If continuation or modification of medications for pain management treatment is necessary based on the physician's evaluation of progress towards or maintenance of treatment objectives and compliance with the treatment plan.

(3) Periodic patient evaluations must also include:

(a) History and physical examination related to the pain;

(b) Use of validated tools or patient report from reliable patients to document either maintenance or change in function and pain control; and

(c) Review of the Washington state PMP at a frequency determined by the patient's risk category in accordance with the provisions of WAC 246-919-985 and subsection (1) of this section.

(4) If the patient violates the terms of the agreement, the violation and the physician's response to the violation will be documented, as well as the rationale for changes in the treatment plan.

(5) Biological specimen testing should not be used in a punitive manner but should be used in the context of other clinical information to inform and improve patient care. Physicians should not dismiss patients from care on the basis of a biological specimen test result alone.

[Statutory Authority: RCW 18.71.017, 18.71.800, 18.71A.800 and 2017 c 297. WSR 18-23-061, § 246-919-920, filed 11/16/18, effective 1/1/19.]

WAC 246-919-950 Tapering considerations—Chronic pain. Not all chronic pain patients will need their opioid prescriptions tapered. Relying on medical decision making and patient-centered treatment, ~~T~~the physician shall consider tapering or referral for a substance use disorder evaluation when:

(1) The patient requests;

(2) The patient experiences a deterioration in function or pain;

(3) The patient is noncompliant with the written agreement;

(4) Other treatment modalities are indicated;

(5) There is evidence of misuse, abuse, substance use disorder, or diversion;

(6) The patient experiences a severe adverse event or overdose;

(7) There is unauthorized escalation of doses; or

(8) The patient is receiving an escalation in opioid dosage with no improvement in their pain or function.

[Statutory Authority: RCW 18.71.017, 18.71.800, 18.71A.800 and 2017 c 297. WSR 18-23-061, § 246-919-950, filed 11/16/18, effective 1/1/19.]

Policy

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Title:	Artificial/Assistive/Augmented Intelligence (AI) Policy	POL202x-0x
References:		
Contact:	Washington Medical Commission	
Phone:	(360) 236-2750	E-mail: medical.commission@wmc.wa.gov
Supersedes:	NA	
Effective Date:		
Approved By:	,Chair	

Introduction

The Washington Medical Commission (Commission) provides practitioners (physicians, physician assistants, and anesthesiologist assistants) this policy to address the use of artificial/assistive/ augmented intelligence (AI) in their delivery of health care in the state of Washington. The Commission recognizes the need for practitioners to understand how AI tools may be used safely in their practices while AI technology continues to evolve. It is estimated that medical knowledge doubles every 73 days,[1] that 30 percent of all the data generated worldwide is estimated to be health care related,[2] and that AI may help to revolutionize the practice of medicine by assisting practitioners with their healthcare delivery and data integration into electronic health records.[3]

While definitions involving AI continue to evolve, Executive Order 14110 issued by the President of the United States in the fall of 2023 defined AI as follows:

> The term "artificial intelligence" or "AI" has the meaning set forth in 15 U.S.C. 9401(3): a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. Artificial intelligence systems use machine- and human-based inputs to perceive real and virtual environments; abstract such perceptions into

[1] Densen, P. Challenges and opportunities facing medical education. Trans. Am. Clin. Climatol. Assoc. 122, 48 (2011).
[2] RBC Capital Markets Episode 1: The Healthcare Data Explosion, available at https://www.rbccm.com/en/gib/healthcare/episode/the_healthcare_data_explosion (Accessed May 6, 2024).
[3] Alanazi A. Clinicians' Views on Using Artificial Intelligence in Healthcare: Opportunities, Challenges, and Beyond. Cureus. 2023 Sep 14;15(9):e45255. doi: 10.7759/cureus.45255. PMID: 37842420; PMCID: PMC10576621, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10576621/ (Accessed May 6, 2024).

models through analysis in an automated manner; and use model inference to formulate options for information or action.[4]

Federal regulators recognize that AI has the potential to improve patient care, augment practitioner capabilities, and advance medical product development,[5] and the Commission concurs. As AI in healthcare continues to evolve, the Commission provides this summary of responsibilities, risks, benefits, and accountability considerations involving practitioners and the use of AI in their practice of medicine.

State and National Considerations

The Federation of State Medical Boards (FSMB) provided guidance in April of 2024 to state medical boards, which includes the Commission, to help ensure the safe and effective use of AI to improve patient care. The FSMB guidance document, adopted by the FSMB House of Delegates, is entitled "Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice," which incorporated input provided by the FSMB Ethics and Professionalism Committee. FSMB's guidance on the use of AI in the practice of medicine includes the following:

> Artificial Intelligence (AI) holds tremendous potential to aid healthcare providers in diagnosis, treatment selection, clinical documentation, and other tasks to improve quality, access, and efficiency. However, these technologies introduce risks if deployed without proper "guardrails" and understanding which may impact considerations in clinical practice as well as regulatory processes of state medical boards. By taking a proactive and standardized governance approach anchored in ethical principles, state medical boards can promote safe and effective integration of AI, in its various forms, while prioritizing patient wellbeing.[6]

As described in the FSMB guidance, multiple AI applications are already being used in healthcare "to analyze large datasets to identify patterns, classify information, and make predictions to support clinical decision-making."[7] While still evolving, AI technology is currently being used in healthcare in the following manner:

- Analyzing medical images thru computer vision systems,
- Reviewing medical records to improve communication thru interpretive services,
- Forecasting clinical trends using predictive algorithms and advanced data analytics,
- Supporting provider medical record documentation thru voice recognition, and

[4] Executive Order 14110 "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence," Section 3(b), issued on October 30, 2023, and published in the Federal Register on November 1, 2023. Available at https://www.federalregister.gov/documents/2023/11/01/2023-24283/safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence (Accessed May 6, 2024).

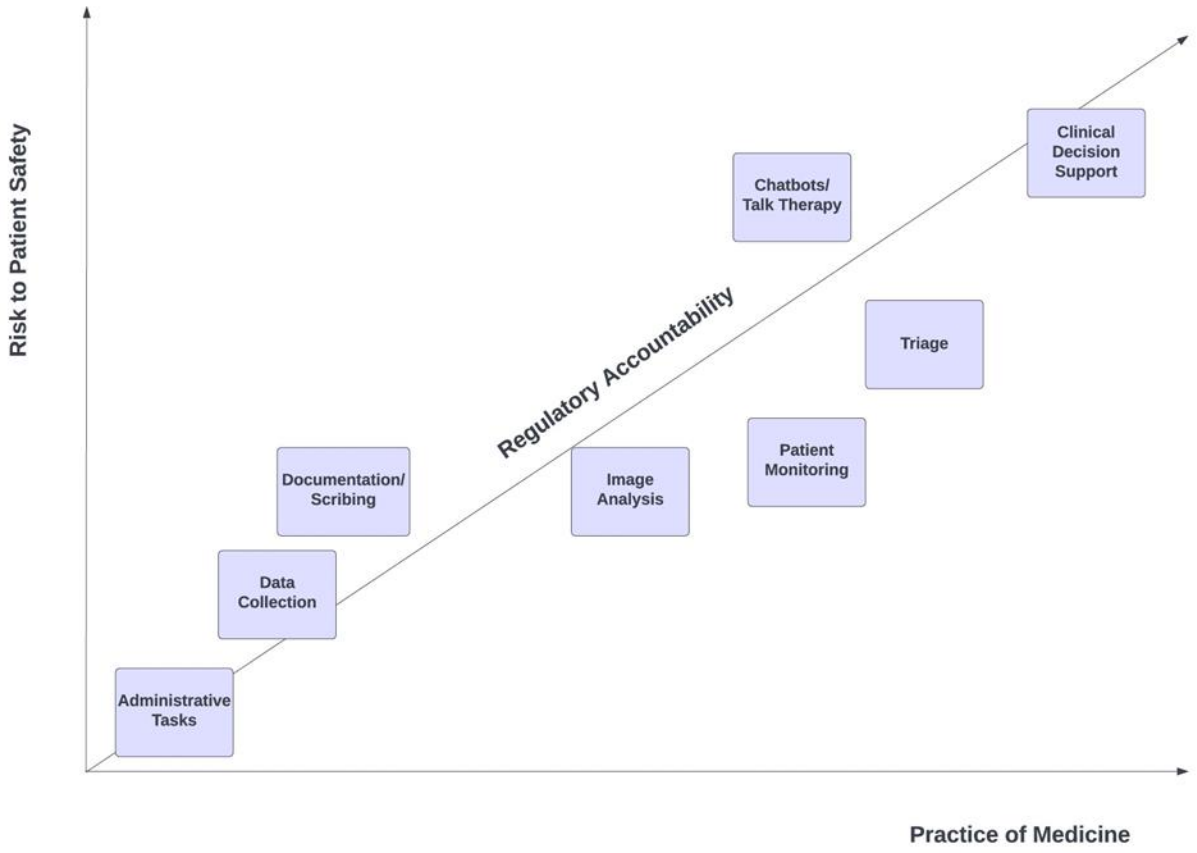
[5] Artificial Intelligence & Medical Products: How CBER, CDER, CDRH, and OCP are Working Together AI Medical Products Paper (fda.gov)

[6] "Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice," Adopted by the FSMB House of Delegates April 2024, p.1, available at incorporation-of-ai-into-practice.pdf (fsmb.org)

[7] "Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice," Adopted by the FSMB House of Delegates April 2024, p.3, available at incorporation-of-ai-into-practice.pdf (fsmb.org)

- Providing patient triage and education using "Chatbots."[8]

The FSMB guidance described numerous benefits of the use of AI in the practice of medicine while also providing guidance on regulatory accountability to limit risk. The following graph visualizes how AI usage in areas of medical practice correlates with risk ratios and a corresponding need for regulatory accountability.[9]



In the state of Washington, Governor Jay Inslee on January 30, 2024, issued Executive Order 24-01 on Artificial Intelligence, and defined the following terminology:

1. "Generative AI Technology" is a technology that can create content, including text, images, audio, or video, when prompted by a user. Generative AI systems learn patterns and relationships from large amounts of data, which enables systems to generate new content that may be similar, but not identical, to the underlying training data.

2. "High-Risk Generative AI System" means systems using generative AI technology that creates a high risk to natural persons' health and safety or

[8] "Navigation the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice," Adopted by the FSMB House of Delegates April 2024, p. 3, available at incorporation-of-ai-into-practice.pdf (fsmb.org)
[9] "Navigation the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice," Adopted by the FSMB House of Delegates April 2024, p. 6, available at incorporation-of-ai-into-practice.pdf (fsmb.org)

fundamental rights. Examples include biometric identification, critical infrastructure, employment, health care, law enforcement, and administration of democratic processes.

Additional definitions that aide in understanding this topic are as follows:

"Artificial intelligence" means any technology that can simulate human intelligence, including but not limited to, natural language processing, training language models, reinforcement learning from human feedback and machine learning systems.

"AI-generated content" shall mean image, video, audio, print or text content that is substantially created or modified by a generative artificial intelligence system such that the use of the system materially alters the meaning or significance that a reasonable person would take away from the content.[10]

"Generative artificial intelligence system" shall mean any system, tool or platform that uses artificial intelligence to generate or substantially modify video, audio, print or text content.[11]

"Metadata" shall mean structural or descriptive information about data such as content, format, source, rights, accuracy, provenance, frequency, periodicity, granularity, publisher or responsible party, contact information, method of collection, and other descriptions.[12]

Generative AI Technology and High-Risk Generative AI Systems are being developed rapidly in the healthcare arena. AI technological advances may create educational, privacy, and use-related challenges for practitioners. As AI technology continues advancing, practitioners must ensure that their use, or their lack thereof, of AI in the practice of medicine complies with evolving standards of care involving ethics and equity, decision making, and information management.

Policy

The Commission policy relating to the incorporation and use of AI tools in the practice of medicine is grounded in the principles of mutual informed consent and autonomy of the practitioner. AI may be used as a tool in the practice of medicine by practitioners. Regardless of whether the practitioner is receiving trend analysis or algorithm treatment recommendations, the practitioner is to remain directly involved in the care of the patient with one exception. The practitioner may participate in quality assurance reviews of AI tools while remaining uninvolved in direct patient care so long as they stay within the guardrails of evaluating for risk, safety, bias, and effectiveness of the AI tools themselves. However, prior to the use of AI involving a patient's care, the practitioner should understand the following:

[10] Commonwealth of Massachusetts HD 4788. Similarly, the Commission recognizes this definition in the state of Washington.
[11] Commonwealth of Massachusetts HD 4788. Similarly, the Commission recognizes this definition in the state of Washington.
[12] Commonwealth of Massachusetts HD 4788 (applying the definition from 44 U.S.C.A. Section 3502(19)). Similarly, the Commission recognizes this definition in the state of Washington.

A. *Informed Consent involving Decision-Making Influences.* When reasonably possible, a practitioner using AI in the practice of medicine should seek to obtain informed consent from the patient, or the patient's authorized representative, in advance of using AI in their treatment and provide them with the option to receive treatment without the use of AI. However, the Commission recognizes that informed consent may not always be possible whereas at times AI is being used without the knowledge of the practitioner or beyond the control of the practitioner. Regardless, any AI system used in the practice of medicine must be designed to prioritize the safety and well-being of individuals seeking treatment and monitored to ensure its safety and effectiveness.[13] The Commission adopts the following FSMB's guidance on AI decision-making influences:

> *"Physicians may consider AI as a decision-support tool that assists, but does not replace, clinical reasoning and discretion. Physicians should understand the AI tools they are using by being knowledgeable about their design, training data used in its development, and the outputs of the tool in order to assess reliability and identify and mitigate bias. Once the treating physician chooses to use AI, they accept responsibility for responding appropriately to the AI's recommendations. For example, if a physician chooses to follow the course of treatment provided by an AI-generated response, then they should be prepared to provide a rationale for why they made that decision. Simply implementing the recommendations of the AI without a corresponding rationale, no matter how positive the outcome may be, may not be within the standard of care. Alternatively, if the physician uses AI and then suggests a course of treatment that deviates from one delineated by AI, they should document the rationale behind the deviation and be prepared to defend the course of action should it lead to a less than optimal or harmful outcome for the patient. Generally, the reason a physician provides for disagreeing with an AI's recommendation should be because following that recommendation would not uphold the standard of care. As with any tool, once it produces a result, the outcomes cannot be ignored; there must be documentation reflecting how it was or will be utilized by the physician in the care provided. While the expanded use of AI may benefit a physician, failure to apply human judgement to any output of AI is a violation of a physician's professional duties."*

B. *Scope of Practice and the Standard of Care.* To be practicing within the practitioner's scope of practice and the standard of care using AI, a practitioner must have the expertise to assess, diagnose, and treat the patient in front of them, and, additionally, should understand the risks and benefits of using AI for the specific function(s) for which it is to be used.

C. *Ethical and Equity Principles.* The Commission ensures the ethical and equitable delivery of healthcare by practitioners, whether or not AI is being utilized, to protect patient safety. The principle of justice dictates that physicians have a professional responsibility to help identify and eliminate biases, including avoiding the use of biased AI algorithms

[13] Modified wording with quotations omitted from wording within the Commonwealth of Massachusetts H.1974.

which may increase the risk of patient harm, in their practice of medicine. The Commission adopts the following FSMB's guidance involving bias:

> *"AI systems encumbered by false or inaccurate information may carry a bias that can be detrimental to providers and harmful to patients. The principle of justice dictates that physicians have a professional responsibility to identify and eliminate biases in their provision of patient care, including those that may arise through biased AI algorithms. AI also poses an opportunity to expand access to care for populations historically marginalized and otherwise disadvantaged. Efforts must be made to ensure that all patients have equitable access to the benefits of AI and that existing disparities are not further exacerbated."*[14]

D. *Information Management Responsibilities.*

a. Protecting Privacy. The use of AI neither decreases a practitioner's duty to protect privacy, nor alters the basic purpose of patient medical records. Practitioners are encouraged to ensure they understand the Commission's Guidance Document of Medical Records.

b. The Commission recommends, but does not require, that practitioners practicing medicine in the state of Washington do the following involving the documentation of their AI use.

> *"Each generative artificial intelligence system used to create audio, video, text or print AI-generated content should include on or within such content a clean and conspicuous disclosure that meets the following criteria: (i) a clear and conspicuous notice, as appropriate for the medium of the content, that identifies the content as AI-generated content, which is to the extent technically feasible, permanent or uneasily removed by subsequent users; and (ii) metadata information that includes an identification of the content as being AI-generated content, the identity of the system, tool or platform used to create the content, and the date and time the content was created."*[15]

E. *Limitations and Education.* The practitioner is encouraged to complete continuing medical education (CME), including self-directed CME, to understand the impact of bias, in addition to limitations in research, involving underrepresented populations in health care technology applications such as AI. Prior to using a specific AI tool, the practitioner should understand limitations including but not limited to the potential for bias against populations that were not adequately represented in testing of AI tools to prevent patient harm.

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[14] "Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice," Adopted by the FSMB House of Delegates April 2024, p. 8, available at incorporation-of-ai-into-practice.pdf (fsmb.org)

[15] Adapted from the Commonwealth of Massachusetts HD 4788. The Commission recognizes this guidance as a best practice in the state of Washington but not a requirement.

Conclusion

This policy seeks to ensure the responsible incorporation and use of AI tools by practitioners in the practice of medicine. AI holds promise of benefitting patients and practitioners; however, irresponsible use will raise the risk of patient harm. Practitioners are encouraged to participate in continuing medical education to gain awareness of the evolving risks, benefits, and alternatives of the use of AI technologies in healthcare. In general, honoring professional standards involving ethics, equity, informed consent, privacy, and documentation will help to minimize the risks to practitioners and the patients that they treat as this technology continues to evolve. The use of AI may raise the risk of patient harm and lead to potential disciplinary action by the Commission for deviations from the standard of care.

Memo

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

To: **Commissioners**

From: **Pam Kohlmeier, MD, JD**
Policy Manager

Subject: **Recommendation to Rescind the Commission's Telemedicine Policy**

The state of Washington became the first state to enact ESSB 5481, the Uniform Telemedicine Act, and this statute just recently went into effect on June 6, 2024. As such, the Commission's Telemedicine policy POL2021-02 became superseded by statutory law. Therefore, the Commission's Telemedicine policy should be rescinded.

Incidentally, that telemedicine policy has a short section at the tail end of it addressing the use of artificial intelligence (AI) in the practice of medicine. That short section was an attempt to address the bare bones regulation of this rapidly evolving tool in medicine. By rescinding the Telemedicine policy, it is timely that the Policy Committee is considering a recommendation to adopt the new Artificial Intelligence (AI) policy that is on the Policy Committee agenda today.

As the Policy Manager, I am recommending that you vote to rescind the Commission's Telemedicine Policy POL2021-02, whereas the policy is now superseded by statute.

Policy

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Title:	Clinical Experience Assessment	POL202x-0x
References:		
Contact:	Washington Medical Commission	
Phone:	(360) 236-2750	E-mail: medical.commission@wmc.wa.gov
Supersedes:		
Effective Date:		
Approved By:	,Chair	

Introduction

In 2020, the Washington State Legislature chose to extend the responsibilities of the International Medical Graduate (IMG) Assistance Work Group with the passage of Senate Bill 6551; thus, creating the IMG Implementation Workgroup (Workgroup). The bill also required that the Washington Medical Commission (Commission) "adopt a clinical assessment to determine the readiness of international medical graduates to apply and serve in residency programs and adopt a grant award process for distributing funds" pursuant to appropriation by the legislature and donations received from public and private entities. After meeting monthly throughout 2022, the Workgroup voted to propose the following Clinical Experience Assessment (CEA) form, Attachment A, which meets the requirement set forth by the legislature.

Policy

Purpose of the CEA Form. The CEA is intended for physician assessors working with IMGs to prepare them for residency and to determine their overall readiness for residency training. The CEA is not an element of application for residency nor is it a qualification for residency.

Assessment of Residency Preparedness. The CEA is to be used to assess what level of "entrustment" seems appropriate for the IMG to enter a residency and to aid the IMG in successfully gaining a residency position.

Frequency of Assessment. The CEA is to be used as a quarterly assessment tool throughout the program until a passing score on all competencies has been attained, signifying residency readiness.

Monitoring of the CEA Form's Effectiveness. As funding and staffing capabilities permit, the Workgroup should develop a monitoring system to track effectiveness and limitations involving the use of the CEA. Once developed, the Workgroup is to begin tracking progress and challenges of IMGs who utilized the CEA form, identify where additional education or targeted trainings may be needed, and adjust to optimize the effectiveness of IMG pre-residency training, and of the CEA form itself.

Attachment A

Clinical Experience Assessment

Name: Date:

Ranking Guidelines		
1	"I did it."	The licensee required complete guidance or was unprepared or not competent; I had to do most of the work myself.
2	"I talked them through it."	The licensee was able to perform some tasks competently but required repeated directions.
3	"I directed them from time to time."	The licensee demonstrated some independence and competence and only required intermittent prompting.
4	"I was available just in case."	The licensee functioned fairly independently and competently and only needed assistance with nuances or complex situations.
5	"Not observed."	The licensee was not seen or observed completing this task.

1. Gather a History and Perform a Physical Examination					
1	2	3	4	5	Task
					Obtain a complete and accurate history in an organized fashion.
					Demonstrate patient-centered interview skills.
					Demonstrate clinical reasoning in gathering focused information relevant to a patient's care.
					Perform a clinically relevant, appropriately thorough physical exam pertinent to the setting and purpose of the patient visit.
2. Prioritize a Differential Diagnosis Following a Clinical Encounter					
1	2	3	4	5	Task
					Synthesize essential information from previous records, history, physical exam, and initial diagnostic evaluations to propose a scientifically supported differential diagnosis.

1	2	3	4	5	Task
					Prioritize and continue to integrate information as it emerges to update differential diagnosis, while managing ambiguity.
					Engage and communicate with team members for endorsement and verification of the working diagnosis that will inform management plans.
3. Recommend and Interpret Common Diagnostic and Screening Tests					
1	2	3	4	5	Task
					Recommend first-line cost-effective screening and diagnostic tests for routine health maintenance and common disorders.
					Interpret results of basic studies and understand the implication and urgency of the results.
4. Enter and Discuss Orders and Prescriptions					
1	2	3	4	5	Task
					Compose orders efficiently and effectively verbally, on paper, and electronically.
					Demonstrate an understanding of the patient's condition that underpins the provided orders.
					Recognize and avoid errors by attending to patient-specific factors, using resources, and appropriately responding to safety alerts.
					Discuss planned orders and prescriptions with team, patients, and families.
5. Document a Clinical Encounter in the Patient Record					
1	2	3	4	5	Task
					Prioritize and synthesize information into a cogent narrative for a variety of clinical encounters (admission, progress, pre- and post-op, and procedure notes; informed consent; discharge summary).
					Follow documentation requirements to meet regulations and professional expectations.

					Document a problem list, differential diagnosis, and plan supported through clinical reasoning that reflects patient's preferences.
6. Provide an Oral Presentation of a Clinical Encounter					
1	2	3	4	5	Task
					Present personally gathered and verified information, acknowledging areas of uncertainty
					Provide an accurate, concise, well-organized oral presentation.
					Adjust the oral presentation to meet the needs of the receiver.
					Demonstrate respect for patient's privacy and autonomy.
7. Form Clinical Questions and Retrieve Evidence to Advance Patient Care (*only level 3 required)					
1	2	3	4	5	Task
					Combine curiosity, objectivity, and scientific reasoning to develop a well-formed, focused, pertinent clinical question (ASK).
					Demonstrate awareness and skill in using information technology to access accurate and reliable medical information (ACQUIRE).
					*Demonstrate skill in appraising sources, content, and applicability of evidence (APPRAISE).
					*Apply findings to individuals and/or patient panels; communicate findings to the patient and team, reflecting on process and outcomes (ADVISE).
8. Give or Receive a Patient Handover to Transition Care Responsibility					
1	2	3	4	5	Task
					Document and update an electronic handover tool and apply this to deliver a structured verbal handover, using communication strategies known to minimize threats to transition of care
					Provide succinct verbal communication conveying illness severity, situational awareness, action planning, and contingency planning.
					Demonstrate respect for patient's privacy and confidentiality.

9. Collaborate as a Member of an Interprofessional Team					
1	2	3	4	5	Task
					Identify team members' roles and responsibilities and seek help from other members of the team to optimize health care delivery.
					Include team members, listen attentively, and adjust communication content and style to align with team-member needs.
					Establish and maintain a climate of mutual respect, dignity, integrity, and trust; prioritize team needs over personal needs to optimize delivery of care; and help team members in need.
10. Recognize a Patient Requiring Urgent or Emergent Care and Initiate Evaluation and Management (*only level 3 required)					
1	2	3	4	5	Task
					Recognize normal and abnormal vital signs as they relate to patient- and disease-specific factors as potential etiologies of a patient's decompensation.
					Recognize severity of a patient's illness and indications for escalating care.
					*Initiate and participate in a code response and apply basic and advanced life support.
					Upon recognition of a patient's deterioration, communicates situation to attending physician.
11. Obtain Informed Consent for Tests and/or Procedures					
1	2	3	4	5	Task
					Describe the key elements of informed consent: indications, contraindications, risks, benefits, alternatives, and potential complications of the intervention.
					Communicate with the patient and family to ensure that they understand the intervention including pre/post procedure activities.

12. Perform General Procedures of a Physician (*only level 3 required)					
1	2	3	4	5	Task
					*Demonstrate technical skills required for the procedure.
					Understand and explain the anatomy, physiology, indications, contraindications, risks, benefits, alternatives, and potential complications of the procedure.
					Completes expected procedures and keeps log book signed by mentor
13. Identify System Failures and Contribute to a Culture of Safety and Improvement (*only level 3 required)					
1	2	3	4	5	Task
					Identify and report actual and potential ("near miss") errors in care using system reporting structure (event reporting systems, chain of command policies).
					Participate in system improvement activities in the context of learning experiences (rapid- cycle change using plan–do–study– act cycles, root cause analyses, morbidity and mortality conference, failure modes and effects analyses, improvement projects).
					Engage in daily safety habits (accurate and complete documentation, including allergies and adverse reactions, medicine reconciliation, patient education, universal precautions, hand washing, isolation protocols, falls and other risk assessments, standard prophylaxis, time-outs).
					Admit one's own errors, reflect on one's contribution, and develop an individual improvement plan.

Staff Reports: July 19, 2024

Kyle Karinen, Executive Director

Dr. Morgan Barrett

As mentioned in an email to all the Commission members, Dr. Barrett retired in June after nine years of service. Morgan's role in charge of the Commission's Compliance Unit was a first for the Commission – a MD in that role. he brought a kindness and humanity to that role made an indelible mark. More than once, we had counsel representing clinicians before the Commission that inquired and requested that he attend settlement conferences. He was always available as a clinical resource to Commission members and staff as well. I wish him the best in retirement after a long clinical career and an impactful tenure with the Commission.

Dr. Pam Kohlmeier

Dr. Kohlmeier resigned from the Commission at the end of June. Pam joined the Commission in January 2022 primarily as staff attorney to assist the Commission's licensing panel. However, from the very start, her unique background as a MD and JD provided benefit to the Commission in multiple areas. Pam worked on issues that ranged from the Public Records Act to additions to the Uniform Disciplinary Act to the Medical Practice Act as well as assisting Micah's team on bills in the last three legislative sessions. As many of you know, Pam is running for the State House of Representatives in the current election cycle. State law mandates silence from both myself and the Commission in that race, nonetheless, I wish her nothing but the best in everything else – her stint with the Commission was impactful and I enjoyed working with her.

Board/Commission/Advisory Leadership Conference

Dr. Murphy and I attended this meeting on behalf of the Commission in Tumwater on June 18. (Thank you again to Dr. Murphy for making a second trek over the mountains in the space of a week.) These meetings used to be held annually, but this was the first time since the COVID-19 pandemic. Much of the information and presentations were at a global level, but it was very nice to see DOH/HSQA colleagues that I had not seen in-person in years. Secretary of Health Dr. Umair Shah made a point of coming over and chatting with Dr. Murphy and I, which was great. The main takeaway was with regard to the HELMS project which I am detailing in a separate item below.

2025 FSMB Annual Meeting

The annual meeting next year will be in Seattle. That, I think, is known to most of the Commission. What may not be known, but I wanted to highlight, is that both PA Ed Lopez and Christine Blake were asked by FSMB to participate in the Education Committee which will assist in planning the agenda for that meeting. Congratulations to Ed and Christine!

Kyle Karinen, Executive Director continued

Board of Optometry Meeting and Correspondence

As part of a bill passed by the Legislature in 2023, the practice of optometry was expanded to include a number of procedures. One feature of the statutory changes included a provision that required optometrists to partner with a "qualified" MD or DO to provide "rapid response" if a patient develops complications. The Commission briefly considered some of the issues that are raised by scope expansion last year and decided to wait until the Board of Optometry was further along in its rulemaking process. In April, on behalf of the Commission, Dr. Murphy and I met with Board members and staff to informally discuss where they were at in their rulemaking process. Some of the same concerns that were present last year remained. With that in mind and with Dr. Murphy's input, the Commission followed up on that meeting with a letter expressing those concerns. A copy of that letter is included in the meeting packet for your reference. Many thanks to Dr. Gina Fino, Dr. Kohlmeier, and Commission member Dr. Janet Barrall for preparing the table that was appended to the letter. We continue to monitor the Board's rulemaking and will update the Commission in the future.

Healthcare Enforcement and Licensing Management System (HELMS)

As a reminder, there is an on-going project to replace the licensing and regulation database used by all healthcare professions in Washington. As Micah notes below, the first phase of the HELMS project went live in late April. The phase was solely to replace the outward-facing portal available to licensees and applicants. Like many of these sorts of software projects, there were some bumps in the road, but as of the middle of June, the phase has been completed. The next phase will replace the actual licensing portion of the database. That is currently scheduled to occur in December with the enforcement portion of the database slated for September 2025. There remains a budget shortfall for the project as a whole and the Department is working to address that. I am happy to give more details to any Commission member that is interested – please do not hesitate to reach out.

Medical Standards – Brain Death

A colleague in the Department's leadership forwarded an email from Dr. Ariane Lewis, a clinical professor of neurology and neurosurgery. That correspondence is included in the meeting packet for your reference. I am pointing it out here to just add the additional context that there are not currently any efforts that we are aware of to adopt the clinical standards that Dr. Lewis mentions in her email. Apologize for the formatting, but it's the cleanest way I could get the information in front of you.

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

Licensing and HELMS

The WMC went through the licensing busy season without significant impacts or delays from the co-scheduled HELMS lite launch. While leaving detailed reporting to Licensing Manager, Marisa Courtney, I do want to give thanks and credit to the entire Licensing Unit for their time and dedication to getting the work of limited licenses processed and complete in the confusion of a new system launch. The proactive engagement of the unit and leadership helped inform stakeholders of the risks of delaying submitting applications. As a result, the vast majority of the applications were submitted prior to the HELMS launch and avoided the numerous glitches that impacted most other professions.

Legislative

I will be bringing legislative proposals for Executive Committee review and WMC for approval this month in the form of memos. They come in two forms. The first is request legislation from the WMC and those require your approval. The second is for your awareness on issues bring brought forward as policy recommendations from the International Medical Graduate Workgroup that have been forwarded to the Legislature and Governor's Office. These do not require your approval, but I would like feedback on the concepts. Feel free to email me with your thoughts.

Budget

We are still tracking the decline in revenue but were informed that at least a portion could be attributed to HELMS glitches which prevent reconciliation. This would only be a small portion of the decline since HELMS lite only processes initial application fees and not renewals, which is where the majority of our revenue comes from. Overall, we are spending below projections in direct and indirect costs. Travel expenditures are slightly up but not unexpected or concerningly so given many of our major conferences have recently occurred.

Amelia Boyd, Program Manager

Change to AMDG Opioid Dose Calculator

In February, 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 the following specialties to serve as Pro Tem Members:

- Urology
- Radiology
- Neurosurgery/Neurology
- General surgery
- 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.

Amelia Boyd, Program Manager continued

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

Public Member, Scott Rodgers' first term expired on June 30, 2023. Mr. Rodgers is eligible for reappointment. We are waiting to hear back about this position. The recommendations were sent to the staff at the Governor's Boards and Commissions Office on June 21, 2023.

Dr. Richard Wohns', representing Congressional District 10, first term expired on June 30, 2023. Dr. Wohns is eligible for reappointment. In May of this year, we initiated recruitment for Congressional District 10. The application deadline was June 21, 2024. The applications are under review.

On July 1, 2024, we had the following vacancies:

- 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

In January 2024, recruitment letters were sent to all MDs with an active license and who have been licensed in our state for at least 5 years in Congressional District 6. The application deadline for these three vacancies was March 22, 2024. The applications and the WMC's recommendations for Congressional District 6 were sent to the staff at the Governor's Boards & Commissions office on June 10, 2024. In May of this year, we initiated recruitment for Congressional District 8. The application deadline was June 21, 2024. The applications are under review.

Mike Hively, Director of Operations and Informatics

Compulsory Requests Overview

During the period from April 8, 2024, to July 2, 2024, the Operations and Informatics team managed five compulsory records requests. This involved processing approximately 9,915 pages, conducting 2,173 redactions, and withholding approximately 1,099 pages containing protected data. Additionally, there are handling eight active litigation holds, necessitating the sorting of more than 5,169 records retrieved through I.T. eDiscovery processes.

Digital Archiving:

- 466 Complaints closed BT
- 202 A-closures
- 232 PA applications
- 196 MD & PA applications checked for accuracy
- 3,800 Demographic census forms

Mike Hively, Director of Operations and Informatics continued

Six boxes of MD applications containing a total of 229 files and five boxes of PA applications totaling 318 files were recalled from the Records Center, converted into electronic formats. After they are digitally archived in .PDF/a format, disposition tickets are submitted for approval.

Data Requests processed include approximately:

- 1,242 open/closed inquiries
    - Each inquiry may contain numerous requests
- 755 address changes

Demographics:

- Scanned and entered approximately 3,760 census forms to ILRS
- Performed 1,340 secondary census contacts
- Build quarterly demographic aggregate report
- Routinely performs quality checks on entries
- Worked to debug new Salesforce census survey tool

We are currently researching I.T. audio/video equipment suitable for hybrid meetings and providing support in identifying and selecting venues for in-person meetings.

Lastly, we extend our sincere appreciation to all individuals, including our Department of Health partners, who contributed to the successful laptop replacement initiative in June, ensuring a smooth transition.

Gina Fino, MD, Medical Consultant, Director of Compliance

Of the 154 respondents in compliance, 47 were scheduled to have personal appearances this year. Twenty-two personal appearances have been completed and there are 25 respondents yet to appear. We are on track to complete the 2024 personal appearances by the end of the November meeting. Looking ahead, there are 50 personal appearances scheduled for 2025. The preliminary schedule is a bit lopsided, but the compliance team will refine as the new year approaches. Thanks to all for your patience as we work to adjust to schedule changes.

Rick Glein, Director of Legal Services

Summary Actions:

In re David B. Benson, MD, Case No. M2022-721. On April 18, 2023, the Commission filed a Statement of Charges (SOC) related to a single complaint of substandard care involving two obstetrical patients and one pediatric patient. At the time, allegations showed a lack of clinical skill, but limited in scope and number of patients. A hearing on the merits of the SOC, scheduled for February 2024, was continued pending service of an Amended SOC. On June 11, 2024, the Commission issued an Ex Parte Order of Summary Restriction which prohibits Dr. Benson from practicing in the areas of obstetrics and newborn care. An Amended SOC

concurrently served on Dr. Benson alleges substandard care in thirteen additional obstetric and pediatric patients. Dr. Benson filed a timely Answer to the Amended SOC and requested a show cause hearing* which is scheduled for July 15, 2024. The show cause hearing will determine if the summary action should remain in place or be modified. A hearing on the merits of the Amended SOC has not yet been scheduled.

In re La Tania M. Akers-White, MD, Case No. M2024-381. On June 21, 2024, a Health Law Judge (HLJ), by delegation of the Commission, issued an Ex Parte Order of Summary Suspension which ordered Dr. Akers-White's medical license be summarily suspended pending further disciplinary proceedings by the Commission. A SOC concurrently served on Dr. Akers-White alleges that the Montana Board of Medical Examiners (Montana Board) issued a Final Order by Default (Final Order) revoking Dr. Akers-White's medical license in that jurisdiction. The underlying conduct for the Montana Board Final Order was failing to report adverse licensing actions in other states and failing to cooperate with the Montana Board's investigation. Neither a request for a show cause hearing* or an answer to the SOC** has been received as of the writing of this staff report.

*The license holder must request the show cause hearing within twenty days of the issuance of the order. At the show cause hearing, the disciplining authority has the burden of demonstrating that more probable than not, the license holder poses an immediate threat to the public health and safety. RCW 18.130.135(1).
**The license holder must file a request for hearing with the disciplining authority within twenty days after being served the statement of charges. RCW 18.130.090.

Orders Resulting from SOCs:
In re Alex L. Nielson, MD, Case No. M2023-645. Agreed Order. In October 2023, the Commission issued a SOC alleging Dr. Nielson made comments of a sexually explicit nature towards his medical assistant (MA), placed his hand on her leg, and drove a vehicle away from the clinic with the MA as a passenger despite the MA asking him to go back. In May 2024, the Commission accepted an Agreed Order which requires Dr. Nielson to maintain satisfactory compliance with the monitoring contract he signed with the Washington Physicians Health Program (WPHP); successfully complete an ethics and boundaries CME course; pay a $5,000 fine; and personally appear before the Commission. Dr. Nielson may petition to terminate this Agreed Order after he successfully completes and is released from his WPHP monitoring contract.

In re Wei-Hsung Lin, MD, Case No. M2022-202. Agreed Order. In May 2023, the Commission issued a SOC alleging Dr. Lin's treatment of five patients was below the standard of care related to Dr. Lin's prescriptions of ivermectin for the treatment of COVID-19. In May 2024, the Commission accepted an Agreed Order in which Dr. Lin is restricted from prescribing ivermectin for non-FDA-approved indications to patients in Washington state and restricted from prescribing medications or providing care to patients without first establishing a physician-patient relationship. Dr. Lin must also complete CMEs on the subjects of (1.) the prevention, treatment, and management of COVID-19, and (2.) establishing a physician-patient relationship and maintaining a medical record. Additionally, Dr. Lin must submit a

paper and written personal reports, permit compliance audits, pay a $5,000 fine, and personally appear before the Commission. Dr. Lin may petition to terminate active oversight of the Agreed Order three years from its effective date and after successful completion of all terms and conditions.

In re Sean P. Pearson, PA, Case No. M2024-55. Agreed Order. In June 2019, the Commission entered a Final Order indefinitely suspending Mr. Pearson's license to practice as a physician assistant. The Commission approved a Modified Final Order in November 2021 reinstating Mr. Pearson's license following a WPHP endorsement that he was safe to practice within the context of treatment and monitoring. The 2021 Modified Final Order required Mr. Pearson to maintain satisfactory compliance with his WPHP monitoring contract until successful completion and discharge. In February 2024, the Commission issued a SOC alleging the WPHP could not endorse Mr. Pearson's ability to practice medicine with reasonable skill and safety. In May 2024, the Commission accepted an Agreed Order which indefinitely suspends*** Mr. Pearson's physician assistant license. Mr. Pearson must pay a $500 fine. In order to petition for reinstatement, Mr. Pearson must (1.) be re-accepted into the WPHP, (2.) submit to any evaluations or re-evaluations recommended by WPHP, (3.) enter into a five-year monitoring contract with WPHP, (4.) complete one year of WPHP monitoring after executing the five-year monitoring contract, and (5.) receive an endorsement by WPHP that he is able to practice with reasonable skill and safety.

In re Dominic Figueras, MD, Case No. M2022-50. Default Order (Failure to Appear).**** In May 2023, the Commission issued a SOC alleging Dr. Figueras was served with an Order for Investigative Mental Examination, but failed to make an appointment for and submit to the examination. Dr. Figueras filed a timely response to the SOC, but failed to appear at the scheduled pre-hearing conference. The HLJ granted the Commission's motion for an order of default and issued a Default Order in May 2024 which concluded sufficient grounds exist to take disciplinary action and ordered Dr. Figueras' medical license be indefinitely suspended.***

In re Sean Ataee, MD, Case No. M2023-774. Default Order (Failure to Appear).**** In September 2023, the Commission issued a SOC alleging Dr. Ataee filed an application with the Commission to activate his expired medical license. The SOC alleges Dr. Ataee held medical licenses in California and New York, which were both revoked based on the Medical Board of California's finding by clear and convincing evidence that Dr. Ataee engaged in sexual misconduct and gross negligence during the physical examination of a female patient in 2016. Although Dr. Ataee filed a timely Answer to the SOC and requested an adjudicative proceeding, he failed to appear at the scheduled pre-hearing conference and the HLJ granted the Commission's motion for an order of default. In June 2024, the Commission issued a Default Order which denied Dr. Ataee's application to renew his license to practice as a physician and surgeon in the state of Washington.

In re Fadi Alhafez, MD, Case No. M2021-656. Agreed Order. In June of 2022, the Commission issued a SOC alleging Dr. Alhafez' liposuction surgery of a single patient was below standard of care. In October 2023, the Commission issued an Amended SOC alleging Dr. Alhafez failed

to assess three patients for conditions that could be exacerbated by testosterone therapy and repeatedly prescribed high doses of testosterone, making misleading and unsubstantiated claims about the benefits of testosterone hormone therapy, and minimizing the nature and severity of potential side effects. In addition to testosterone, Dr. Alhafez also prescribed growth-hormone-releasing hormone to the three additional patients without medical justification. In June 2024, the Commission accepted an Agreed Order which restricts Dr. Alhafez from performing cosmetic surgery without the oversight of a Commission-approved physician who is board certified in plastic surgery. Additionally, Dr. Alhafez will obtain a board-certified endocrinologist to perform periodic reviews of his hormone replacement practice. Dr. Alhafez must complete CMEs in record-keeping, informed consent, testosterone replacement therapy, and pre-operative evaluation of surgical patients, along with writing a paper stating how he intends to apply what he learned in his practice. Dr. Alhafez must pay a $20,000 fine and personally appear before the Commission. Dr. Alhafez may petition to terminate the Agreed Order three years from its effective date and after successful completion of the terms and conditions.

In re Michael Turner, MD, Case No. M2022-194. Final Order.**** On May 4, 2023, the Commission filed a SOC alleging standard of care issues with five patients, including failing to establish a physician[1]patient relationship prior to prescribing medications; prescribing ivermectin to patients based solely on an online questionnaire and without sufficient evidence it was an effective treatment for COVID-19; failing to discuss the use of vaccines or other treatments to prevent COVID-19; and failing to discuss alternative treatments with patients at high risk of serious illness. The Commission held a virtual hearing March 18-20, 2024. A Final Order was issued in June 2024 which restricts Dr. Turner's medical license and places him on oversight. Dr. Turner is restricted from prescribing ivermectin for the prevention and/or treatment of COVID-19 until such time the U.S. Food and Drug Administration has approved ivermectin for such indications. Additionally, Dr. Turner must complete CMEs in medical record-keeping, telehealth, and prevention and treatment of COVID-19, and submit a paper addressing how he intends to reshape his medical practice in light of what he learned from the CMEs. Dr. Turner must also allow practice audits, pay a $5,000 fine, and personally appear before the Commission. Dr. Turner may not seek modification of the Final Order for two years from its effective date.

***A person whose license has been suspended under chapter 18.130 RCW may petition the disciplining authority for reinstatement. RCW 18.130.150.
****Either party may file a petition for reconsideration within ten days of service of the order. RCW 34.05.461(3); 34.05.470. A petition for judicial review must be filed and served within 30 days after service of the order. If a petition for reconsideration is filed, the 30-day period does not start until the petition is resolved. RCW 34.05.542; 34.05.470(3).

Virtual Hearing:
In re Wilson F. Bernales, MD, Case No. M2023-469. On October 27, 2023, the Commission filed a Notice of Decision on Application denying Dr. Bernales' application for a license to practice as a physician and surgeon in the State of Washington. The Commission held a

virtual hearing on May 30, 2024. A Final Order is expected to be issued by end of August 2024.*****

*****The HLJ has 90 days after the conclusion of the hearing to issue a decision. RCW 34.05.461.

Legal Unit Statistics and Costs**

Over the Fiscal Year (FY) 2023-2024, the Legal Unit closed out 80 cases with disciplinary orders:

Agreed Orders	16
Stipulations to Informal Disposition (STIDs)	42
Default/Waiver Orders	14
Final Orders	9

Other Legal Unit stats for FY 2023-2024:

Summary Actions	8
Statements of Charges (SOCs)	27
Formal Hearings	5

Expert Witness Costs for 2022 through May 2024 equaled $301,875.

2022	$99,755
2023	$149,860
January – May 2024	$52,260

Notice of Intent (NOI) Evaluation Costs for 2022 through May 2024 equaled $57,662.61.

2022	$99,755
2023	$149,860
January – May 2024	$52,260

Breakdown of NOI Evaluations Authorized 2022 through May 2024.

EVALUATOR	DATE NOI SENT	DATE ORDER SERVED	DATE EVALUATION BEGINS	EVAL REPORT RECEIVED	TOTAL COST
Acumen	04/21/22	06/01/22	06/02/22	08/26/22	$11,921
Acumen	08/19/22	10/11/22	12/12/22	12/16/22	$8,057
Aimee Asgarian, PsyD	09/02/22	12/07/22	No response. SOC and Default Order issued.		
Acumen	09/16/22	11/29/2022; modified 4/17/23	6/19/23	07/07/23	$10,454
Pine Grove	09/16/22	12/09/22	No response. SOC and Default Order issued.		
Acumen	09/19/22	11/17/22	03/20/23	04/07/23	$10,703
Pine Grove	10/13/22	02/08/23	07/13/23	08/16/23	$9,703
Pine Grove or Talbott	11/30/22	Request for NOI Order Denied 2/14/23.			

Rick Glein, Director of Legal Services continued

EVALUATOR	DATE NOI SENT	DATE ORDER SERVED	DATE EVALUATION BEGINS	EVAL REPORT RECEIVED	TOTAL COST
Megan Gary, MD Psychiatric Medicine Associates	01/19/23	03/27/23	05/26/23	06/15/23	$2,625
Amy Asgarian, PsyD	08/30/23	09/14/23	10/11/23	10/27/23	$4,200
Pine Grove	02/09/23	Request for NOI Order Denied 6/15/23.			
Pine Grove	03/30/23	Request for NOI Order Denied 6/6/23.			
Pine Grove	11/14/23	01/09/24	Failed to schedule evaluation. SOC served and hearing scheduled.		
Pine Grove	1/10/2023	03/03/23	Failed to schedule evaluation. SOC authorized.		
Acumen	NOI authorization subsequently withdrawn.				
Acumen	NOI authorization subsequently withdrawn.				
Acumen	NOI authorization subsequently withdrawn.				
Pine Grove	Pending service.				

**Special thanks to Carolynn Bradley, Lynne Miller, and Jen Batey for compiling the data!

Item of Interest:

On June 12-13, Rick, Lisa, Gina, along with several other WMC staff attended the Center for Telehealth & e-Health Law (CTeL) Digital Health Summit in Washington D.C. CTeL was created to provide vital support to the medical community on topics such as licensure, credentialing and privileging, reimbursement, and private insurance. The two-day sessions were focused on congressional dialogues and developments; digital and tele-health; artificial intelligence; and risk management.

CTeL just released three 50-State Survey research reports. These reports offer a state-by-state review of relevant statutes, regulations, and case law in these critical areas of telehealth policy. They were meticulously prepared by CTeL's Law Fellows and reviewed by CTeL's Legal Resource Team.

- 50-State Survey: State Telehealth Parity for Private Payers,
- 50-State Survey: Informed Consent for Telehealth Services, and
- 50-State Survey: Prescribing Controlled Substances via Telehealth.

Freda Pace, Director of Investigations

Second Quarter Complaint Intake Statistics					
	New Cases	Closed		Authorized	
April	202	153	75.7%	49	24.3%
May	203	146	71.9%	57	28.1%
June	152	116	76.3%	36	23.7%
	557	**415**	74.5%	**142**	25.5%

CMT Refresher

Medical Unknown (Respondent)
When reviewing new complaints, there are times when the respondent is listed as **Medical Unknown**. There are several justified reasons for labeling as such (i.e., the provider was referenced only by their last name, or the complainant failed to identify the provider and there is no follow-up contact information available to inquire further, or the provider is a resident/fellow, etc.). However, even in these types of situations, it is important for the voting panel to focus attention on the issues raised in the complaint, whether the standard of care was met or not). If the panel believes the standard of care *was not* met, voting to authorize an investigation will allow the assigned investigator an opportunity to identify the provider(s) involved. **Reminder**: *The labeling of a complaint as Medical Unknown should not be a standalone reason for closing a complaint*.

Insufficient Information
When access to medical records is the essential information lacking in a complaint being assessed, commissioners are advised to defer to the complainant's experience and authorize an investigation to obtain and evaluate the medical records. Refer to our guideline entitled: **Addressing Inequitable Barriers**, which is included as an attachment in each CMT packet.

Practitioner Support Program (PSP)
This program consists of tailored letters that give the practitioner an educational opportunity to consider and provide resources and materials that relate directly to the report received. **Reminder:** *Currently, we do not offer this resource to complainants. However, this is a program that we are looking to develop in a future phase which will also consist of a tailored letter to complainants.*

CMT Sign-up for 2024
Our 2024 CMT sign up slots are ready, awaiting your name! Please take some time to check out the new CMT calendar to find a vacant slot – there are plenty. 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, at your earliest opportunity, please promptly notify Chris Waterman at chris.waterman@wmc.wa.gov. This courtesy cancellation notice will allow Chris the opportunity to fill any last-minute vacancy needs. If you have any CMT process questions, please do not hesitate to reach out to me directly – freda.pace@wmc.wa.gov.

Jimi Bush, Director of Quality and Engagement

WMC Original Research Making an Impact

WMC research, An Evaluation of Clinicians with Subsequent Disciplinary Actions, selected for presentation in the Research and Ideas Forum at the Coalition for Physician Enhancement Conference this fall. Jimi will be presenting the research for discussion amongst the group. This research was also presented at National Council of State Boards of Nursing (NCSBN) 2024 Discipline Case Management Conference in Annapolis, MD in May.

Commissioner Input Requested for Upcoming Research

At the April meeting of the FSMB, we presented a poster on common complaints by specialty. This research is still in its infancy, and we received a lot of encouraging comments at the poster session for expanding this research. The next step is writing a paper with WMC case studies and perspectives from commissioners on how to address these common complaint instances. It is paramount to hear from you! Please take a moment to review the poster and reflect on its initial findings. Contact Jimi to set up a time to share your thoughts and perspective from your specialty and expertise. This information is also available in word format upon request.

Outreach Update

1) As of July 1st, we have provided over 250 hours of free CME, with more on the way.
2) Upcoming CME topics:
   - The role of artificial intelligence in healthcare
   - The ethical implications of gene editing
   - The future of primary care
   - The importance of diversity and inclusion in medicine
   - The impact of social media on medicine
   - Advancing mRNA technology
   - Physician burnout: causes and solutions
   - How to improve communication with patients
   - How to deal with difficult patients
   - How to maintain a healthy work-life balance
   - The business of medicine
   - Issues related to the healthcare system

If you are interested in contributing to the development of any of these topic areas, please contact Jimi.

3) In January, I asked commissioners to suggest an area of concern in your community, practice, specialty or organization. I have not received any responses to date, and we are planning outreach for 2025. This was called out at the 2023 commissioner retreat as an important service to our licensees and our communities and is a commissioner goal within the strategic plan. Please take a moment to reflect on how we can serve your colleagues and communities through personalized outreach and send Jimi any ideas you may have.

Fall 2024 Newsletter

The quarterly newsletter is an excellent place to reach our entire licensee population. I would

Jimi Bush, Director of Quality and Engagement continued

like to continue to expand on the topics and contributors. I would like to hear from more public members on their perspective of medical regulation. I would like to stand up a technology section that discusses advancements in healthcare such as: Telehealth, Artificial Intelligence, wearable devices, 3D printing, and VR / AR usage. If you would like to write on any of these topics, or have an idea of your own, please let me know. The Fall 2024 newsletter deadline is October 1.

Fiscal Year 2024 Report

The 2024 Fiscal Year (FY) came to a close on June 30th . We publish an annual report after the closing of the fiscal year. We are currently gathering the data for this report, but if you have any suggestions for improvement or have a topic that you would like to see covered, please let Jimi know ASAP so that it can be included. The report is a public facing document and last years report can be found here.

Staff Professional Development – LEAN White Belt Training

Our Business Practices and Productivity Manager, Anjali has recently completed a LEAN white belt training for our staff. The Lean Six Sigma White Belt certification provides foundational knowledge of Lean and Six Sigma principles, enabling individuals to support improvement projects and contribute to organizational efficiency and quality. Lean Six Sigma White Belt training equips individuals with a foundational understanding of process improvement methodologies. This training introduces key concepts and principles of Lean and Six Sigma, providing a solid base for recognizing areas of waste and inefficiency in everyday work activities. At the time of writing, we have 19 WMC staff members that have completed the training. Congratulations!

Amelia Boyd	Jennifer Batey	Kelly Elder	Meghan Howell	Stormie Redden
Christopher Knight	Joe Mihelich	Ken Imes	Mike Hively	Sylke Dixon
Emma Marienthal	Joel DeFazio	Mahlet Zeru	Mike Piechota	Trisha Wolf
Jeff Kinstler	Kayla Bryson	Marne Nelson	Shelley Kilmer-Ready	

Mahi Zeru, Equity and Social Justice Manager

PSP

Physician Support Program (PSP) is an approach used to educate and provide corrective action for providers who have had complaints submitted against them that do not meet the threshold to authorize an investigation. Complaints that can be self-corrected with identification of a single educational training or awareness of current policies are usually thought to be ideal for PSP but reports that demonstrate patient harm, a pattern of previous violations, discrimination, sexual misconduct, impairment, or violations of state or federal law are exempt from PSP considerations. Staff will continue to provide guidance and provide consultation on a case-by-case basis during Case Management Team (CMT) meetings.

Gender Neutral Language

We are conducting a review of all WMC policies, interpretive statements, guidance documents and procedures to ensure the commission consistently uses gender neutral language. As part of the rulemaking process -all rules in WAC 246-919 and 246-918 and PA subsections WAC 246-918-410(2) and WAC 246-918-420(1)) will also undergo a review that includes a gender-neutral language.

Marisa Courtney, Licensing Manager

Total licenses issued from = 04/17/2024-07/10/2024= 1311

Credential Type	Total Workflow Count
Physician And Surgeon Clinical Experience License	4
Physician And Surgeon Fellowship License	3
Physician And Surgeon Institution License	0
Credential Type	**Total Workflow Count**
Physician And Surgeon License	571
Credential Type	**Total Workflow Count**
Physician and Surgeon License Interstate Medical Licensure Compact	231
Physician And Surgeon Residency License	415
Physician And Surgeon Teaching Research License	8
Physician And Surgeon Temporary Permit	2
Credential Type	**Total Workflow Count**
Physician Assistant Interim Permit	3
Physician Assistant License	74
Physician Assistant Temporary Permit	0
Totals:	**1311**

Information on Renewals: April Renewals- 74.13% online renewals

Credential Type	# of Online Renewals	# of Manual Renewals	Total # of Renewals
IMLC	0	108	108
MD	999	279	1278
MDFE	1	0	1
MDIN	1	0	1
MDRE	34	1	35
MDTR	1	3	4
PA	199	40	239
	74.13%	**25.87%**	**100.00%**

Marisa Courtney, Licensing Manager continued

Information on Renewals: May Renewals- 73.44% online renewals

Credential Type	# of Online Renewals	# of Manual Renewals	Total # of Renewals
IMLC	0	124	124
MD	981	310	1291
MDFE	2	0	2
MDRE	137	11	148
MDTR	6	6	12
PA	204	30	234
	73.44%	**26.56%**	**100.00%**

Information on Renewals: June Renewals- 77.66% online renewals

Credential Type	# of Online Renewals	# of Manual Renewals	Total # of Renewals
IMLC	0	70	70
MD	916	191	1107
MDFE	1	1	2
MDRE	235	91	326
MDTR	7	3	10
PA	169	26	195
	77.66%	**22.34%**	**100.00%**

WASHINGTON
Medical
Commission
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Amber Freeberg, Executive Director
Washington State Board of Optometry
May 16, 2024

Via email to Amber.Freeberg@doh.wa.gov

Dear Ms. Freiburg –

Thank you again for your time and discussion on April 26th and please extend the Commission's thanks to Drs. Prothero and Dacumos for joining us. As discussed, the Commission remains committed to dialogue with the Board regarding the structure put in place by Senate Bill 5389. When issues arise that cross regulatory authorities' jurisdiction, it can always be a challenge, so the Board's willingness to meet was appreciated. The Commission offers the following observations:

1. The inclusion of the word "qualified" in RCW 18.53.010(5)(a)(iii) signals intent by the Legislature that it is not merely a licensed allopathic or osteopathic that should serve as a partner to advanced practice optometrists. If that was the Legislature's intent, then the word "qualified" would be unnecessary. (I am not sure if "partner" is the preferred term to describe the relationship created by the required written agreement, but it seems like a choice that strikes a collaborative tone.)

2. The increasing specialization of the medical profession has rendered many benefits for healthcare and society in general, but it also represents challenges when questions arise like the one here. Many physicians may not have recent experience in treating conditions in or around the eyes, let alone acute infections. For your consideration, attached to this letter is a chart of the procedures listed in RCW 18.53.010(2)(a) along with known complications and some additional relevant factors.

3. The same factor mentioned above in #2 also raises serious concerns about referring patients with complications to an acute care hospital's emergency department. Hospitals do not necessarily have specialists, like ophthalmologists, who have experience in treating infections in and around the eyes.

4, As the attached chart outlines, many of the known complications involve post-procedure infection. However, there are others that are specific to issues that are best treated by a board-certified ophthalmologist. There may be other physicians who have the training and experience to partner – I believe Dr. Prothero mentioned dermatologists as a possible option. While not as directly on point as ophthalmologists, if the physician has significant recent experience treating all of the conditions on the chart that occur in and around a patient's eyes, that may be appropriate.

5. The Legislature included a second consideration in RCW 18.53.010(5)(a)(iii) – the word "rapid". As outlined in the attached chart, many of the known complications have a

short timeframe in which the patient will need treatment. If the physician is not readily available, the patient is at increased risk for serious and often permanent impacts.

The path forward that best ensures patients receive high-quality care is to define "qualified" as a board-certified or board-eligible ophthalmologist. The most recent demographic census conducted by the Commission shows approximately 400 allopathic physicians in Washington with board-certification from the American Board of Ophthalmology. In prior discussions with the Board, there was a sentiment expressed that definition was too restrictive and does not honor the Legislature's intent to increase access to care when it passed SB 5389. However, the Commission firmly believes the underlying priority for all parties should be for the safety of the patients. To that end, verifiable training and experience for the partner physicians should be the predominant factor in defining "qualified".

Thank you again, for the opportunity to discuss the matter. As the Board goes forth in its rule-making process, please do not hesitate to reach out if the Boards wants to continue the discussion with the Commission.

/s Kyle S. Karinen

Kyle Karinen, Executive Director
Washington Medical Commission

cc James Chaney, Executive Director for Washington Board of Osteopathic Medicine and Surgery

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Potential complications/disorders for treatment of conditions listed under RCW 18.53.010(2)(a)

(i) Managing common complications/disorders of the lids, lashes, and lacrimal systems

Disorder & Description	Known Complications of Disorder or Treatment Procedures	Complications Generally Arise Within	Treatment of Complications Must Occur	Long-term Impact if Not Addressed Adequately
Acute Hordeolum / Stye Localized eyelid infection (90-95% are caused by the bacteria *Staph aureus*) involving the hair follicles of eyelashes or the meibomian glands.	• Periorbital cellulitis • Abscess or eyelid necrosis • Marginal blepharitis • Permanent vision loss (notably from accidental perforation of the eye during injection or procedural treatment) • Rare, but possible, progressive infection which may lead to death due to systemic infection	Minutes – Days Minutes involving accidental injection of the eye or orbital cellulitis.	Urgently (within 4-6 hours) IMMEDIATELY if vision loss or perforation of the eye, then the patient must be seen ASAP (any delay may contribute to permanent vision loss).	Systemic infections are rare but if/when they occur may lead to upper eyelid necrosis, eyelid deformity, ptosis, proptosis, blindness, or worsening systemic involvement. May deform the cornea and cause permanent vision loss. The risk of permanent vision loss increases with inadvertent/accidental perforation of the eye itself.
Acute Dacryocystitis Lacrimal sac inflammatory condition caused by obstruction of nasolacrimal ducts which may involve an infection (*Staph aureus*, *Haemophilus influenzae*, *Strep pneumoniae*, or *Candida albicans*).	• Orbital cellulitis • Optic nerve compression • Cavernous sinus thrombosis • Brain abscess • Permanent vision loss (notably from accidental perforation of the eye during injection or procedural treatment) • Rare, but possible, progressive infection which may lead to death due to systemic infection	Minutes – Days Minutes involving accidental injection of the eye, orbital cellulitis, or brain abscess.	Urgently (within 4-6 hours) IMMEDIATELY if vision loss, orbital cellulitis, or perforation of the eye, the patient must be seen ASAP (any delay may contribute to permanent vision loss).	Systemic infections are rare but if/when they occur, they may lead to upper eyelid necrosis, eyelid deformity, ptosis, proptosis, blindness, or worsening systemic involvement. May deform the cornea and cause permanent vision loss. The risk of permanent vision loss increases with inadvertent/accidental injection/perforation of the eye itself.

(ii) Managing common complications/disorders of the lids, lashes, and lacrimal systems (cont'd)				
Disorder & Description	**Known Complications**	**Complications May Arise Within**	**Treatment of Complications Must Occur**	**Long-term Impact if Not Addressed Adequately**
Acute Dacryoadenitis Acute inflammation from systemic disease involving the lacrimal gland.	• Lacrimal gland abscess • Preseptal or orbital cellulitis • Rare, but possible, progressive infection which may lead to death due to systemic infection	Minutes – Days Minutes involving accidental injection of the eye or orbital cellulitis.	Urgently (within 4-6 hours) IMMEDIATELY if vision loss or eye penetration occurs during treatment.	Systemic infections are rare but if/when they occur may lead to blindness or worsening systemic involvement.
Acute or Chronic Blepharitis Inflammation of the eyelid which may be acute or chronic and caused by bacteria (*e.g.*, *Staph aureus*), a noninfectious skin condition *(e.g.,* seborrhea or rosacea), or allergies.	• Keratopathy • Dry eyes • Corneal neovascularization and ulceration • Permanent eyelid margin deformity • Vision loss	Minutes – Weeks Minutes involving accidental injection of the eye during injection or biopsy.	Urgently (within 4-6 hours) IMMEDIATELY if vision loss or eye penetration occurs during treatment.	Permanent eyelid deformity and permanent vision loss.
Chronic Chalazion A chronic painless granuloma of the meibomian glands.	• Permanent eyelid deformity • Inability to close the eyelid properly • Permanent corneal damage • Vision loss	Minutes – Weeks Minutes involving accidental injection of the eye during injection or biopsy.	Urgently (within 4-6 hours) IMMEDIATELY if vision loss or eye penetration occurs during treatment.	Permanent eyelid deformity and permanent vision loss.
Lid Skin Lesions Acrochordon (skin tag), benign and malignant skin lesions including nevi and melanoma.	Differentiating benign vs. malignant is imperative as a misdiagnosis may lead to cancer progression and an increased mortality risk.	Minutes – Years Hours involving acute infection or inability to fully close an eyelid. Minutes involving vision loss or eye penetration.	Urgently (involving acute infection or inability to fully close an eyelid). IMMEDIATELY if vision loss or eye penetration occurs during treatment.	If a specimen is not adequately excised and sent for pathology exam, malignancies could be missed. Subsequent risk of local recurrence and metastatic disease are rare but may occur months to years later.

(iii) Injections, including intramuscular injections of epinephrine and subconjunctival and subcutaneous injections of medications				
Procedure	**Known Complications**	**Complications May Arise Within**	**Treatment of Complications Must Occur**	**Long-term Impact if Not Addressed Adequately**
(iii) Injections	• Infection • Cellulitis • Abscess • Tissue necrosis • Nerve injury • Pain • Bleeding • Orbital cellulitis • Permanent vision loss *A misplaced injection carries a real risk of* • Permanent vision loss • Glaucoma risk of ≈ 10% *Injections of Botox* • Facial paralysis • Corneal exposure • Eye penetration • Permanent vision loss • Paralysis of muscles that are necessary to close the eyelid • Paralysis may cause the cornea to dry out which may lead to a corneal transplant	Minutes – Days Signs or symptoms typically begin to develop within minutes but should be recognized within 48 hours.	Urgently (within 4-6 hours) IMMEDIATELY if orbital injection, loss of vision, severe allergic reaction, or significant pain, bleeding, or infection.	Permanent tissue/nerve/organ damage, permanent vision loss including blindness, or death.

(ii) Chalazion management, including injection and excision;
(iv) Management of lid lesions, including intralesional injection of medications; [or]
(vii) Eyelid surgery, excluding any cosmetic surgery or surgery requiring the use of general anesthesia

Disorder & Description	Known Complications	Complications May Arise Within	Treatment of Complications Must Occur	Long-term Impact if Not Addressed Adequately
Acute Issues	• Infection • Pain • Bleeding • Allergic reaction • Difficulty closing eyelids • Dry/irritated eyes • Tearing issues • Eyelid scarring	Minutes to hours post-op but may also occur after a few days.	Urgently or within 6 hours.	Acute issues can lead to chronic issues (as described below)
Chronic Issues	• Dry and irritated eyes • Tearing issues • Eyelid scarring	May develop or persist over weeks.	Typically, within a few weeks.	Generally, involve cosmetic defects (e.g., eyelid deformity) or inconveniences (e.g., dry eyes), but an inability to close the eyelid completely/properly may cause corneal damage which may permanently decrease vision. If there is orbital cellulitis or orbital injection, then permanent blindness of the affected eye may occur. If severe allergic reaction, infection/sepsis, or significant blood loss occurs, then multisystem organ failure (e.g., renal failure needing dialysis) or even death may occur.

Email forwarded from Kristin Peterson, JD, in the Dept. of Health Exec. Office of Policy, Planning, and Evaluation:

***

Dear Dr. Shah and Dr. Kwan-Gett and Dr. Peterson,

As a Professor of Neurology and Neurosurgery at NYU Langone Medical Center with expertise in brain death/death by neurologic criteria, I am writing to respectfully request the Washington State Department of Health acknowledge the 2023 American Academy of Neurology (AAN)/American Academy of Pediatrics (AAP)/Child Neurology Society (CNS)/Society of Critical Care Medicine (SCCM) Pediatric and Adult Brain Death/Death by Neurologic (BD/DNC) Criteria Consensus Practice Guideline as the accepted medical standard for determination of BD/DNC.

The legal definition of death in Washington, which was established In re: Welfare of Bowman, 617 P. 2d 731 (Wash. 1980), indicates that, "An individual who has sustained either irreversible cessation of all functions of the entire brain, including the brain stem, or irreversible cessation of circulatory and respiratory functions is dead. A determination of death must be in accordance with accepted medical standards." However, it defers to physicians to identify the accepted medical standards for BD/DNC determination. The AAN published a practice guideline for BD/DNC determination in adults in 1995, then updated it in 2010. A guideline for BD/DNC determination in pediatric patients was published by the AAP in 1987, then updated in 2011 by the AAP, CNS and SCCM. Last year the AAN, AAP, CNS and SCCM published a guideline for BD/DNC for persons of all ages. No other medical societies have published a BD/DNC guideline, so this is the accepted medical standard in the United States for BD/DNC determination.

Unfortunately, in the absence of stipulated accepted medical standards, reviews of hospital BD/DNC policies demonstrated inconsistencies compared with the standards published by the 2010 AAN and 2011 AAP/CNS/SCCM guidelines. This is problematic because it could lead to inaccurate BD/DNC determination, which would have major negative medical, legal, and ethical implications and erode public trust in the ability of clinicians to accurately determine BD/DNC.

As such, I respectfully request the Washington State Department of Health acknowledge the 2023 AAN/AAP/CNS/SCCM Pediatric and Adult BD/DNC Consensus Practice Guideline as the accepted medical standard for determination of BD/DNC.

Thank you for your consideration.

Sincerely,

Ariane Lewis, MD

Professor of Neurology and Neurosurgery, NYU Langone Medical Center
Professor, Departments of Neurology and Neurosurgery, Director of Neurocritical Care
Co-Editor-in-Chief, Journal of Clinical Neuroscience
Deputy Editor, Seminars in Neurology
Deputy Editor, Neurology Disputes and Debates
NYU Langone Medical Center
***

From: Ariane Lewis

Sent: Thursday, April 11, 2024 1:16 PM

To: Shah, Umair A (DOH); Kwan-Gett, Tao (DOH); Peterson, Kristin I (DOH)

Subject: Re: Washington State Department of Health Guidance on Brain Death Determination

I am writing to follow up on my below email regarding clarification of the accepted medical standards for brain death determination in your state. For your awareness, Nevada is actually the only state that clearly stipulates the accepted medical standards for brain death determination in their statute on determination of death. They modified their statute in 2017 after the Supreme Court of Nevada ruled that it was not clear which standards represented the accepted medical standards such that it now notes the accepted medical standards are those written by the American Academy of Neurology and the Society of Critical Care Medicine or their successor organizations. Other states use vague terminology like "accepted medical standards" without providing a definition of said standards. For the past few years, the Uniform Law Commission considered revising the Uniform Determination of Death Act to address a number of concerns, and one revision that was discussed was specification of the accepted medical standards. However, for a variety of reasons, the revision process was abandoned. Nonetheless, it is problematic that reviews of hospital brain death determination policies demonstrate there are some inconsistencies compared with the medical society guidelines because a person should not be considered dead at one hospital, but alive at another.

For your knowledge, here is a link to New York State Department of Health's post about the accepted medical standards for BD/DNC determination: https://www.health.ny.gov/professionals/hospital_administrator/determining_brain_death/.

I would appreciate you taking the time to consider this issue and let me know what you and your team decide about whether/how to address it. I am happy to answer any questions.

Thank you.

Ariane

***

WASHINGTON MEDICAL
COMMISSION
P.O. BOX 47866
OLYMPIA, WA. 98504-7866

PHYSICIAN'S PRESCRIPTIONS SHOULD BE LIMITED TO PRESENT DISORDERS.

THANK YOU,
Frank E. Madura
FRANK E. MADURA
c/o 1504-S.W. 130TH
BURIEN, WA.
98146

TRULINCS 66857019 - RUAN, XIULU - Unit: OAK-V-A

Xiulu Ruan, MD; 66857019
F.C.I. Oakdale 1, V1, P.O. Box 5000
Oakdale, LA 71463

Re: Your Understanding and Support

June 21, 2024

Ms. Melanie de Leon, JD, Executive Director
Washington Medical Commission
P.O. Box 47866, Olympia, WA 98504-7866

Dear Ms. de Leon:

Three years ago Physicians Against Abuse (PAA) filed an amicus brief in support of my Supreme Court petition in which PAA made the following observation regarding the unique formula used by federal prosecutors to prosecute physicians as "drug traffickers":

"This formula has made U.S the only country in the world mass incarcerating physicians. This is not because all the criminal doctors miraculously reside in the United States, but rather, because there is something significantly wrong in the manner federal prosecutors have been allowed to litigate these cases as if they are in the 'wild west'...No other country criminalizes physician behavior like the federal prosecutors have done in the U.S....Doctors are just a 'sitting duck' for these federal prosecutors who raid medical offices and unlike the career drug pusher on the streets who gets caught and charged with one or two counts, federal prosecutors pike up count after count because doctors are required to keep records and those records are used against them in these out of control prosecution against physicians."

The attached essay -- my critical analysis on the criminal standard used by the Government to prosecute medical providers as "drug traffickers" under the Controlled Substances Act (CSA) Section 841 -- has fully demonstrated how blatantly absurd and egregiously unconstitutional this prosecutorial "formula" is. It is deeply disturbing to see that such a nonsensical, illogical, and barbarous criminal standard has remained invincible for the past half a century, during which thousands of well-intentioned healthcare providers have been vilified as "notorious drug dealers."

The goal of this essay is to illustrate that this draconian criminal standard is fatally flawed on multiple grounds and its use in prosecuting healthcare providers as "drug traffickers" is gravely unconstitutional. I have taken the liberty of including a letter written to some of the nation's top lawyers/law firms for your convenience, as it provides a summary for the lengthy essay.

It has been more than seven years since Dr. John Patrick Couch and I were convicted as "drug dealers" under this absurd and unjust criminal standard, following a lengthy jury trial in 2017. My case has been brought to the U.S. Supreme Court twice, the Eleventh Circuit four times, and the District Court several times. Currently, my case, along with that of Dr. Couch's, is back before Judge Callie V. S. Granade, Southern District of Alabama, awaiting resentencing. (The address of Judge Granade is: John A. Campbell U.S. Courthouse, 113 St. Joseph Street, Room 123, Mobile, AL 36602)

I wonder if you and your colleagues may kindly write a letter to Judge Granade in support of our resentencing, realizing that an amicus brief may be too time-consuming and costly?

Thank you very much in advance for your time and attention to this matter.

Very truly yours,

PR

Xiulu Ruan, MD

TRULINCS 66857019 - RUAN, XIULU - Unit: OAK-V-A

Xiulu Ruan, MD; 66857019
F.C.I. Oakdale 1, V 1
P.O. Box 5000, Oakdale, LA 71463

Re: Your Understanding and Support

Date: June 15, 2024

John B. Quinn, Co-Owner
Quinn Emanueal Urquhart & Sullivan
865 S. Figueroa St., 10th Floor, Los Angeles, CA 90017

Dear Mr. Quinn:

Please excuse me for taking the liberty of sending you this unsolicited mail. To raise the awareness of the barbarous criminal liability standard used to prosecute medical providers as "drug traffickers," I humbly share with you the attached essay. Realizing that you may not have time to read this lengthy essay, I decided to provide a brief summary here.

For decades this criminal standard had taken the form of a hybrid consisting of CSA 841 statute, a federal regulation, 21 C.F.R. Section 1306.04(a), and the Supreme Court's Caselaw, U.S. v. Moore 423 U.S. 122 (Moore 1975).

i. Section 841 statute aims at nonregistered drug traffickers and contains no such word as "physician" or "pharmacist." Thus Section 841 statute does not relate to registered professionals.
ii. 21 C.F.R. Section 1306.04(a), promulgated by the DOJ/DEA, contains two prongs, "usual course of professional practice" and "legitimate medical purpose." This regulation serves to tie physicians' prescribing conduct to Section 841.
iii. In U.S. v. Moore, 423 U.S. 122, the Court held: "Registered physicians can be prosecuted under Section 841 when their activities fall outside the usual course of professional practice [OUCPP]." The Moore Court stipulated "OUCPP" to mean felonious drug trafficking under Section 841.

The problem is: There is no logical connection between violation of Section 1306.04(a) and violation of Section 841 -- because the former contemplates a civil offense, while the latter represents a felonious offense of drug trafficking. Courts, however, managed to falsely establish the connection between the two by equivocally using the term, "OUCPP." Indeed convictions of medical providers under Section 841 as "drug traffickers" invariably hinged on making Section 1306.04(a) the surrogate "except as authorized" clause of Section 841 so as to tie physicians' prescribing to Section 841.

Inconceivably, for half a century, no literature has persuasively challenged the blatant absurdity and unconstitutionality of this hybrid standard. This essay aims to fill the void. Specifically I have shown that both Section 1306.04(a) and Moore 1975 are fatally flawed on multiple grounds; their uses as elements of an felonious offense under Section 841 are unconstitutional.

On June 27, 2022, the Supreme Court handed down Xiulu Ruan v. U.S., 142 S. Ct. 2370. The Court, however, did not expressly define the "except as authorized" clause. The lack of clarity was exploited by lower courts to continue misusing Section 1306.04 (a) as the surrogate "except as authorized" clause in wrongfully convicting medical providers under Section 841. In this essay I have identified with reasonable confidence the crucial "except as authorized" clause that the Court did not make clear.

It has been more than seven years since Dr. John Patrick Couch and I were convicted under Section 841 as "drug traffickers," following a lengthy jury trial in 2017. My case has been brought to the Supreme Court twice, the Eleventh Circuit four times, and the District Court several times. Currently my case, along with Dr. Couch's, is back before Judge Callie V. S. Granade, Southern District of Alabama, Mobile, Alabama, awaiting resentencing on July 17, 2024. I wonder if you and your colleagues may kindly write a letter to Judge Granade in support of our resentencing, realizing that an amicus brief may be too time-consuming and costly? Thank you very much in advance for your time and attention to this matter.

Most respectfully,

Xiulu Ruan, MD

Re-Examining The Criminal Standard Of Prosecuting Physicians As "Drug Traffickers" And Searching For The True Identity Of The "Except As Authorized" Clause In the Supreme Court's Caselaw, Xiulu Ruan v. U.S., 142 S. Ct. 2370

Xiulu Ruan, MD; June 2, 2024

I. INTRODUCTION

In recent years thousands of law suits have been filed throughout the country relating to the "Opioid Crisis." One case caught my attention: City of Huntington and Cabell County v. AmerisourceBergen Drug Corp., 609 F. Supp. 3d 408 (S.D. W. Va. 2022), where a West Virginia City and West Virginia County filed lawsuits against three wholesale distributors of medical products -- claiming that defendants' wholesale distribution of prescription opioids in Huntington and Cabell County created an opioid epidemic and caused a public nuisance in these localities. I chose this case for my introduction because it contains much important, rarely-seen-elsewhere background information revealing how exactly the nation's "Opioid Crisis" had occurred. At the bench trial held from May 3, 2021 to July 28, 2021, seventy witnesses had testified, producing massive amount of testimony from which I have selected the following:

(1) There is and has been an opioid epidemic in the City of Huntington and Cabell County. A Plaintiff expert witness testified West Virginia as "Ground Zero" for the national opioid epidemic, the hardest-hit State in the country;

(2) The roots of the nation's "Opioid Crisis" were complex and inextricably entangled with the treatment of pain, the increased awareness of the undertreatment of pain, and the changes in the standard of care for the treatment of pain, collectively brought about or contributed by a host of organizations, including but not limited to various state medical boards, the Federation of State Medical Boards, the Joint Commission on Accreditation of Healthcare Organizations, the Institute of Medicine, the World Health Organization, etc. For example, in 2001, the Drug Enforcement Administration (DEA) and 21 Health organizations including the American Medical Association ("AMA") released "A Joint Statement" that states: "undertreatment of pain is a serious problem in the United States...effective pain management is an integral and important aspect of quality of medical care, and PAIN SHOULD BE TREATED AGGRESSIVELY." (emphasis added).

(3) Opioid Manufacturers, not defendants, exploited the new standard of care to aggressively market prescription opioids; and

(4) It was the good-faith prescribing by medical providers that drove the increased volume of opioid prescriptions. Specifically on this aspect experts on both sides testified similarly to the following:

i. The Chief of the Division of Pain Medicine at Brigham & Woman's Hospital of Harvard Medical School, Dr. Chris Gilligan opined that, even at the peak of opioid prescribing, "the great majority of the over-prescribing was well-intentioned." ("I think there was a great majority of cases of well-intentioned clinicians trying to follow what they understood, or in some cases what they had been told, was the right way to treat patients.")

ii. Dr. Timothy Deer (who runs the largest pain clinic in West Virginia, specializing in pain medicine and anesthesia) testified that doctors who prescribed more opioids in accordance with the changing standard of care were acting reasonably based on the information available. ("Many physicians adopted the philosophy that you upped the dose of opioids until someone got better, their pain below a 3 or a 4, or they had a side effect. And there was no ceiling, was what Dr. Portenoy always stated in his lectures around the country.")

iii. Plaintiff witness, former Commissioner for the Bureau of Public Health for the State of West Virginia, Dr. Rahul Gupta, testified that most doctors' intent in prescribing opioids was to help their patients because "that was the culture. That was the education. That was the influence. That was the understanding."

iv. Plaintiff witness, Dr. Katherine Keyes, Associate Professor of Epidemiology at Columbia University's Mailman School of Public Health, testified that the "overwhelming majority of doctors prescribe opioids to their patients in good faith." She also testified that "pill mills do not explain in any significant way the expansion of opioid prescribing and opioid-related harm."

v. Plaintiff witness, Dr. Robert "Corey" Waller, a physician and Associate Professor at Michigan State University, testified that doctors prescribing opioids for chronic non-cancer pain in the mid-2000s "were in good faith."

vi. Most remarkably, Plaintiff witness, the former Head of the DEA's Office of Diversion Control, Mr. Joseph Rannazzisi had testified twice before Congress, stating: (1) "99 percent of the doctors are perfect" and "that the overwhelming majority of prescribing in America is conducted responsibly"; and (2) "99.5 percent of the prescribers...are not overprescribing."

Based on the foregoing testimony, undeniably physicians' prescribing activities should be inherently lawful. This presumption of innocence is crucial because it distinguishes medical providers' good-faith prescribing activities from those of illicit street corner drug dealing. The constitutional principle of presumption of innocence until proven otherwise demands so. However, for four and a half decades, the criminal standard to prosecute medical providers as "drug traffickers" violated this basic constitutional principle by requiring medical providers to show their innocence, namely their prescribing of controlled substances was "in the usual course of professional practice" and "for a legitimate medical purpose."

For instance, in our interventional pain clinic, Physicians' Pain Specialists of Alabama, Mobile, Alabama, Dr. John Patrick Couch and I provided much needed multi-disciplinary pain management, including prescribing opioids in treating patients' pain in those who had failed other non-opioid therapies; our prescribing activities were treated by the prosecution as inherently unlawful. At our trial, in the prosecutor's opening argument, Mr. Chris Bodnar so told the jury: "[P]rescribing a controlled substance is illegal unless there's two things that happen: It's prescribed in the usual course of professional practice and it's prescribed for a legitimate medical purpose." (Tr.1/5/2017, p. 27).

Since mid 1970's, the criminal standard to convict physicians as "drug traffickers" has employed a hybrid standard, consisting of: the Controlled Substances Act (CSA) Section 841 statute, a federal regulation, 21 C.F.R. Section 1306.04(a), and the Supreme Court's Caselaw, U.S. v. Moore, 423 U.S. 122 (1975). (See U.S. v. Lague, 971 F.3d 1032 (9th Cir. 2020)). This hybrid standard presumed providers' prescribing of controlled substances to be inherently unlawful. For example, the Eighth's Circuit in U.S. v. Smith, 573 F.3d 639, 664, n.3 (2009) held that the Controlled Substances Act and regulations make distribution unlawful unless there is an "effective prescription." 21 U.S.C.S. Section 841, 822(b), and 21 C.F.R. Section 1306.04, which provides that a prescription is only effective if it is both issued in the usual course of professional practice and for a legitimate medical purpose. In other words, a prescription is unlawful unless the physician can prove that his prescription was issued in the usual course of professional practice and for a legitimate medical purpose.

For half a century medical providers have been prosecuted under the CSA Section 841 as though they were illicit drug dealers to begin with, despite the fact that 99 to 99.5% of them practiced medicine lawfully and in good faith in helping their patients. This indiscrimination is fundamentally unfair. Indeed in U.S. v. Litwin, 2023 U.S. Dist. LEXIS151063 (D. Nev. 2023), the Court held that "certain individuals are inherently authorized, by law, to deal in and handle controlled substances... registered medical practitioners who dispense controlled substances cannot be presumed to do so unlawfully.... Such a presumption is irrational and hence unconstitutional" (2023 U.S. Dist. LEXIS 6).

On June 27, 2022, the Supreme Court (the Court) handed down Xiulu Ruan v. U.S., 142 S. Ct. 2370. In a unanimous decision the Court vacated the judgment by the Eleventh Circuit, holding that CSA 841's "knowingly or intentionally" mens rea applies to "except as authorized" clause. The Government must prove beyond a reasonable doubt that the practitioner defendant knowingly or intentionally acted in an unauthorized manner. Prior to the publication of Ruan Caselaw, lower courts had allowed convictions of medical providers as "drug traffickers" under Section 841 without requiring the Government to prove that the defendant physician had a criminal mind, or mens rea. The Ruan Court, however, did not expressly state what the "except as authorized" clause is, or practically what the standard of evaluation should be respecting the term, "knowingly or intentionally acted in an unauthorized manner." This lack of clarification led to the continued misuse and abuse of Section 1306.04(a) as the surrogate "except as authorized" clause in wrongfully convicting medical providers under Section 841.

This essay aims to show (1) that the criminal standard used to prosecute physicians under Section 841 is gravely erroneous because both the Moore Caselaw and 21 C.F.R. Section 1306.04(a) are fatally flawed on multiple grounds and the Ruan Court failed to address related problems; (2) what the "except as authorized" clause is or should be, since the Ruan Court repeatedly referenced but did not expressly define it. Or, what the practical standard of evaluation should be respecting "knowingly or intentionally acted in an unauthorized manner"; and (3) why the use of vague 21 C.F.R. Section 1306.04(a) as the surrogate "except as authorized" clause to convict medical providers under Section 841 as "drug traffickers" is unconstitutional.

II. LEGAL FRAMEWORK

For close to half a century courts widely used a hybrid criminal standard consisting of: the CSA 841 statute, a federal regulation, 21 C.F.R. Section 1306.04(a), and the Supreme Court's Caselaw, U.S. v. Moore, 423 U.S. 122 (1975).

21 U.S.C. Section 841(a) states: "Except as authorized by this subchapter, it shall be unlawful for any person to knowingly or intentionally...manufacture, distribute, or dispense, or possess with intent to manufacture... or dispense a controlled substance."

21 C.F.R. Section 1306.04(a) provides that "a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."

In U.S. v. Moore, 423 U.S. 122 (1975) ("Moore 1975"), the Court held that "Registered physicians can be prosecuted under Section 841, when, as here, their activities fall outside the usual course of professional practice."

In Xiulu Ruan v. U.S., 142 S. Ct. 2370, 2372 (2022) ("Ruan 2022"), the Court held that the CSA 841's "knowingly or intentionally" mens rea applies to the "except as authorized" clause. Once the defendant meets the burden of producing evidence that his or her conduct was "authorized," the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner.

III. DISCUSSION

A. The Government And Courts Made Section 841's "Except As Authorized" Clause A Chameleon.

In 1970 the Controlled Substances Act (CSA) replaced the Harrison Narcotics Act (HNA) of 1914 with a series of provisions specifically designed to treat registered and unregistered individuals differently (U.S. v. Moore, 505 F.2d 426, 431) ("Moore 1974"). CSA Section 841 aims at nonregistered drug traffickers; Section 842 is a regulatory provision that primarily aims at "technical violations," a civil penalty; and Section 843 defines more serious criminal offenses for registrants (Id., at 430).

To begin with, the "except as authorized" clause in the CSA 841 statute had nothing to do with 21 C.F.R. Section 1306.04(a), because the latter was nonexistent when the CSA was enacted in 1970. 21 C.F.R. Section 1306.04(a) was re-designated in 1975 from Section 306.04(a), which was published in 1973 (Moore 1975, 423 U.S. 122, 146, n.12). Any physician who was licensed by a state medical board would satisfy the "except as authorized" clause in Section 841. (U.S. v. Rosenberg, 515 F.2d 190, 203)(Ely, Circuit Judge)(dissenting). In other words, being a licensed physician alone satisfied the "except as authorized" clause. On this basis, only when a physician stopped being a physician did his prescribing become unauthorized.

This, however, gradually changed years later in a insidious way, after the Government succeeded in misrepresenting that 21 C.F.R. Section 1306.04(a) was the intended "except as authorized" clause. As a result, the connotation of "except as authorized" changed from being a licensed practitioner to the practitioner's showing that his practice satisfied the two prongs in Section 1306.04(a). This change allowed the presumption of guilt by the Government and courts as described. Thus instead of the Government's burden to prove the defendant acted in an unauthorized manner, it becomes defendant's burden to show he is innocent by satisfying the two vague prongs in Section 1306.04(a).

The Ruan Court appeared reluctant to equate Section 1306.04(a) to the "except as authorized" clause. Although it repeatedly referenced "except as authorized," it did not clearly state what the "except as authorized" clause is. Instead, it explicitly expressed its concern with using Section 1306.04(a)'s languages as the statute's "except as authorized" clause: "Moreover, the language defining an authorized prescription is 'ambiguous' and 'open to varying construction.' (142 S. Ct., at 2372) More than a decade ago, in Gonzales v. Oregon, 546 U.S. 243 (2006), the Court criticized that the terms at issue described in Section 1306.04(a) were circular. "The regulation uses the terms 'legitimate medical purpose' and 'the course of professional practice,' but this just repeats two statutory phrases and attempts to summarize the others. It gives little or no instruction on a central issue in this case: Who decides whether a particular activity is in the 'course of professional practice' or done for a 'legitimate medical purpose'?" (Gonzales, at 257).

B. The Ruan Court Did Not Regard Section 1306.04(a) As The "Except As Authorized" Clause.

The most compelling evidence that the Ruan Court did not regard Section 1306.04(a) as the "except as authorized" clause is: Section 1306.04(a) already has its own knowing element; it does not need an extra one from Ruan 2022. It was unlikely that the Ruan Court failed to notice the already existent knowing element in Section 1306.04(a) and went through all the troubles in Ruan 2022 to conclude that 841's "knowingly or intentionally" mens rea applies to the "except as authorized clause" while believing the "except as authorized" clause and Section 1306.04(a) to be the same thing. The full text of 21 C.F.R. Section

1306.04(a) provides:

"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice [Sentence A]. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription [Sentence B]. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Section 309 of the Act (21 U.S.C. 829) and the person KNOWINGLY filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances [Sentence C]." (21 C.F.R. Section 1306.04(a)) (emphasis added).

As seen Section 1306.04(a) contains the two prongs at issue in Sentence A, but Section 1306.04(a) actually contains a knowing element, "KNOWINGLY filling such a purported [or invalid] prescription... the person issuing it" in Sentence C. Again it is highly unlikely that Justices of the Supreme Court failed to read Section 1306.04(a) in its entirety and simply missed this knowing element in Sentence C of Section 1306.04(a). Therefore, when the Ruan Court held that Section 841's "knowingly or intentionally" mens rea applies to the "except as authorized" clause, it believed the "except as authorized" clause to be something different from Section 1306.04(a). In other words, the Ruan Court did not believe the "except as authorized" clause and Section 1306.04(a) to be the same thing. This inference further confirms my assertion that there is no logical connection between Section 841 violation and Section 1306.04(a) violation.

C. There Is No Logical Connection Between Violation of Section 1306.04(a) And Violation of Section 841.

CSA 841 statute was designed to punish nonregistered drug pushers; it does not contain the word "registrant(s)" such as "physician(s)" or "pharmacist(s)" within Section 841 statute. 21 C.F.R. Section 1306.04, promulgated by the DOJ/DEA, attempts to tie registrants' conduct to Section 841 statute. Examining the full text of Section 1306.04(a), we see that Sentence C expressly states that a knowing violation of Section 1306.04(a) would lead to violation of Section 309, which relates to 21 U.S.C. 829 (dealing with prescriptions), the punishment of which is provided in Section 842 (civil) and probably Section 843 (criminal). As a matter of fact, the Moore Court clearly distinguished violation of Section 829 from violation of 841, calling the latter a "significantly greater offense." (Moore 1975, at 138). The following case laws support the lack of logical connection between violation of Section 1306.04(a) and violation of Section 841:

i. In Zaidi v. DEA, 841 F.3d 707, 712 (6th Cir. 2016), the Sixth Circuit held that the DEA administrator properly suspended the physician's certificate of registration because of his violation of Section 1306.04.

ii. In U.S. v. Howen, 2022 U.S. Dist. Lexis 236721 (E.D. Cal. 2022), the Howen Court held that "Section 1306.04(a) explicitly subjects pharmacists to civil penalties if they "knowingly" fill an invalid prescription." (2022 U.S. Dist. LEXIS 14).

iii. In U.S. v. Patka, 2018 U.S. Dist. LEXIS 110133 (S.D. Ga. 2018), defendant Dr. Patka would pre-sign blank prescriptions so that his physician assistants could prescribe Schedule II drugs in his absence . Plaintiff alleged that Dr. Patka violated 21 U.S.C. 842, which states that "[i]t shall be unlawful for any person who [is registered to dispense controlled substances] to distribute or dispense a controlled substance in violation of Section 829 of this title." 21 U.S.C. Section 842(a)(1). The Court entered judgement in favor of the Plaintiff in the amount of $1,200,000. (2018 U.S. Dist. LEXIS 6).

All of the above violations of Section 1306.04 (even if "knowing") were civil in nature, not criminal, let alone felonious. This further confirms that the Ruan Court could not have decided to apply Section 841's felonious mens rea to a civil conduct of Section 1306.04(a) violation.

D. If There Is No Logical Connection Between Section 1306.04(a) Violation And Section 841 Violation, How Could Courts Widely Use The Hybrid Criminal Standard Of Section 1306.04(a), Section 841 Statute, And The Supreme Court Caselaw Moore (1975) To Convict Medical Providers Under Section 841?

The Supreme Court's Caselaw Moore 1975 (423 U.S. 122) played a vital role in erroneously connecting Section 1306.04(a) violation to Section 841 violation. The Court in Moore 1975 held that "Registered physicians can be prosecuted under Section 841, when, as here, their activities fall outside the usual course of professional practice." Thus the Moore Court made the term "outside the usual course of professional practice" ("OUCPP") equate to "drug trafficking" under Section 841.

It is crucial to realize that the term, "outside the usual course of professional practice" (OUCPP), in the context of violation of Section 1306.04(a) is materially different from that in the context of Moore 1975. The former contemplates a civil violation whereas the latter represents drug trafficking under Section 841 as a result of Moore Court's stipulative ruling. It is only through

the equivocal usage of the term, "outside the usual course of professional practice" (OUCPP) that a false connection between the violation of Section 1306.04(a) and violation of Section 841 is established. As a consequence, innocuous conduct such as OUCPP in violation of Section 1306.04(a) becomes notorious felonious offense under Section 841.

E. Several Major Flaws In Moore 1975

1. Moore 1975 eliminated the Government's burden of proving that the defendant had a guilty mens rea. Moore's conclusive ruling, "registered physicians can be prosecuted under Section 841 when their activities fall outside the usual course of professional practice" ("Moore's OUCPP Rule") is erroneous because it left no room for the physicians' subjective mens rea. In Ruan 2022 (142 S. Ct. 2370, 2372), the Court held that Section 841's "knowingly or intentionally" mens rea applies to the statute's "except as authorized" clause. Once a defendant meets the burden of producing evidence that his or her conduct was "authorized," the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner. What matters is the defendant's subjective mens rea. (Id., at 2382)

Moore's OUCPP Rule completely eliminated Government's burden to prove a requisite mens rea; therefore Moore 1975 cannot be squared with Ruan 2022 or a host of Supreme Court cases on which Ruan 2022 relied, e.g., Morissette v. U.S., 342 U.S. 246, 251 (1952); U.S. v. U.S. Gypsum Co., 438 U.S. 422 (1978); Liparota v. U.S., 471 U.S. 419, 426 (1985); U.S. v. X-Citement Video, Inc., 513 U.S. 64, 72-73 (1994); Staples v. U.S., 511 U.S. 600, 619 (1994); Elonis v. US., 575 U.S. 723, 736-737 (2015); and Rehaif v. U.S., 588 U.S.__(2019). On this basis alone, Moore 1975 should be invalidated.

2. Moore 1975 misled the lower courts to assert facts as matters of truth respecting OUCPP -- when it failed to warn the lower courts of the limitation that Moore's conclusive ruling was a result of Moore Court's stipulation. The Moore Court, in essence, stipulated the term "outside the usual course of professional practice" (OUCPP) to be "drug trafficking" by physicians under Section 841. This is because the former, based on its dictionary meaning, has no criminal connotation and thus cannot be equal to the latter -- no matter how hard one intends to so stretch it. Through stipulation the Moore Court drew an equal sign between the two. However, a stipulated definition is neither true nor false. In their book, "Introduction to Logic," Professors Irving M. Copi and Carl Cohen admonished that "the definition that arises from the deliberate assignment of a meaning is properly called 'stipulative.' The term newly defined need not itself be entirely novel; it may be new only in the context in which the definition takes place." ("Introduction to Logic," Ninth Edition, Macmillan Publishing Company, 1994, p. 171). "A stipulative definition is neither true nor false; neither accurate nor inaccurate; in this respect, it differs sharply from a dictionary definition...They actually do have the same meaning for anyone who accepts the definition, but that is a consequence of the definition rather than fact asserted by it...In this sense, a stipulative definition is directive rather than informative." (Id.).

There has been no clear definition of OUCPP in any statutory framework (U.S. v. Orta-Rosario, 469 Fed. Appx. 140, 143 (4th Cir. 2012; U.S. v. Birbragher, 603 F.3d 478, 485 (8th Cir. 2010)). Thus lower courts used OUCPP based on its dictionary meaning in asserting facts as matters of truth. The dictionary meaning of OUCPP courts took simply meant that the physician's practice was somehow unusual, or not in a way that was most often observed. For instance, Dr. Smith always wore a white coat when seeing his patients and prescribing medications. When one day he happened to wear a black jacket, his prescribing of controlled substances on that day was unusual for him. Based on the dictionary meaning of OUCPP, he could be prosecuted under Section 841 as a "drug trafficker"! Under Moore's OUCPP Rule, unusual medical practice became unlawful drug trafficking. No wonder Moore's OUCPP Rule resulted in massive incarceration of medical providers under Section 841.

3. The Moore Court committed the fallacy of hasty generalization in deriving the Moore's OUCPP Rule. In his book, "Logic for Lawyers: A Guide to Clear Legal Thinking" ("Logic for Lawyers," National Institute for Trial Advocacy, Third Edition, 1997), Reggero J. Aldisert, former Chief Justice of the Third Circuit, explained that the fallacy of hasty generalization results from enumerating instances without obtaining a representative number to establish an inductive generalization. It appears when one or two decisions are used to make a quantum leap to a conclusion that these decisions form a rule of a generalization. (Id., p. 276) "What it does is to anoint an isolated instance[ ] with the chrism of generality, and create a general rule from an exceptional circumstance." (Id.)

Dr. Moore's practice was unparalleled: Dr. Moore prescribed as many methadone (Schedule II opioid) tablets as patients asked, and patients would pay sliding scale fees according to the number of methadone tablets prescribed. The Senate Report on Narcotic Addict Treatment Act of 1974 used Dr. Moore's case as the most egregious example of unscrupulous physician operating in illicit drug trafficking. (Moore 1974, 505 F.2d 426, 475) (dissenting). The Moore Court drew a hasty generation of

the OUCPP Rule from exceptional circumstances of Dr. Moore's practice not shared by other physicians' cases.

The formal syllogism the Moore Court used in arriving at Moore's OUCPP Rule is:

Major Premise: Registered physicians can be prosecuted under Section 841 when their activities fall OUCPP.
Minor Premise: Dr. Moore's activities fell OUCPP.
Conclusion: Registered physicians can be prosecuted under Section 841 when their activities fall OUCPP.

The Moore Court made a much broader ruling concerning "registered physicians" in general, rather than Dr. Moore in particular. This generalization was based on one case only, i.e. Dr. Moore's case. This is an egregious generalization. In "Logic for Lawyers," Judge Aldisert so warned against hasty generalization: "It is important to understand that a single court decision cannot give birth to an all-inclusive principle. Formulation of a broad principle from a single case decision exemplifies the material fallacy of hasty generalization." (Id., p. 35)

In "Introduction to Logic" (Pearson Education, Inc. 14th Edition, 2011, p. 132), Professors Irving M. Copi, Carl Cohen, and Kenneth McMahon, pointed out a hasty generalization as "the fallacy we committed when we draw conclusions about all persons or things in a given class on the basis of our knowledge about only one (or only a few) of the members of that class." They further explained: "To move from a single case, or a very few cases, to a large-scale generalization about all or most cases, is fallacious reasoning, but it is common and tempting." (Id., p. 133) Undeniably the Moore Court committed the fallacy of hasty generalization when deriving the Moore's OUCPP Rule.

4. The Moore Court also committed the fallacy of misplaced literalism when deriving the Moore's OUCPP Rule. In his book, "Historians' Fallacies" (Harper Perennial, 1970), the author, Professor David H Fischer, explained: "[T]he fallacy of misplaced literalism is a form of context error, which consists in the misconception of a statement-in-evidence so that it carries a literal meaning...the attribution of a general meaning where a specific one was meant." (Id., p. 58). Dr. Fischer warned that the fallacy of misplaced literalism can make a shambles of institutional history.

The Moore Court oversimplified a complex issue by stripping the issue of its complexities and by forcing the issue into some convenient general category. In deriving the OUCPP Rule, the Court epitomized the fallacy of misplaced literalism by using a general term, "outside the usual course of professional practice" (OUCPP), to represent the egregious and specific conduct by Dr. Moore, namely Dr. Moore prescribed methadone tablets as many as patients asked, but charged patients sliding-scale fees based on the number of methadone tablets prescribed. This stipulative, yet undefined term, OUCPP, is so broad that it essentially prevents any discernment of distinguishable facts between Dr. Moore and other accused physicians' cases (more discussion on this issue later).

F. Several Major Flaws In 21 C.F.R. Section 1306.04(a)

21 C.F.R. Section 1306.04(a) is so impermissibly vague that it violates the due process, which bars enforcement of a criminal statute for vagueness if it fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement. (U.S. v. Williams, 553 U.S. 285, 304(2008)). I will demonstrate below Section 1306.04(a) is extremely vague and ambiguous on multiple grounds.

1. I will start with my observation that there are two lines of precedents interpreting Section 1306.04(a) with opposing stances. Sentence A of Section 1306.04(a), i.e. "A prescription for a controlled substances to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice" (Sentence A), contains two prongs, "usual course of professional practice" and "legitimate medical purpose." Sentence A is stated in an affirmative tone. When courts needed to state Sentence A in a negative tone to describe a "prohibited act," some would put the word "not" before Prong A only, ignoring Prong B, while others would put the word "not" before both Prong A and Prong B. As a result, we see two lines of precedents interpreting Section 1306.04(a) with opposing stances respecting Prong B, namely "in the usual course of professional practice" and "not in the usual course of professional practice." Absurdly, all would lead to convictions of the prosecuted medical providers.

For instance, the Fifth Circuit considers Section 1306.04(a) having only one element, i.e. Prong A. In U.S. v. Rosen, 582 F.2d 1032,1033 (5th Cir. 1978), it stated: "To convict...in violation of 21 U.S.C.S. 841(a)...that he did so other than for a legitimate medical purpose and IN the usual course of professional practice." (Id., at 1033) ("Rosen Court Language," or "RCL") (emphasis added). By contrast, in U.S. v. Feldman, 2016 U.S. Dist. LEXIS 66868 (M.D. Fla. 2016), the Court stated: "Feldman prescribed controlled substances for other than legitimate medical purpose and NOT in the usual course of professional practice." (2016 U.S. Dist. LEXIS 5) ("Feldman Court Language," or "FCL") (emphasis added). Apparently the Feldman Court considered Section 1306.04(a) involving two elements, i.e. both Prong A and Prong B.

To argue that RCL and FCL are the same is to violate the Law of NonContradiction, which dictates that contradictory propositions cannot both be true at the same time in the same sense (the premises "A is B" and "A is not B" are mutually exclusive and collectively exhaustive and therefore cannot be both true). If FCL is true, then RCL must be false. The problem is obvious because both RCL and FCL are courts' interpretations of the same 21 C.F.R. Section 1306.04(a). These opposing interpretations of the same regulation indicate Section 1306.04(a) is vague and confusing even to courts. Nonetheless both FCL and RCL would lead to convictions of accused medical providers under Section 841. How could this be fair?

Indeed although a majority of courts cited FCL in their cases, RCL is still frequently used by the Fifth Circuit and the Eleventh Circuit. For example, RCL was cited in U.S. v. Webman, 2014 U.S. Dist. LEXIS 27504 (N.D. Ga. 2014); U.S. v. Roland, 2016 U.S. Dist. LEXIS 196922 (N.D. Ga. 2016); U.S. v. Buckingham, 2018 U.S. Dist. LEXIS 210350 (N.D. Ala. 2018); U.S. v. Ignasiak. 808 Fed. Appx. 709 (11th Cir. 2020); U.S. v. Bacon, 809 Fed. Appx. 757 (11th Cir. 2020); U.S. v. Iriele, 977 F.3d 1155 (11th Cir. 2020), and U.S. v. Ruan, 966 F.3d 1101,1140-1141 (11th Cir. 2020) ("In order to secure a conviction for unlawfully dispensing under Subsection 841(a)(1), the government must prove that the defendants 'dispensed controlled substances for other than legitimate medical purpose IN the usual course of professional practice.'") (citations omitted) (emphasis added).

2. There has been unsettled confusion respecting the meanings of Prong A and Prong B as well as the significance of Prong A v. Prong B. For example, in U.S. v. Rottschaefer, 178 Fed. Appx. 145, 147-148 (3rd Cir. 2006), the Third Circuit held:

"[T]here is considerable room to doubt whether the distinction between the 'no legitimate medical reason' and 'outside the usual course of professional practice' standards is of any importance. Nelson 383 F.3d at 1231 (10th Cir. 2004). Several courts have held that there is no difference in the meanings of the statutory phrase, 'in the usual course of professional practice' and regulatory phrase, 'legitimate medical purpose' standard... The Fourth Circuit of Appeals goes even further holding that the 'without medical purpose' standard that Rottschaefer challenges is 'more strict than [the 'outside the usual course of professional practice's standard] required by Moore." (citations omitted).

"As Nelson observed: 'It is difficult to imagine circumstances in which a practitioner could have prescribed controlled substances within the usual course of professional practice but without legitimate medical purpose. Similarly, it is difficult to imagine circumstances in which a practitioner could have prescribed controlled substances with a legitimate medical purpose and yet be outside the usual course of professional practice. 383 F.3d at 1231.'"

3. If the interpretation of Section 1306.04(a)'s illegality relies on some logical notions such as "logical converse" or "contrapositive" to make sense, then it is apparent that Section 1306.04(a) is too vague and confusing for medical providers.

Sentence A of Section 1306.04(a) states: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice"; this narrative, however, does not inform medical practitioners what activity is prohibited or unlawful. In order to convey a meaning of illegality, some courts introduce some logical concept(s) in their reasoning: Both prongs are necessary for a prescription to be legitimate; one is not sufficient. The LOGICAL CONVERSE is that a practitioner is unauthorized to dispense a controlled substance if the prescription either lacks a legitimate medical purpose or is outside the usual course of professional practice. 21 C.F.R. Section 1306.04(a) (emphasis added). (U.S. Armstrong, 550 F.3d 382 (5th Cir. 2008); U.S. v. Bothra, 2022 U.S. Dist. LEXIS 84971 (E.D. Mich. 2022): U.S. CRIM. Action v. Lamartiniere, 2023 U.S. Dist. LEXIS 40932 (M.D. La. 2023). The Bothra Court further added: "While the regulation is written in conjunctive, the CONTRAPOSITIVE, a statement of conduct that violates the law, must be formed in the disjunctive." (Bothra, 2022 U.S. Dist. LEXIS 8) (emphasis added). But, what is logical converse or contrapositive?

i. Logical conversion is used to draw immediate inference in a categorical syllogism. In "Introduction to Logic," Professors Copi and Cohen explained the difference between mediate and immediate inferences: "[A]ny inference is the drawing of a conclusion from one or more premises. Where there is more than one premise involved, as in a syllogism, which has two premises, the inference is said to be mediate, presumably because the conclusion is supposed to be drawn from the first premise through the mediation of the second [premise]. Where a conclusion is drawn from only one premise, there is no such mediation, and the inference is said to be immediate." (Introduction to Logic, p. 217) Professors Copi and Cohen provided an example of conversion in a categorical syllogism by interchanging the subject and predicate terms of the proposition: "'Some writers are women' and 'Some women are writers' are logically equivalent, so by conversion either can be validly inferred from the other." (Id., p. 219).

ii. The logical process of contraposition (to arrive at a proposition's logical contrapositive) involves both the processes of obversion and conversion. To understand obversion, we have to start with the notion of a "class," which is the collection of objects having a certain common attribute that we refer to as the "class-defining characteristic. (Id., p. 220) Every class has associated with it a complementary class, or complement, which is a collection of things that do not belong to the original class. Thus the complement of the class of all people is the class of all things that are not people. (Id., p . 221) To obvert a proposition, we change its quality (from affirmative to negative or vice versa) and replace the predicate term by its complement. Thus "All residents are voters" has its logical obverse "No residents are nonvoters." (Id.)

iii. To form the contrapositive of a given proposition, one replaces its subject term by the complement of its predicate term and replaces its predicate term by the complement of its subject term. For example, the contrapositive of the categorical proposition "All members are voters" is "All nonvoters are nonmembers." (Id., p. 222-223)

However, the above examples regarding how to draw immediate references using conversion and contraposition apply only to simple categorical syllogism. Regarding Section 1306.04(a), courts usually interpreted it in disjunctive and conditional proposition, e.g., if a physician either acted "not for a legitimate medical purpose" or "outside the usual course of professional practice," then he violated Section 841. The validity of court's using conversion and contraposition to draw immediate references in such a compound, conditional proposition is questionable. Professors Copi and Cohen gave no guidance on this. Nor could I find any reference that supports such usage. Regardless, there is still an unsolved problem which follows.

The problem is: If such complex logical reasoning is required in order for Section 1306.04(a) to allegedly make sense as a criminal standard, then 21 C.F.R. Section 1306.04(a) is way to vague and confusing for physicians to understand because physicians and other medical practitioners are not logicians or philosophers. On this basis, Section 1306.04(a) cannot be used as a criminal standard because it does not inform medical providers what conduct is prohibited. Next, I will follow up with my observations to show that different appellate courts committed the logical fallacy of "denying the antecedent" when interpreting Section 1306.04(a), further proving that Section 1306.04(a) is extremely vague and confusing.

4. 21 C.F.R. Section 1306.04(a) is so vague that even appellate courts committed the logical fallacy of "denying the antecedent" while interpreting this regulation.

i. In "Logic For Lawyers," Judge Aldisert explained that the fallacy of denying the antecedent takes the following form:

If A, then B.
Not A.
Therefore, not B. (Logic For Lawyers, p. 215).

This fallacy can be easily appreciated when replacing A and B with some real entities:

If Mr. Biden is in his basement, then he is in the United States.
Mr. Biden is not in his basement.
Therefore, Mr. Biden is not in the United States.

ii. Relevant caselaw involving the fallacy of antecedent includes:

(a) In NLRB v. Canning, 134 S. Ct. 2550, 2603 (2014), in a concurrence by Justice Scalia, joined by Chief Justice Roberts, Justices Thomas and Alito, Justice Scalia reasoned: "To assume otherwise ... is to commit the fallacy of inverse (otherwise known as denying the antecedent): the incorrect assumption that if P implies Q, then not-P implies not-Q."

(b) In Admiral Ins. Co. v. Niagara Transformer Corp., 2023 U.S. App. LEXIS 297 (2nd Cir. 2023), the Second Circuit reasoned: "To conclude as such...is to succumb to the 'fallacy of denying the antecedent' Crouse-Hinds Co. v. InterNorth, Inc., 634 F.2d 690, 707 n.20 (2nd Cir. 1980) ('the proposition that 'A implies B' is not the equivalent of 'non-A implies non-B,' and neither proposition follows logically from the other')" (citation omitted). (2023 U.S. App. LEXIS 30, n.6)

iii. Again, 21 C.F.R. Section 1306.04(a) in entirety provides:

"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice [Sentence A]."

"The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription [Sentence B]."

"An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances [Sentence C]."

Sentence A is awkwardly phrased. It does not inform medical providers what conduct is prohibited. Courts, however, handled this problem by interpreting Sentence A as a conditional proposition (i.e., if...then...) to the effect of the following: If the prescription is issued in the usual course of professional practice and for a legitimate medical purpose, then the prescription is effective (or lawful). I will label this equivalent and agreed-upon proposition of Sentence A as Sentence A'.

For instance, the Tenth Circuit in U.S. v. Khan, 989 F.3d 806, 822 (10th Cir. 2021) interpreted Sentence A of Section 1306.04(a) as a conditional proposition: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. In other words, a practitioner is authorized to dispense controlled substances ONY IF he acts with a legitimate medical purpose in the usual course of professional practice." (emphasis added).

Similarly, the Eleventh Circuit in U.S. v. Heaton, 59 F.4th 1226 (11th Cir. 2023), the Ninth Circuit in U.S. v. Lague, 971 F.3d 1032 (9th Cir. 2020), the Eighth Circuit in U.S. v. Smith, 573 F.3d 639 (8th Cir. 2009), the Fourth Circuit in U.S. v. Boccone, 556 Fed. Appx. 215, 288 (4th Cir. 2004), and the First Circuit in U.S. v. Sabean, 885 F.3d 27 (1sth Cir. 2018) all interpreted Sentence A of Section 1306.04(a) as a conditional proposition, conveying the same message as in Sentence A'.

Sentence B of Section 1306.04(a) is straightforward and not of our concern.

Sentence C of Section 1306.04(a), however, is rather prolix, and it, in essence, expresses the inverse of Sentence A', namely: When a prescription is issued not in the usual course of professional practice, the prescription issued is ineffective or unlawful. I will label this logically equivalent proposition of Sentence C as Sentence C'.

Now I will present the reasoning within Section 1306.04(a) by putting Sentence A' and Sentence C' together to show why the fallacy of denying the antecedent occurred:

If the prescription is issued in the usual course of professional practice...then the prescription is effective (or lawful). (Sentence A')

If the prescription is issued not in the usual course of professional practice, the prescription is ineffective (or unlawful). (Sentence C')

The problem of the above reasoning is: Sentence C' does not follow from Sentence A'. The inference of Sentence C' from Sentence A' exemplifies the fallacy of denying the antecedent or the fallacy of the inverse. (If p, then q. Not p. Therefore, not q.) No logical inference of any kind can be drawn from Sentence A' or Sentence C'.

iv. Next, I will present some examples on how appellate courts committed the fallacy of denying the antecedent when interpreting Section 1306.04(a).

(a) In U.S. v. Khan, 989 F.3d 806, 824-825 (10th Cir. 2021), the Tenth Circuit held: "A prescription is lawful...if the prescription is 'issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. [Sentence AA]' 21 C.F.R. Section 1306.04(a). ACCORDINGLY, [a]n order purporting to be a prescription issued not in the usual course of professional treatment...is not a prescription within the meaning and intent of [21 U.S.C. Section 829] and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to penalties provided for violations of the provisions of law relating to controlled substances.' [Sentence CC'] (Id.)" (emphasis added).

As seen in the above reasoning, the Tenth Circuit used the adverb, "accordingly," a common "conclusion indicator," to show that Sentence CC was an inferred conclusion from Sentence AA. However, Sentence CC essentially describes the inverse of Sentence AA. As a result, Sentence CC cannot be logically inferred from Sentence AA. In fact there can be no logical inference of any kind between Sentence CC and Sentence AA. The illogical inference of Sentence CC from Sentence AA exemplifies the

fallacy of denying the antecedent (otherwise known as the fallacy of inverse). (If p, then q. Not p. Therefore, not q.)

(b) Similarly the Fifth Circuit committed the fallacy of denying the antecedent in U.S. v. Craig, 823 Fed. Appx. 231, 240 (5th Cir. 2020), where it reasoned: "[T]he present iteration of Section 1306.04 states: a controlled-substance prescription is 'effective' only if 'issued for...usual course of professional practice'; and 'a [purported] prescription issued not in the usual course of professional...is not a prescription." 21 C.F.R. Section 1306.04(a)."

(c) Further, the Eleventh Circuit committed the fallacy of denying the antecedent in U.S. v. Joseph, 709 F.3de 1082, 1094 (11th Cir. 2013), when it reasoned: "Prescriptions are lawful if they are 'issued... usual course of professional practice.' 21 C.F.R. Section 1306.04(a)...If a prescription is issued...outside the usual course of professional practice, 'the person knowingly filling such a purported prescription, as well as the person issuing it,' is subject to the criminal penalties of Section 841."

(d) Further more, the Fourth Circuit also committed the same fallacy in U.S. v. Hurwitz, 459 F.3d 463, 475 (4th Cir. 2006), where it reasoned: "The regulations provide that a prescription is effective only if it is 'issued ...in the usual course of professional practice.' 21 C.F.R. Section 1306.04(a) The regulation further provides: An order purporting to be a prescription issued not in the usual course of professional...violations of the provisions of law relating to controlled substances. (Id.)"

The above precedents from different appellate courts have provided compelling evidence that Section 1306.04(a) is impermissibly vague and confusing because even appellate courts have similarly committed the logical fallacy of denying the antecedent when interpreting Section 1306.04(a) during adjudication of their cases. On this basis alone, Section 1306.04(a) cannot be used in any meaningful way, let alone as a criminal standard.

More commonly, however, courts have managed to sidestep this problem by plucking Sentence A out of 21 C.F.R. Section 1306.04(a). Indeed none of the circuit precedents mentioned earlier such as Heaton (11th Cir. 2023), Lague (9th Cir. 2020), Smith (8th Cir. 2009), Boccone (4th Cir. 2014), or Sabean (1st Cir. 2018) made any reference to Sentence C in their rulings when referring to Section 1306.04(a) -- they simply plucked out Sentence A (while ignoring Sentence C) as though Sentence A represented Section 1306.04(a) in its entirety. This practice is cunning in two ways: (1) It dissembled the fallacy of antecedent because the fallacy occurred when one tried to draw the conclusion from Sentence C from Sentence A. When Sentence A was isolated out while Sentence C was ignored,the fallacy of denying the precedent in Section 1306.04(a) became invisible; and (2) Since the knowing element of Section 1306.04(a) appeared in Sentence C, when Sentence C was left out, the prosecution and courts could easily find the defendants in violation of Section 1306.04(a) by misinterpreting Sentence A at will, without needing to show the knowing element, expressly stated in Sentence C of Section 1306.04 (a).

Circuit Judge Ely was quite perplexed by the illogical reasoning used in the prosecution of physicians under Section 841 in U.S. v. Rosenberg, 515 F.2d 190, 205 (9th Cir. 1975) (dissenting): "It seems to me impossible to construe the statute as tacitly making such acts, however foolish, crimes, by saying that what is in form a prescription and is given honestly in the course of a doctor's practice, and therefore, so far as the words of the statute go, is allowed in terms, is not within the words, is not a prescription and is not given in the course of practice, if the Court deems the doctor's faith in his patient manifestly unwarranted. It seems to me wrong to construe the statute as creating a crime in this way without a word of warning."

In sum, 21 C.F.R. Section 1306.04(a) is extremely vague, confusing, and is fatally flawed. This regulation cannot be used in any meaningful way, let alone be used as a criminal standard of convicting medical providers as "drug traffickers" under Section 841. Its widespread misuse over half a century allowed courts and the Government to presume medical providers' prescribing activities to be inherently unlawful. This presumption egregiously violated medical practitioners' constitutional rights.

In the remaining section, I attempt to answer the key question: What was the identity of the "except as authorized" clause repeatedly referenced in Ruan 2022, knowing that it could not be 21 C.F.R. Section 1306.04(a)?

G. Finding The True Identity Of The Supreme Court's "Except As authorized" Clause In Ruan 2022

1. To accomplish this task, a brief review of Moore 1975 is warranted because it was the first Supreme Court's Caselaw that addressed the issue whether a licensed physician could ever be held liable under Section 841. Indeed the Ruan Court so explained: "But the question in Moore was whether doctors could ever be held criminally liable under Section 841." (Ruan 2022, at. 2381)

As I discussed earlier, Dr. Moore's practice was unparalleled. The Moore Court noted that Dr. Moore "in billing his patients he used a 'sliding-fee scale' pegged solely by the quantity prescribed, rather than to the medical services performed. The fees ranged from $15 for a 50-pill prescription to $50 for 150 pills." (Moore 1975, at 126) The Government's position was that

Dr. Moore in fact operated as a pill "pusher." (Id.)

The Moore Court determined that Dr. Moore's conduct was that of a pill "pusher." (Id., at 143) ("In practical effect, he acted as a large-scale 'pusher.'") It further suggested that Dr. Moore's "greater offense as a drug pusher" was why he became reachable under Section 841. (Id., at 138) ("There is nothing in the statutory scheme or the legislative history that justifies a registrant who may be prosecuted for the relatively minor offense of violating Section 829 is thereby exempted from prosecution under Section 841 for the significantly greater offense as a drug "pusher.")

However, the Moore Court assigned a general term, "outside the usual course of professional practice" (OUCPP), to Dr. Moore's specific factual context, i.e. Dr. Moore allegedly acted as a drug "pusher." Doing so the Moore Court committed the logical fallacy of misplaced literalism, i.e. the attribution of a general meaning where a specific one was meant. This fallacy created shambles in the process of jury's factfinding in subsequent prosecution of physicians under Section 841.

i. In "Logic for Lawyers," Judge Aldisert explained the judicial process under the common-law tradition: "[T]he common law decisional process starts with the finding of facts in a dispute by a factfinder...Once the facts are ascertained, the court compares them with fact patterns from previous cases and decides whether there is sufficient similarity to warrant applying the rule of an earlier case to the facts of the present one." (Id., p. 33). Needless to say the process of jury's factfinding is a critical one. Moore's OUCPP Rule, however, effectively frustrated this critical step (explained below).

ii. When the Moore Court assigned a general term, OUCPP, to mean Dr. Moore's specific activities akin to that of a drug "pusher" (but without warning the lower courts that OUCPP was a stipulated term therefore cannot be either true or false), it invited lower courts to use OUCPP based on its dictionary meaning in asserting facts as matters of truth. Doing so lower courts essentially eliminated the possibility of the jury's findings of distinguishable facts. This is because the term, OUCPP, is so broad that it could subsume all alleged improper activities of physicians under the general category of OUCPP, thus frustrating any effort in showing distinguishable factual situations between Dr. Moore's and other practitioners' cases. In other words, Moore's OUCPP Rule rendered all distinguishable facts indistinguishable.

iii. In U.S. v. Mencia, 2022 U.S. App. LEXIS 33048 (11th Cir. 2022), Dr. Mencia was convicted under Section 841. Dr. Mencia argues that his case is different because he was not acting as a drug "pusher." The Eleventh Circuit responded: "But that is exactly the question that the Act seeks to answer -- when does a physician stop acting as a doctor and start acting as a "drug pusher." The answer under the Act is when he prescribes controlled substances outside the usual course of professional practice or without a legitimate medical purpose." (2022 U.S App. LEXIS 40-41)

As seen, the Eleventh Circuit equated acting as a drug "pusher" to the violation of the two prongs stated in Section 1306.04(a). As a result, Dr. Mencia's argument in showing distinguishable facts on the point of whether or not he acted as a "drug pusher" was rejected, or rather, evaded even though the factual context of acting as a drug 'pusher" was precisely the basis of Moore Court's affirmation of Dr. Moore's convictions. Turing to and relying on the vague languages of 21 C.F.R. Section 1306.04(a) the Eleventh Circuit upheld Dr. Mencia convictions, despite the fact Dr. Mencia's argument was precisely on point and that Section 1306.04(a) is fatally flawed on multiple grounds as I have shown previously.

Recall that there is no logical connection between the violation of Section 1306.04(a) and Section 841. The Moore's OUCPP Rule, which stipulatively equated OUCPP to "drug trafficking" under Section 841, served as the bridge that falsely connected the violation of Section of 1306.04(a) to Section 841 violation -- through the equivocal usage of the shared term, OUCPP.

2. Section 841's "except as authorized" clause should be based on whether or not the physician acted as a drug "pusher."

When Congress enacted the CSA in 1970, being a licensed physician satisfied the "except as authorized" clause of CSA 841. (U.S. v. Rosenberg, 515 F.2d 190, 203) (Ely, Circuit Judge) (Dissenting). When a physician acted as a drug "pusher," or when he stopped acting as a physician, his prescribing action became unauthorized under Section 841. The Moore Court found Dr. Moore liable under Section 841 because Dr. Moore "acted as a large-scale 'pusher" -- not a physician." (Moore 1975, at 143)

i. The D.C. Circuit in Moore 1974 (505 F.2d 426) did not believe that Section 1306.04(a) clause equated to Section 841's "except as authorized." In fact, it actually doubted that whether the violation of Section 1306.04(a) should lead to a criminal sanction at all. It so opined: "We need not and do not decide whether Section 306.04 [predecessor of Section 1306.04] of the

regulations is sufficiently specific for the invocation of criminal sanctions, nor whether Congress intended that violations of regulations trigger criminal prosecution under the CSA." (Id., at 458, n.21).

ii. Further, the Moore Court clearly did not intend the prongs of Section 1306.04(a) to be tantamount to Section 841's "except as authorized" clause. It did not even use the language "legitimate medical purpose" or its equivalent, one of the two prongs from Section 1306.04(a). It only commented on that the lower court suggested that the violation of a "medical purpose" requirement violated Section 829 which was punishable under Section 842 (Moore 1975, at 146, n.12.).

iii. Even though the Moore Court did use "outside usual course of professional practice" (OUCPP), it did not treat it as violation of Section 1306.04(a). Rather, it did so to answer the specific question raised by the D.C. Circuit that used the term, "usual course of professional practice" -- when the D.C. Circuit held that Dr. Moore could not be convicted merely for acting "outside of usual course of professional practice" even assuming he could be reached under Section 841 (Moore 1975, at. 139). Indeed the Moore Court stipulated the term, OUCPP, to represent that Dr. Moore acted as a drug "pusher," thus violating Section 841; it said nothing, expressly or implicitly, about Dr. Moore's prescribing violated Section 1306.04(a).

It is worth repeating that even though the Moore Court chose the term OUCPP as a criminal standard sufficient for Section 841 conviction, the OUCPP in the Moore context is materially different from the OUCPP when the "usual course of professional practice" prong of Section 1306.04(a) is violated, even though the language OUCPP is the same in both contexts. When the term OUCPP is used equivocally by courts, the connection between Section 841 violation (expressed as OUCPP per Moore's OUCPP Rule) and violation of Section 1306.04(a) (also expressed as OUCPP) is falsely established.

Remarkably, Circuit Judge Ely had opined that Congress intended to treat registered and nonregistered violators differently in U.S. v. Rosenberg, 515 F.2d 190, 202-203 (9th Cir. 1975) (dissenting): "After studying the Act in its entirety, I am impelled to the conclusion that Congress chose not to place a physician in jeopardy of the severe criminal sanctions of Section 841 on such a slender thread as a jury's later conclusion that the physician has prescribed a drug with accepted medical values for an improper purpose. Congress obviously intended for any such abuses to be halted through professional administrative action through imposition of the less severe criminal and civil sanctions provided in Section 842 and 843."

Indeed there are sufficient remedies to hold irresponsible physicians' behavior accountable: There are federal remedies such as Section 842 (civil), Section 843 (criminal), and Section 824 (administrative proceeding to revoke the physician' certificate of registration with the Attorney General). In addition there are also state remedies whereby various state medical licensing boards can suspend or revoke physicians' medical licenses when indicated.

Congress designed different CSA provisions to treat registered and unregistered individuals differently. Since Moore 1975, however, the overwhelming majority of medical providers have been convicted under Section 841. Thus the interpretation and application of Moore's OUCPP Rule and Section 1306.04(a) to convict medical providers under Section 841 far deviated from Congress's intention, rendering Sections 842 and 843 inoperative or superfluous, in violation of a basic rule when interpreting a statute. The Supreme Court in Corley v. U.S. 129 S. Ct. 1558 (2009) admonished: "A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void, or insignificant."

In sum, medical providers should not be prosecuted under Section 841 as nonregistered "drug traffickers." Under rare circumstances (such as Dr. Moore's case), when an accused physician has been charged with allegedly violating Section 841, the "except as authorized" clause should reflect the factual situation that a physician acted as a drug "pusher" or stopped acting as a physician. This should be the standard when it comes to deicide whether or not the physician acted "unauthorized" under Section 841, not by using the two vague prongs of 21 C.F.R. Section 1306.04(a), namely "outside the usual course of professional practice" or "not for a legitimate medical purpose," both of which have been misused and abused for close to half a century. Similarly the Ruan Court's holding that Section 841's "knowingly or intentionally" mens rea applies to the "except as unauthorized" means that, practically, the Government must prove that the accused physician knowingly or intentionally acted as a drug "pusher," or knowingly or intentionally stopped acting as a physician.

3. Conclusion

The criminal standard used to prosecute medical providers as "drug traffickers" under CSA Section 841 is fatally flawed on multiple grounds. Applying the "knowingly or intentionally" mens rea to Section 841's "except as authorized" clause should be based on whether the physician "knowingly or intentionally" acted as a drug pusher, or whether he or she "knowingly or intentionally" stopped acting as a physician. The use of vague and ambiguous 21 C.F.R. Section 1306.04(a) as the surrogate "except as authorized" clause to convict medical providers under Section 841 as "drug traffickers" is unconstitutional.

----------The End----------