WASHINGTON

Medical Commission

Licensing. Accountability. Leadership.

Regular Meeting April 13-14, 2023

2nd Revised - April 12, 2023

2023 Meeting Schedule

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Dates	Location	Meeting Type
January 12-13	Virtual options available for open sessions Capitol Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater, WA	Regular Meeting
March 2-3	Virtual options available for open session Capitol Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater, WA	Regular Meeting
April 13-14	Virtual options available for open sessions Capitol Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater, WA	Regular Meeting
May 25-26	Virtual	Regular Meeting
July 13-14	Virtual options available for open sessions Capitol Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater, WA	Regular Meeting
August 24-25	Virtual options available for open sessions Capitol Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater, WA	Regular Meeting
October 5-6	Tumwater, WA	Tentative: Case Reviews Commissioner Retreat
November 16-17	Virtual options available for open sessions Capitol Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater, WA	Regular Meeting

Association Meetings

Association	Date(s)	Location
Federation of State Medical Boards (FSMB) Annual Conf.	May 4-6, 2023	Minneapolis, MN
WAPA Spring Conference	TBA	TBA
WSMA Annual Meeting	September 23-24, 2023	Bellevue, WA
WAPA Fall Conference	TBA	TBA

Other Meetings

Program	Date(s)	Location
Council on Licensure, Enforcement & Regulation (CLEAR) Winter Symposium	January 11, 2023	Savannah, GA
CLEAR Annual Conference	September 27-30, 2023	Salt Lake City, UT
FSMB Board Attorneys Workshop	TBA	TBA

2024 Meeting Schedule

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Dates	Location	Meeting Type
January 11-12	TBD	Regular Meeting
March 7-8	TBD	Regular Meeting
April 18-19	TBD	Regular Meeting
May 23-24	TBD	Regular Meeting
July 11-12	TBD	Regular Meeting
August 22-23	TBD	Regular Meeting
October 3-5	TBD	TBA
November 21-22	TBD	Regular Meeting

FORMAL HEARING SCHEDULE

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Hearing	Respondent	Case No.	Location
2023 April			
3-Apr **through** 7-Apr	Wilkinson, Richard, MD	M2022-196	TBD
2023 May			
8-May	Kimura, Irene, MD	M2020-930	TBD
24-May **through** 26-May	Eggleston, Richard, MD	M2022-204	TBD
2023 June			
2-Jun	Lee, Katherine, MD	M2022-504	TBD
15-Jun **through** 16-Jun	Wingfield, Guito, MD	M2022-502	TBD
2023 July			
20-Jul	Ilg, Ron, MD	M2022-712	TBD
28-Jul	Pothini, Gouri, MD	M2022-852	TBD
2023 August			
3-Aug **through** 4-Aug	Pugh, Steven, MD	M2022-611	TBD
18-Aug	Alhafez, Fadi, MD	M2021-656	TBD
22-Aug **through** 23-Aug	Aljumaili, Wisam, MD	M2021-444	TBD
31-Aug	Riyaz, Farhaad, MD	M2022-716	TBD
2023 October			
5-Oct **through** 6-Oct	Ruiz, Nathaniel, MD	M2022-846	TBD

Commission Meeting Agenda
April 13-14, 2023

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 Policy Committee Meeting will begin at 4:00 pm on April 13, 2023 until all agenda items are complete. The WMC will take public comment at the Policy Committee Meeting. The Business Meeting will begin at 8:00 am on April 14, 2023 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 civil.rights@doh.wa.gov.

The Washington Medical Commission (WMC) is providing a virtual option for members of the public for several of the open sessions in this agenda. Registration links can be found below.

Capital Event Center (ESD 113), 6005 Tyee Drive SW, Tumwater, WA 98512

Time — Thursday – April 13, 2023

Closed Sessions

8:00 am	Case Reviews – Panel A	Pacific
8:00 am	Case Reviews – Panel B	Grays Harbor

Open Session

12:30 pm — Lunch & Learn — Thurston

To attend virtually, please **register** at: https://attendee.gotowebinar.com/register/2075369309466177887
After registering, you will receive an email containing a link that is unique to you to join the webinar.

Annual Licensing Report
Marisa Courtney, Licensing Manager

Closed Sessions

1:30 pm	Case Reviews – Panel A	Pacific
1:30 pm	Case Reviews – Panel B	Grays Harbor

Open Session

4:00 pm — Policy Committee Meeting — Grays Harbor

To attend virtually, **register** at: https://attendee.gotowebinar.com/register/8593907557619885664
After registering, you will receive an email containing a link that is unique to you to join the webinar.

Agenda Items	Presented By:	Page(s)
Proposed Interpretive Statement: Application of the Office-based Surgery Rule, WAC 246-919-601, to the Use of Nitrous Oxide *Review and discussion of proposed interpretive statement.*	Mike Farrell	18-19
Interpretive Statement: Opioid Prescribing & Monitoring for Allopathic Physicians and Physician Assistants *Secretary review complete - review, discussion, and possible revisions to interpretive statement.*	Mike Farrell	20-25
Interpretive Statement: Opioid Prescribing & Monitoring for Patients *Secretary review complete - review, discussion, and possible revisions to interpretive statement.*	Mike Farrell	26-30
Comparing New CDC Guidelines to WMC Opioid Prescribing Rules *Review document and decide whether to initiate rulemaking.*	Mike Farrell	31-49
Report: High Reliability Organizations Workgroup	Mike Farrell	NA

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Time	Friday – April 14, 2023	
Open Session		
8:00 am	**Business Meeting**	Thurston

To attend virtually, **register** for this meeting at: https://attendee.gotowebinar.com/rt/8011164195875333984
After registering, you will receive an email containing a link that is unique to you to join the webinar.

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 during this time, 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.***

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 Minutes – Approval of the March 3, 2023 Business Meeting minutes. — Pages 8-11

4.2 Agenda – Approval of the April 14, 2023 Business Meeting agenda. — Pages 5-7

5.0 New Business

5.1 **WMC Statement** — Action

Discussion of *WMC Supports State Protection of MDs and PAs Who Prescribe Mifepristone and Provide Reproductive Health Care* statement, possible revisions, and vote. — Page 12

6.0 Old Business

6.1 **Committee/Workgroup Reports** — Update

The Chair will call for reports from the Commission's committees and workgroups. Written reports begin on page 13.

See page 14 for a list of committees and workgroups.

6.2 **Nominating Committee** — Update

Announcement of nominees for the following positions:

- Chair
- Chair Elect
- Vice Chair

The election of leadership will take place at the May 26, 2023, Business Meeting.

6.3 **Rulemaking Activities** — Update

Rules Progress Report provided on page 15.

- Request for Expedited Rulemaking Rescinding Portions of WAC 246-919-330. See memo on page 16 for more information. Discussion and vote on whether to initiate rulemaking. — Action — Pages 16-17

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7.0 Policy Committee Report

Christine Blake, Public Member, Chair, will report on items discussed at the Policy Committee meeting held on April 13, 2023. See the Policy Committee agenda on page 1 of this agenda for the list of items to be presented.

Report/Action Begins on page 18

8.0 Member Reports

The Chair will call for reports from Commission members.

9.0 Staff Member Reports

The Chair will call for further reports from staff.

Written reports on pages 50-58

10.0 AAG Report

Heather Carter, AAG, may provide a report.

11.0 Adjournment of Business Meeting

Open Sessions

10:00 am	Personal Appearances – Panel A	Page 59	Pacific
10:00 am	Personal Appearances – Panel B	Page 60	Grays Harbor

Closed Session

Noon to 1:00 pm	High Reliability Organizations Workgroup Meeting	Grays Harbor

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Business Meeting Minutes
March 3, 2023

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Link to recording: https://youtu.be/CPBi4YZR07I

Commission Members

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

WMC Staff in Attendance

Christine Babb, Investigator
Colleen Balatbat, Staff Attorney
Morgan Barrett, Director of Compliance
Jennifer Batey, Legal Support Staff Manager
Anjali Bhatt, Business Practices & Efficiency Manager
Amelia Boyd, Program Manager
Carolynn Bradley, Management Analyst & Contracts Specialist
Renee Bruess, RN, Investigator
Kayla Bryson, Executive Assistant
Jimi Bush, Director of Quality & Engagement
Adam Calica, Chief Investigator
Melanie de Leon, Executive Director
Joel DeFazio, Staff Attorney
Kelly Elder, Staff Attorney (Virtual)
Mike Farrell, Policy Development Manager
Gina Fino, MD, Investigator
Ryan Furbush, Paralegal
Rick Glein, Director of Legal Services
George Heye, MD, Medical Consultant
Jenelle Houser, Investigator
Ken Imes, Information Liaison
Kyle Karinen, Staff Attorney
Shelley Kilmer-Ready, Legal Assistant (Virtual)
Pam Kohlmeier, MD, JD, Attorney
Lisa Krynicki, Staff Attorney
Emma Marienthal, Licensing Lead (Virtual)
Stephanie Mason, Public Relations & Legislative Liaison
Micah Matthews, Deputy Executive Director
Joe Mihelich, Health Services Consultant (Virtual)
Lynne Miller, Paralegal
Fatima Mirza, Program Case Manager
Marne Nelson, ARNP, Investigator
Freda Pace, Director of Investigations
Mike Piechota, Investigator
Stormie Redden, Legal Assistant
Chris Waterman, Complaint Intake Manager
Tricia Wolf, Staff Attorney
Mahi Zeru, Equity & Social Justice Manager

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Others in Attendance

Chris Bundy, MD, Executive Medical Director, Washington Physicians Health Program (WPHP)
Terry Burton (Virtual)
Heather Cantrell, Policy Analyst, Department of Health (DOH) (Virtual)
Heather Carter, Assistant Attorney General
Tom Gumprecht, MD (Virtual)
Maria Higginbotham (Virtual)
Barbi Jones (Virtual)
Shelby Wiedmann, Washington State Medical Association (WSMA)

1.0 Call to Order

Jimmy Chung, MD, Chair, called the meeting of the Washington Medical Commission (WMC) to order at 8:05 a.m. on March 3, 2023.

2.0 Public Comment

Tom Gumprecht, MD, provided comments regarding gender reassignment surgery in Washington state.

3.0 Chair Report

Jimmy Chung, MD, Chair, had nothing to report.

4.0 Consent Agenda

The Consent Agenda contained the following items for approval:

4.1 Minutes from the January 13, 2023 Business Meeting
4.2 Agenda for March 3, 2023.

***Motion**:* The Chair entertained a motion to approve the Consent Agenda. The motion was seconded and approved unanimously.

5.0 Old Business

5.1 Outstanding Performance Awards

Melanie de Leon, Executive Director, presented the Outstanding Performance Awards as follows:

- Administrative Staff – Kayla Bryson, Executive Assistant
- Investigative Staff – Mike Piechota, Investigator
- Legal Staff – Ryan Furbush, 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 Nominating Committee

Dr. Chung asked for volunteers for the committee. The following Commissioners were nominated to be members of the committee:

- April Jaeger, MD
- Richard Wohns, MD
- Ed Lopez, PA-C

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Nominees for leadership will be announced at the April 14, 2023, Business Meeting. The election of leadership will take place at the May 26, 2023, Business meeting.

6.3 Rulemaking Activities

The rulemaking progress report was provided in the meeting packet. There were no additional reports.

7.0 Policy Committee Report

Christine Blake, Public Member, Policy Committee Chair, asked Mike Farrell, Policy Development Manager to report on the items discussed at the Policy Committee meeting held on March 2, 2023. The Policy Committee did not have a quorum of Commissioners attend the March 2 meeting. As such, each item requires a motion from the floor and a second. The agenda was as follows:

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

Mr. Farrell presented the document and stated there were some revisions that were suggested in addition to the revisions on the document that was provided in the packet. Mr. Farrell stated the next steps could be to rewrite the document or if the panel approves the document with revisions, it can be forwarded on to the Secretary's office for review.

> ***Motion:*** The Chair entertained a motion to approve the document as presented and discussed for review by the Secretary's office. The motion was approved unanimously.

Interpretive Statement: Opioid Prescribing & Monitoring for Patients

Mr. Farrell presented the document and stated there were some revisions that were suggested in addition to the revisions on the document that was provided in the packet. Mr. Farrell stated the next steps could be to rewrite the document or if the panel approves the document with revisions, it can be forwarded on to the Secretary's office for review.

> ***Motion:*** The Chair entertained a motion to approve the document as presented for review by the Secretary's office. The motion was approved unanimously.

Guidance Document: Treating Partners of Patients with Sexually Transmitted Chlamydia and Gonorrhea

Mr. Farrell presented the document and stated it was up for routine review. He stated the classification of the document would be changed from Guideline to Guidance Document. Other than that change, he suggested the document be reaffirmed as written.

> ***Motion:*** The Chair entertained a motion to reaffirm the document. The motion was approved unanimously.

Interpretive Statement: Physician Assistants' Use of DEA Waiver for Buprenorphine

Mr. Farrell presented the document and stated a waiver for Physician Assistants to prescribe buprenorphine is no longer a requirement. Mr. Farrell requested the document be rescinded.

> ***Motion:*** The Chair entertained a motion to rescind the document. The motion was approved unanimously.

Proposed Interpretive Statement: Application of the Office-based Surgery Rule, WAC 246-919-601, to the Use of Nitrous Oxide

Mr. Farrell presented the document and explained reasons it might be needed. He asked that the

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Commissioners think about the document and send him any questions or suggestions. He stated that it will be brought back at a future Policy Committee meeting for consideration. Micah Matthews, Deputy Executive Director, provided additional background information.

8.0 Member Reports

Scott Rodgers, Public Member, praised the WMC staff for their professionalism and high quality work.

9.0 Staff Reports

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

Ms. de Leon, presented the following Service Awards:

- Emma Marienthal, Licensing Lead – 5 years of service
- Renee Bruess, RN, Investigator – 20 years of service
- Amelia Boyd, Program Manager – 10 years of service
- Mike Kramer, Compliance Officer – 30 years of service
- Christine Babb, Investigator – 5 years of service

Mr. Matthews reported that the masking requirements in long-term care and correctional facilities will end at midnight on April 3, 2023.

Rick Glein, Director of Legal Services, introduced a new staff attorney, Lisa Krynicki. Ms. Krynicki gave a brief statement about her background.

10.0 AAG Report

Heather Carter, AAG, had nothing to report.

11.0 Adjournment

The Chair called the meeting adjourned at 8:48 am.

Submitted by

Amelia Boyd, Program Manager

Jimmy Chung, MD, Chair Elect
Washington Medical Commission

Approved April 14, 2023

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

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Position Statement

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

WMC Supports State Protection of MDs and PAs Who Prescribe Mifepristone and Provide Reproductive Health Care

The Washington Medical Commission (WMC) is taking proactive steps to assure Washington licensed providers that, regardless of action in other states, medication abortions will remain classified as reproductive health care services and well within the standard of care in the State of Washington.

The most common medication abortion regimen in the U.S. involves the use of two different medications: mifepristone and misoprostol. Currently, access to mifepristone, which has been approved by the Federal Drug Administration (FDA) for two decades, is the focus of legal challenges.

On April 7, 2023, conflicting rulings on mifepristone were issued by two separate federal court judges, one in Texas and one in Washington. Because these two federal court rulings conflict, the Supreme Court could be called upon to resolve this conflict.

In Washington, legislators and the governor supported bills this session which protect access to reproductive health care and mifepristone. The Washington state Department of Corrections (DOC), using its existing pharmacy license, recently purchased a three-year supply of mifepristone. Additionally, there is pending legislation which would authorize the DOC to distribute or sell mifepristone to Washington's licensed health care providers.

The WMC finds that,

> *Participation in reproductive health care services, including the prescription of mifepristone by health care providers, does not constitute unprofessional conduct under the Uniform Disciplinary Act (UDA) and may not serve as the solitary basis for professional discipline. And further, a conviction or disciplinary action based solely on a health care provider's violation of another state's laws prohibiting participation in reproductive health care services or gender-affirming treatment does not constitute unprofessional conduct under the UDA and may not serve as the basis for professional discipline, with some exceptions. Within these laws and regulatory interpretation, the WMC retains its ability to take action against practitioners who violate the standard of care in their prescription of any drug.*

The WMC is committed to protecting access to reproductive health care and the practitioners who provide such care. Therefore, MDs and PAs in Washington who continue to provide a full spectrum of reproductive health care services, which may include prescribing mifepristone, may generally do so within the standard of care and without concern for their licenses being at risk.

WASHINGTON Medical Commission
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Committee/Workgroup Reports: April 2023

High Reliability Organizations Workgroup – Chair: Dr. Chung Staff: Mike Farrell
The workgroup met in March with the investigators to discuss communication between investigators and RCMs. The workgroup will meet in April to discuss training of Commission members.

Healthcare Disparities Workgroup – Chair: Dr. Currie Staff: Melanie de Leon
No updates to report.

Committees & Workgroups

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Executive Committee
Chair: Dr. Chung
Chair Elect: Dr. Domino
Vice Chair: Dr. Murphy
Policy Chair: Christine Blake, PM
Immediate Past Chair: John Maldon, PM
Melanie de Leon
Micah Matthews
Heather Carter, AAG

Policy Committee
Christine Blake, PM, Chair (B)
Dr. Domino (B)
Dr. Trescott (B)
Scott Rodgers, PM (A)
Ed Lopez, PA-C (B)
Heather Carter, AAG
Melanie de Leon
Mike Farrell
Amelia Boyd

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

Legislative Subcommittee
Dr. Chung, Chair
John Maldon, PM. Pro Tem Commissioner
Christine Blake, PM
Dr. Wohns
Melanie de Leon
Micah Matthews

Healthcare Disparities Workgroup
Dr. Currie, Chair
Dr. Browne
Dr. Jaeger
Christine Blake, PM
Melanie de Leon

Panel L
Dr. Chung, Chair
Christine Blake, PM
Dr. Browne, Pro Tem
Dr. Chung
Arlene Dorrough, PA-C
Dr. Lyle
Dr. Wohns
John Maldon, PM, Pro Tem
Dr. Roberts, Pro Tem
Dr. Trescott
Dr. Barrett, Medical Consultant
Marisa Courtney, Licensing Supervisor
Pam Kohlmeier, MD, JD, Staff Attorney
Micah Matthews

Finance Workgroup
Dr. Chung, WMC Chair, Workgroup Chair
Dr. Domino, WMC Chair Elect
Melanie de Leon
Micah Matthews
Jimi Bush

High Reliability Workgroup
Dr. Domino, Chair
Dr. Chung
Christine Blake, PM
Dr. Jaeger
Scott Rodgers, PM
Dr. Chang
Ed Lopez, PA-C
Dr. Lyle
Dr. Roberts, Pro Tem
John Maldon, PM, Pro Tem
Melanie de Leon
Mike Farrell

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

Updated: March 7, 2023

WMC Rules Progress Report								Projected filing dates		
Rule	**Status**	**Date**	**Next step**	**Complete By**	**Notes**	**Submitted in RMS**	**SBEIS Check**	**CR-101**	**CR-102**	**CR-103**
Collaborative Drug Therapy Agreements (CDTA)	CR-101 filed	7/22/2020	Workshops	TBD				Complete	TBD	TBD
SB 5229 - Health Equity CE	CR-101 filed	2/10/2023	Workshops 1st scheduled for April 20, 2023	August 2023				Complete	TBD	TBD

Updated: 4/6/2023

Memo

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

To: WMC Commissioners

From: Micah Matthews, Deputy Executive Director

Subject: Request for Expedited Rule Making Rescinding Portions of WAC 246-919-330

In 2020, the Washington Medical Commission (WMC) finished rule making for a complete chapter revision of WAC 246-919 that resulted in the following change to section 330 (4) :

"*A physician must complete two consecutive years of postgraduate medical training in no more than two programs. The physician must acquire this training after completion of a formal course of undergraduate medical instruction outlined in RCW* ***18.71.055***…"

For reference, the statute states the following on postgraduate medical training in RCW 18.71.050:

"(b) That the applicant has completed two years of postgraduate medical training in a program acceptable to the commission…"

The requirement of, "two years of consecutive training in no more than two programs", is consistent with the law but is not consistent with training program operations, specifically those of the University of Washington (UW).

Due to the practitioner shortage, multiple pathways to board certification eligibility have been opened by the UW, the Accreditation Council for Graduate Medical Education (ACGME), and the American Board of Medical Specialties (ABMS). Multiple ABMS boards have programs that specifically target international medical graduates and place them in four-year training programs, with only years one and three ACGME accredited. The outcome of these programs would be physicians who are ineligible for licensure through WMC, despite four-years of postgraduate training through the UW. The first graduates of those programs will complete their training in June 2023.

Separately and recently, we have seen applicants come through Panel L who possess six-years of postgraduate training from their efforts to become dual licensed as physicians and dentists. This clause has resulted in denial of those applications since parts of the training are accredited under ACGME and the rest under The Commission on Dental Accreditation (CODA), the dental profession equivalent of ACGME.

There is not adequate documentation in the analysis, or in the recordings, of the rules workshops to understand the reason for the change. However, it is clear subject matter experts were not involved in the change and would have legitimately objected to the language. Since that time, WMC has implemented changes which guarantee management level involvement in the rule making process to avoid issues like this.

I am requesting the WMC authorize an emergency expedited rulemaking to rescind portions of WAC 246-919-330 (4) that state, "*a physician must complete two consecutive years of postgraduate medical training in no more than two programs."* Eliminating this language removes a barrier to licensure. We do not anticipate opposition to this process. We have a letter of support for this action from the Washington State Medical Association and expect one from UW Graduate Medical Education programs.

Washington State Medical Association
Physician Driven, Patient Focused

March 22, 2023

Micah Matthews
Deputy Executive and Legislative Director
Washington Medical Commission
111 Israel Road SE
Tumwater, WA 98501

Delivered electronically

Dear Mr. Matthews,

Thank you for bringing to our attention concerns that have been raised regarding continuous postgraduate medical training requirements at WAC 246-919-330.

The Washington State Medical Association's leadership has discussed and supports the Washington Medical Commission's desire to run a narrow emergency rulemaking to address this barrier to physician training as quickly as possible.

Please do not hesitate to reach out with any questions or concerns. We appreciate your collaboration around this effort.

Sincerely,

Jeb Shepard
Director of Policy
Washington State Medical Association

Seattle Office
2001 Sixth Avenue, Suite 2700
Seattle, WA 98121
o / 206.441.9762 *fax* / 206.441.5863
email / wsma@wsma.org

Olympia Office
1800 Cooper Point Road SW
Building 7, Suite A
Olympia, WA 98502
o / 360.352.4848 *fax* / 360.352.4303

Interpretive Statement

WASHINGTON Medical Commission
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Title:	Application of the Office-based Surgery Rule, WAC 246-919-601, to the Use of Nitrous Oxide	INS2023-0x
References:	WAC 246-919-601	
Contact:	Washington Medical Commission	
Phone:	(360) 236-2750	E-mail: medical.commission@wmc.wa.gov
Supersedes:	None	
Effective Date:	April 14, 2023	
Approved By:	Jimmy Chung, MD, Chair (signature on file)	

The Washington Medical Commission (WMC) interprets WAC 246-919-601, ~~which~~ regulat~~es~~ing the use of analgesia, anesthesia, and sedation in office-based settings, to apply to the use of nitrous oxide. ~~The use of n~~Nitrous oxide, a systemic analgesic, has a dose-dependent sedating effect, ~~is not considered "minimal sedation"~~ and, therefore, an allopathic physician who uses nitrous oxide in an office-based setting must comply with the requirements of WAC 246-919-601.

The WMC adopted WAC 246-919-601 in 2010 to promote patient safety by establishing consistent standards and competency for procedures requiring analgesia, anesthesia, or sedation performed in an office-based setting. The rule was designed to complement new legislation requiring the licensing of ambulatory surgical facilities.

The rule contains certain requirements to ensure that patients are safe when undergoing procedures in a physician's office. These requirements include accreditation or certification of the facility where the procedures take place; competency; separation of surgical and monitoring functions; written emergency care and transfer protocols; the ability to rescue a patient who enters a deeper level of sedation than intended; and having a licensed health care practitioner currently certified in advanced resuscitative techniques appropriate for the patient age group present or immediately available.

WAC 246-919-601 provides in relevant part:

> (2) Definitions. The following terms used in this subsection apply throughout this section unless the context clearly indicates otherwise:
> ...
> (e) "Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Minimal sedation is limited to oral, intranasal, or intramuscular medications.
> ...

(g) "Office-based surgery" means any surgery or invasive medical procedure requiring analgesia or sedation, including, but not limited to, local infiltration for tumescent liposuction, performed in a location other than a hospital or hospital-associated surgical center licensed under chapter 70.41 RCW, or an ambulatory surgical facility licensed under chapter 70.230 RCW.

(3) Exemptions. This rule does not apply to physicians when:
(a) Performing surgery and medical procedures that require only minimal sedation (anxiolysis), or infiltration of local anesthetic around peripheral nerves. Infiltration around peripheral nerves does not include infiltration of local anesthetic agents in an amount that exceeds the manufacturer's published recommendations.

When the WMC adopted WAC 246-919-601 in 2010, and when the WMC made a minor definition amendment a decade later, the WMC did not intend for the use of nitrous oxide to qualify for the above rule exemptions. WAC 246-919-601(3)(a) specifically exempts from the rule requirements procedures that require only minimal sedation. WAC 246-919-601(2)(e) clarifies that minimal sedation is limited to oral, intranasal, or intramuscular medications. The WMC revised the rule in 2020 to add the term "intranasal" to the definition of minimal sedation to permit the use of midazolam when sprayed into the nose. The addition of the term "intranasal" was not meant to include the use of inhaled anesthetic agents such as nitrous oxide. Since its inception, WAC 246-919-601 was not intended to include, nor does it include, an exemption to the rule for the use of nitrous oxide in an office-based setting.

Based on the language of the rule and the intent behind the revision in 2020, the WMC interprets WAC 246-919-601 to apply to the use of nitrous oxide. ~~The use of nitrous oxide is not considered "minimal sedation," and, therefore, an allopathic physician who uses nitrous oxide in an office-based setting must comply with the requirements of WAC 246-919-601~~ Nitrous oxide, a systemic analgesic, has a dose-dependent sedating effect, and, therefore, an allopathic physician who uses nitrous oxide in an office-based setting must comply with the requirements of WAC 246-919-601.

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Interpretive Statement

WASHINGTON Medical Commission
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Title:	Opioid Prescribing & Monitoring for Allopathic Physicians and Physician Assistants	INS2023-03
References:	RCW 18.71.800; RCW 18.71A.800; WAC 246-919-850 through WAC 246-919-985; WAC 246-918-800 through WAC 246-918-935	
Contact:	Washington Medical Commission	
Phone:	(360) 236-2750 E-mail: medical.commission@wmc.wa.gov	
Effective Date:	March 3, 2023	
Supersedes:	INS2019-01, effective March 8, 2019	
Approved By:	Jimmy Chung, MD, Chair (signature on file)	

Description of the Issue

The Washington Medical Commission (Commission) is aware of concerns by practitioners that the Commission's opioid prescribing rules are inflexible and do not allow for variation based on patient presentation. The Commission is also aware that some practitioners are refusing to see or continue to treat patients who have taken or are currently using opioids.

Interpretive Statement

~~WAC 246-919-850 – Intent and scope, and its corresponding Washington Administrative Code for allopathic physician assistants (WAC 246-918-800),~~ The Intent and Scope section of both the physician opioid prescribing rule, WAC 246-919-850, and the physician assistant opioid prescribing rule, WAC 246-918-800, states that appropriate pain management is the responsibility of the treating practitioner and the inappropriate treatment of pain, including lack of treatment, is a departure from the standard of care. The Commission ~~in WAC 246-919-850 and WAC 246-918-800~~ encourages practitioners, especially those in primary care, to view pain management as a part of standard medical practice for all patients and to become knowledgeable about assessing pain and effective treatments.

It is important to note that the rules are not inflexible and recognize the importance of sound clinical judgment. Those concerned about the use of the word "shall" within the rules are encouraged to ~~consider~~review the Intent and Scope Section. This opening provision describes the purpose of the rules and sets the tone for interpretation and application of the entire opioid prescribing rule set by the Commission. ~~The intent provision explicitly states that the rules are not inflexible and repeatedly recognizes the importance of clinical judgment.~~

Background

In 2011, the Commission established rules for managing chronic, noncancer pain to alleviate practitioner uncertainty, encourage better pain management, and assist practitioners in providing appropriate medical care for patients. Since 2011, the Legislature and Commission have made changes on the management of chronic pain to improve patient care and safety.

In 2018, at the direction of the Legislature,[1] the Commission created new rules regarding opioid prescribing for acute nonoperative, acute perioperative, and subacute pain, including the use of multimodal pharmacologic and nonpharmacological therapies as possible alternatives to opioids. The Commission made minor modifications to the existing rules for managing chronic pain ~~rules~~ as well.

In 2020, at the direction of the Legislature, the Commission revised its rules to require a physician to inform a patient that the patient has the right to refuse an opioid prescription for any reason and to require documentation and clarification regarding honoring that refusal.[2]

Additionally, in 2022, the Commission ~~modified~~ amended the rules to state that the rules do not apply to~~exempt from the requirements of the rules~~for the treatment of patients in nursing homes, long-term acute care facilities, residential treatment facilities, and residential habilitation centers.[3]

Analysis

The opioid prescribing rules describe the Commission's intent and scope of the rules as follows:

> The ~~[Washington medical commission] ([~~commission~~)]~~ recognizes that principles of quality medical practice dictate that the people of the state of Washington have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity, mortality, and costs associated with untreated or inappropriately treated pain. For the purposes of these rules, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.
>
> The diagnosis and treatment of pain is integral to the practice of medicine. The commission encourages ~~physicians~~[practitioners] to view pain management as a part of quality medical practice for all patients with pain, including acute, perioperative, subacute, and chronic pain. All [practitioners] should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as become knowledgeable about the statutory requirements for prescribing opioids, including co-occurring prescriptions. Accordingly,

[1] RCW 18.71.800.
[2] RCW 18.71.810.
[3] WAC 246-919-851.

these rules clarify the commission's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from a ~~physician~~[practitioner's] lack of knowledge about pain management. Fears of investigation or sanction by federal, state, or local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the commission will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The commission recognizes that controlled substances including opioids may be essential in the treatment of acute, subacute, perioperative, or chronic pain due to disease, illness, trauma or surgery. The commission will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain.

The medical management of pain should consider current clinical knowledge, scientific research, and the use of pharmacologic and nonpharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration, impact of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioids and are not the same as opioid use disorder.

The commission is obligated under the laws of the state of Washington to protect the public health and safety. The commission recognizes that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society. The inappropriate prescribing of controlled substances, including opioids, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the commission expects that [practitioners] incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

[Practioners] should not fear disciplinary action from the commission for ordering, prescribing, dispensing or administering controlled substances, including opioids, for a legitimate medical purpose and in the course of professional practice. The commission will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a [practitioner]-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The commission will judge the validity of the [practitioner's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

These rules are designed to assist [practitioners] in providing appropriate medical care for patients. The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these rules will not guarantee an accurate diagnosis or a successful outcome. The sole purpose of these rules is to assist [practitioners] in following a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care.

For more specific best practices, the [practitioner] may refer to clinical practice guidelines including, but not limited to, those produced by the agency medical directors' group, the Centers for Disease Control and Prevention, or the Bree Collaborative.

Commonly Asked Questions

1. What is episodic care and how does it apply to my practice?

For the purpose of these rules, episodic care usually includes patients seen in an emergency department or urgent care facility for chronic pain when complete medical records are not available. Additionally, patients seen in an ambulatory care setting with complaints associated with chronic pain whose complete medical records are not available would also be covered by this rule. However, some healthcare systems and clinics may have an associated urgent care facility with complete availability of medical records. These facilities would be excluded from the definition of episodic care for the purposes of these rules.

2. Does the rule define the entire standard of care for the management of pain?

No. The contents of the rules do address some important elements of the standard of care for pain management, but they do not define the entire standard of care. The rules are not exhaustive. The standard of care (current practice guidelines articulated by expert review) will continue to control circumstances and issues not addressed by the rule.

3. Is the 120 mg. MED "consultation threshold" a maximum dose under the rules?

No. The 120 mg. morphine equivalent dose (MED) threshold is a triggering dose, intended to alert the practitioner to the fact that prescribing at this dose or higher significantly increases

the potential for morbidity and mortality, and requires a consultation with a pain specialist unless the practitioner or circumstances are exempted under the rules. The articulation of this dose in the rules is consistent with the ~~l~~Legislature's requirement in RCW 18.71.450[4] to adopt rules that contain a dosage amount that must not be exceeded without pain specialist consultation.

Some have referred to the 120 mg. ~~(~~MED~~)~~ threshold (or "triggering") dose as a "maximum dose". The rules do not provide a maximum dose. They simply require, absent an exemption, that the practitioner obtain a pain specialist consultation before continuing ~~on~~ to prescribe opioids at a level that is associated with significant increases in opioid-related overdoses and deaths.

4. Is the 120 mg. MED "consultation threshold" the minimum dosage at which a consultation should be obtained under the rules?

No. A physician or physician assistant should obtain a consultation when warranted. In WAC 246-919-930(2) and WAC 246-918-880(2), the threshold for mandatory consultation is set at 120 mg. ~~(~~MED~~)~~ for adult patients. However, WAC 246-919-930(1) and WAC 246-918-880(1) reference, more generally, additional evaluation that *may* be needed to meet treatment objectives. This provision makes specific reference to evaluation of patients under age 18 who are at risk, or who are potential high-risk patients. However, other circumstances may call for a consultation with a pain management specialist for patients who have not yet met the "consultation threshold" dose.

Specific Guidance from the Rules

WAC 246-919-955 and 246-918-905 provide specific guidance to the practitioner to do the following with new patients on high dose opioids:

- Maintain the patient's current opioid doses until an appropriate assessment suggests that a change is indicated (see second bullet point).
- Evaluate over time if any tapering can or should be done.
- New patients on high dose opioids are exempt from mandatory pain specialist consultation requirements for the first three months of newly established care if:
    - The patient was previously being treated for the same conditions;
    - The patient's dose is stable and nonescalating;
    - The patient has a history of compliance with written agreements and treatment plans; and
    - The patient has documented function improvements or stability at the presenting dose.

WAC 246-919-950 clearly explains that tapering would be expected for chronic pain patients when:

[4] ESHB 2876, effective June 10, 2010.

- The patient requests tapering;
- The patient experiences an improvement in function or pain;
- The patient is noncompliant with the written agreement;
- Other treatment modalities are indicated;
- There is ~~E~~evidence of misuse, abuse, substance use disorder, or diversion;
- The patient experiences a severe adverse event or overdose;
- There is ~~U~~unauthorized escalation of doses;
- The patient is receiving ~~A~~an authorized escalation of dose with no improvement in pain or function.

A practitioner treating a patient on a stable, non-escalating dose with positive impact on function would be ~~exempt from any need for~~ not be required to seek additional consultation with a pain specialist ~~regarding treatment~~. Additionally, there is no upper MED limit in Washington State or federal law. ~~The Centers for Disease Control (CDC) has a 90 MED descriptor in their guidelines, which, while a valid indication for consultation, does not have the force of law in Washington.~~ The Commission's opioid prescribing rules represent the only legal requirement and cite a 120 mg MED "consultation threshold" for allopathic physicians and physician assistants who are not considered pain management specialists under the rule. The rules do not prohibit practitioners from referring a patient to a pain specialist before patients reach the "consultation threshold," nor do they prevent a practitioner from self-imposing a smaller MED limit for their patients.

For ~~those~~ practitioners not considered pain management specialists treating patients over the 120 mg MED "consultation threshold," there are several options to satisfy the exemption consultation requirement, including but not limited to:

- Receive~~e~~ing a peer-to-peer consult with a pain management specialist;
- Participat~~e~~ing in an electronic (audio/video) case consult ~~such as~~with the University of Washington (UW) Telepain, ~~or~~ the Washington Health Care Authority (HCA) Opioid Hotline, or other pain consulting service;
- ~~Chart note d~~Documenting in a chart note the attempt to get a consult but the lack of success in attaining one; and
- Successfully completing a minimum of twelve category I continuing education hours in chronic pain management within the previous four years with at least two of those hours dedicated to substance use disorders. ~~For a full list of options to satisfy the exemption consultation requirement, please see the rules.~~

~~For all of these options, documenting the outcomes or reasoning in the patient medical record satisfies the consultation exemption and would be part of the normal course of medical practice to do so.~~ The practitioner should document the outcomes, reasoning, and discussions with the patient as outlined in the rules and described in this interpretive statement in the patient's medical record as part of the normal course of medical practice.

Interpretive Statement

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Title:	Opioid Prescribing & Monitoring for Patients	INS2023-04
References:	RCW 18.71.800; RCW 18.71A.800; WAC 246-919-850 through WAC 246-919-985; WAC 246-918-800 through WAC 246-918-935	
Contact:	Washington Medical Commission	
Phone:	(360) 236-2750	E-mail: medical.commission@wmc.wa.gov
Effective Date:	March 3, 2023	
Supersedes:	INS2019-02 effective January 18, 2019	
Approved By:	Jimmy Chung, MD, Chair (signature on file)	

Description of the Issue

The Washington Medical Commission (Commission) is aware that some practitioners are refusing to see or continue to treat patients who have taken or are currently using opioids. To help underscore and clarify the need for patient access and the rights of patients for treatment, the Commission issues this interpretive statement for patient and practitioner use.

Interpretive Statement

The Intent and Scope section of both the physician opioid prescribing rule, WAC 246-919-850, and the physician assistant opioid prescribing rule, WAC 246-918-800, states that appropriate pain management is the responsibility of the treating practitioner and that the inappropriate treatment of pain, including lack of treatment, is a departure from the standard of care. The Commission~~, in Washington Administrative Code (WAC) 246-919-850 and 246-918-800~~ encourages practitioners, especially those in primary care, to view pain management as a part of standard medical practice for all patients and to become knowledgeable about assessing pain and effective treatments. ~~The intent provision explicitly states that the rules are not inflexible and repeatedly recognizes the importance of clinical judgment.~~

The Commission interprets physician rules WAC 246-919-850 to 246-919-985 and corresponding physician assistant rules WAC 246-918-800 to WAC 246-918-935~~,~~ as encouraging~~ement to~~ practitioners to not exclude, undertreat, or dismiss a patient from a practice solely because the patient has used or is currently using opioids in the course of normal medical care. While in most circumstances a practitioner is not legally required to treat a particular patient, the refusal to see or continue to treat a patient merely because the patient has taken or is currently using opioids is contrary to the clear intent of the Commission's rules governing opioid prescribing. Ending opioid therapy or initiating a forced tapering of opioids to a particular morphine equivalent dose (MED) level for reasons outside of abuse or clinical

efficacy or improvement in quality of life and/or function ~~or abuse~~ would violate the intent of the rules.

Background

In 2011, the Commission established rules for managing chronic, noncancer pain in 2011 to alleviate practitioner uncertainty, encourage better pain management, and assist practitioners in providing appropriate medical care for patients. Since 2011, the Legislature and Commission have made changes on the management of chronic pain to improve patient care and safety.

In 2018, at the direction of the Legislature, the Commission created new rules regarding opioid prescribing for acute nonoperative, acute perioperative, and subacute pain, including the use of multimodal pharmacologic and nonpharmacological therapies as possible alternatives to opioids.[1] The Commission made minor modifications to the existing rules for managing chronic pain ~~rules~~ as well.

In 2020, at the direction of the Legislature, the Commission revised its rules to require a physician to inform a patient that the patient has the right to refuse an opioid prescription for any reason.[2]

In 2022, the Commission ~~modified~~ amended the rules to state that the rules do not apply to ~~exempt~~ ~~from the requirements~~ ~~of the rules for~~ the treatment of patients in nursing homes, long-term acute care facilities, residential treatment facilities from the rules, and residential habilitation centers.[3]

Analysis

The opioid prescribing rules, WAC 246-919-850, and its corresponding physician assistant rule (WAC 246-918-800), describe the Commission's intent and scope of the rules as follows:

> The ~~[Washington medical commission] ([~~commission~~)]~~ recognizes that principles of quality medical practice dictate that the people of the state of Washington have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity, mortality, and costs associated with untreated or inappropriately treated pain. For the purposes of these rules, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.
>
> The diagnosis and treatment of pain is integral to the practice of medicine. The commission encourages [practitioners] to view pain management as a part of quality medical practice for all patients with pain, including acute, perioperative, subacute, and chronic pain. All

[1] Engrossed Substitute House Bill 1427.
[2] RCW 18.71.810.
[3] WAC 246-919-851.

[practitioners] should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well become knowledgeable about the ~~as~~ statutory requirements for prescribing opioids, including co-occurring prescriptions. Accordingly, these rules clarify the commission's position on pain control, particularly as related to the use of controlled substances, to alleviate [practitioner] uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from a [practitioner's] lack of knowledge about pain management. Fears of investigation or sanction by federal, state, or local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating [practitioner's] responsibility. As such, the commission will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

...

These rules are designed to assist [practitioners] in providing appropriate medical care for patients. The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these rules will not guarantee an accurate diagnosis or a successful outcome. The sole purpose of these rules is to assist [practitioners] in following a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care.

...

Examples

Existing Patient

A patient with a longstanding history in a medical practice develops an injury or condition that becomes a pain condition requiring chronic opioid therapy. Generally, a practitioner who refuses to treat the condition properly, including the appropriate utilization of opioids when opioids are clearly indicated, would be practicing below the standard of care. Similarly, a practitioner who refers the patient to a pain management specialist as defined by Commission rule but refuses to continue or support the pain management treatment plan designed by the specialist while responding to all other aspects of patient care, would generally be practicing below the standard of care. Finally, electing to terminate the patient from the practice, because their regular care involves pain management or opioid therapy, would be generally be practicing below the standard of care.

New Patient

The Commission's opioid prescribing rules provide incentives for practitioners to take new patients into their practice who are on existing opioid therapy regimens.

WAC 246-919-955 and 246-918-905, and the corresponding physician assistant rules, provide specific guidance to the practitioner to do the following with new patients on high dose opioids:

- Maintain the patient's current opioid doses until an appropriate assessment suggests that a change is indicated (see second bullet point).
- Evaluate over time if any tapering can or should be done.
- Be aware that new patients on high dose opioids are exempt from mandatory pain specialist consultation requirements for the first three months of newly established care if:
  - The patient was previously being treated for the same condition(s);
  - The presenting dose is stable and nonescalating;
  - There is a history of compliance with written agreements and treatment plans; and
  - There is documented function improvements or stability at the presenting dose.

Tapering

A patient on opioid therapy, chronic or otherwise, is on a stable non-escalating dose. A practitioner has observed the patient's function and quality of life to be positive. However, citing reasons related to state or federal law or desire to have the patient below a certain MED per day, the practitioner initiates a tapering schedule without receiving the patient's consent or considering the patient's function or quality of life. This would be a clear violation of the Commission opioid prescribing rules.

WAC 246-919-950 clearly explains that tapering would be expected for chronic pain patients when one or more of the following occurs:

- The patient requests tapering;
- The patient experiences an improvement in function or pain;
- The patient is noncompliant with the written agreement;
- Other treatment modalities are indicated;
- There is evidence of misuse, abuse, substance use disorder, or diversion;
- The patient experiences a severe adverse event or overdose;
- There is an unauthorized escalation of doses; or
- The patient is receiving an authorized escalation of dose with no improvement in pain or function.

A practitioner treating a patient on a stable non-escalating dose with positive impact on function would be not be required to seek~~exempt from any need for~~ additional consultation with a pain specialist ~~regarding treatment~~. Additionally, there is no upper MED limit in Washington State or federal law. ~~The Centers for Disease Control and Prevention (CDC) has a 90 MED descriptor in their guidelines, which, while a valid indication for consultation, does not have the force of law in Washington.~~ The Commission's opioid prescribing rules represent the

only legal requirement for licensed allopathic physicians and physician assistants in Washington state, and set a 120 MED consultation threshold for practitioners who are not considered pain management specialists under the rule. . The rules do not prohibit practitioners from referring a patient to a pain specialist before patients reach the "consultation threshold," nor do they prevent a practitioner from self-imposing a smaller MED limit for their patients.

The practitioner should~~shall~~ document the outcomes, reasoning, and discussions ~~help~~ with the patient as outlined in the ~~various~~ rules and described in this interpretive statement in the patient's medical record as part of the normal course of medical practice.

Comparing and Contrasting the 2022 CDC Opioid Prescribing Guideline and the 2019 Washington State Prescribing Rules

January, 2023

Gregory Terman MD, PhD
Professor of Anesthesiology and Pain Medicine
University of Washington
Seattle, Washington

On November 3rd 2022, the Center for Disease Control and Prevention (CDC) released an update to their 2016 "*Clinical Practice Guideline for Prescribing Opioids for Chronic Pain"*, entitled "*CDC Clinical Practice Guideline for Prescribing Opioids for Pain*". As the name implies the new guideline expands its scope to include opioid prescribing for all pain (with certain exemptions). As such, the Guideline more closely parallels the Washington State Opioid Prescribing Rules developed in 2017-2018 and implemented in January of 2019, mandated by Washington HB 1427 and covering all Washington State opioid prescriber groups – including all allopathic physicians and physician assistants overseen by the Washington Medical Commission (WMC). The obvious question is how similar to or different from the 2022 CDC Guideline are the 2019 Washington State Opioid Prescribing Rules covering physicians (WAC 246-919-850 through WAC 246-919-990) and physician assistants (WAC 246-918-800 through WAC 246-918-835). The WMC, aware of my involvement in the formation of the CDC Guidelines and the Washington Prescribing Rules (as a technical expert) as well as the Washington Agency Medical Director Group's opioid prescribing guidelines first published in 2007, contracted with me to compare and contrast the 2022 CDC Guideline and the 2019 Opioid Prescribing Rules pertinent to the WMC and report on my findings. The remainder of this document are my efforts to do so. In the document I will frequently quote both the 2022 CDC Guideline and the Washington State WAC. However, for conciseness I will refer exclusively to the WAC covering physicians – with the understanding that the WAC related to physican assistants is identical although designated with different numbers

Any payment I receive for this work will be the first I receive for any of my guideline development or rule making activities. The opinions expressed in this document are mine alone and do not represent my employer (the Department of Anesthesiology and Pain Medicine at the University of Washington) or any other agency – although after drawing my own conclusions I have since reviewed slide sets from Deborah Dowell of the CDC and Gary Franklin of Washington L&I concerning their thoughts on the 2022 CDC Guideline which were kindly sent to me by email at my request.

<u>Rationale</u>

As an executive summary, it is fair to say that there are few meaningful clinical practice differences between the recommendations of the 2022 CDC Guideline (CDC) and the 2019 Opioid Prescribing Rules (Rules) apart from the fact that many of the Rules are mandatory (delineated in the rules as "shall") whereas the 2022 CDC Rules are repeatedly described as voluntary "recommendations" within the 96 page document. For example, in the abstract the "*CDC recommends that persons with pain receive appropriate pain treatment, with careful consideration of the benefits and risks of all treatment options in the context of the patient's circumstances. Recommendations should not be applied as inflexible standards of care across patient populations."* CDC goes on to define the purpose of the Guideline saying*, "This clinical practice guideline is intended to improve communication between clinicians and patients about the benefits and risks of pain treatments, including opioid therapy; improve the effectiveness and safety of pain treatment; mitigate pain; improve function and quality of life for patients with pain; and reduce risks associated with opioid pain therapy, including opioid use disorder, overdose, and death."* This focus on patient-centered pain care is mirrored in the initial section of the Rules (WAC 246-919-850), reminding prescribers that although there are mandatory

elements of the Rules the *"sole purpose of these rules is to assist physicians in following a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care*" and that the "*appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity, mortality, and costs associated with untreated or inappropriately treated pain. For the purposes of these rules, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments."*

The CDC states that one of the primary reasons for updating the rules, was "*misapplication of the 2016 CDC Opioid Prescribing Guideline (66), benefits and risks of different tapering strategies and rapid tapering associated with patient harm (68,71–73), challenges in patient access to opioids (6), patient abandonment and abrupt discontinuation of opioids (71*)" (page 4). In perhaps the clearest example of the CDC attempting to avoid inflexible interpretations of this version of the Guideline, CDC removed all specific doses and durations from all 12 of the 2022 recommendations – relegating the same doses seen in the 2016 recommendations (based largely on the same data) to the supporting text. The Rules attempted to avoid dose-focused inflexibility of care by reassuring prescribers that the "*commission will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration"* (WAC 246-919-850). Whether this has been successful in avoiding opioid treatment related patient stigma, abandonment and inappropriate discontinuation of opioids is a matter of discussion beyond the scope of this document but the desire to avoid these patient punishments is clearly a similarity between the CDC and the Rules.

Other reasons stated by the CDC (pages 4-7) for the update include:

1) Pain continues to affect the lives of millions of Americans and opioids continue to be commonly used to treat pain.
2) New scientific evidence supports expanded guidance and specificity for
    - treatment modalities for different types of pain
    - acute and subacute pain treatment
    - opioid tapering
3) Many can't access the full range of potentially helpful therapies
    - lack of clarity around evidence supporting pain treatments
    - limited access to treatment modalities
    - Pain-management disparities persist

With regard to the predicted likely continued need for opioids to relieve pain the Rules, again in their very first section (WAC 246-919-850), predicted this: "*The commission recognizes that controlled substances including opioids may be essential in the treatment of acute, subacute, perioperative, or chronic pain due to disease, illness, trauma or surgery*" and rather than attempting to place a pain medicine primer into statute the Rules promised to *"refer to current clinical practice guidelines and expert review in approaching cases involving management of*

pain." The 2022 CDC Guideline should now be considered another of these "clinical practice guidelines" and many of the first 28 pages and last 23 pages relate to nonopioid pain management strategies and the research findings in support of them. As in the 2016 Guideline (and the 2016 National Pain Strategy - https://www.iprcc.nih.gov/node/5/national-pain-strategy-report- released the same week), the 2022 Guideline warns against the limited access that some patients have for these nonopioid and, particularly, non-pharmacological pain management therapies - creating therapeutic disparities. Similarly, the Rules also encourage the use of nonopioid treatments for pain for all patients:

WAC 246-919-870 Use of alternative modalities for pain treatment. *The physician shall exercise their professional judgment in selecting appropriate treatment modalities for acute nonoperative, acute perioperative, subacute, or chronic pain including the use of multimodal pharmacologic and nonpharmacologic therapy as an alternative to opioids whenever reasonable, clinically appropriate, evidence-based alternatives exist.*

In summary, the rationale for the 2022 CDC Guideline is encompassed by what is called the "*five guiding principles*" (text box 4 on page 17):

- "Acute, subacute, and chronic pain needs to be appropriately assessed and treated independent of whether opioids are part of a treatment regimen.
- Recommendations are voluntary and are intended to support, not supplant, individualized, person-centered care. Flexibility to meet the care needs and the clinical circumstances of a specific patient are paramount.
- A multimodal and multidisciplinary approach to pain management attending to the physical health, behavioral health, long-term services and supports, and expected health outcomes and well-being needs of each person is critical.
- Special attention should be given to avoid misapplying this clinical practice guideline beyond its intended use or implementing policies purportedly derived from it that might lead to unintended consequences for patients.
- Clinicians, practices, health systems, and payers should vigilantly attend to health inequities, provide culturally and linguistically appropriate communication, and ensure access to an appropriate, affordable, diversified, coordinated, and effective nonpharmacologic and pharmacologic pain management regimen for all persons."

None of these principles are incongruent with the 2019 Washington State Prescribing Rules and, indeed many of these CDC principles (including the designation of pain as acute, subacute or chronic), instead, seem to mirror 2019 Rules (and the 2015 AMDG Guideline on which many of the Rules are based).

<u>Scope and Audience</u>

As evident from the title, the scope of the 2016 "*CDC Clinical Practice Guideline for Opioid Prescribing for Chronic Pain"* is expanded in 2022 to address prescribing for acute, subacute as well as chronic pain. The definitions of acute and subacute pain differ somewhat from the

Washington State Rules – with the transition from acute to subacute pain being 1 month in the CDC document (e.g., Text box 2, page 7) instead of the 6 weeks defined in the Rules (WAC 246-919-852). Although this is a clear difference between the two, there is no literature cited for choice of acute pain duration by either and the CDC admits that the "*durations used to define acute, subacute, and chronic pain might imply more specificity than is found in real-life patient experience, when pain often gradually transitions from acute to chronic. These time-bound definitions are not meant to be absolute but rather to be approximate guides to facilitate the consideration and practical use of the recommendations by clinicians and patients"* (page 7-8). The practical differences between the two definitions of subacute pain are over-shadowed by the identification of opioid prescribing for subacute pain as a mechanism for avoiding *"unintentional"* transitions from short-term opioid prescribing to long-term opioid prescribing in both the CDC guideline (page 26) and the Rules (e.g., WAC 246-919-895).

Exemptions from the opioid prescribing recommendations per CDC (pages 7-9) include:

- "Patients less than 18 years old.
- Hospitalized patients or patients in an emergency department or other observational setting (discharge medications ARE covered by the guideline)
- Management of cancer-related pain
- Palliative care
- End-of-life care
- Opioids prescribed for opioid use disorder
- Management of sickle cell disease-related pain"

These largely mirror the stated exclusions in the Rules (WAC 246-919-851) with the exception of opioids for opioid use disorder (perhaps obvious since these are Rules for "*the prescribing of opioids in the treatment of pain*"- 1st sentence of WAC 246-919-850), children and sickle cell disease-related pain. Even the CDC, however, includes these exemptions primarily because of other guidelines available for these patients - rather than data supporting differences in best practice (page 8).

As a result, the 2022 CDC Guideline is aimed, not just at the primary care prescriber audience targeted in 2016, but all opioid prescribing clinicians. "Pain management specialists" are not specifically defined by CDC (unlike in the Rules - WAC 246-919-945), but are given some leeway (page 8, "*the balance of benefits and risks to patients might differ when the treating clinician is a pain management specialist.")* although NOT exemption from the Guideline (similar to the Rules).

<u>Recommendations</u>

The twelve recommendations from the CDC are the result of a literature review, expert and stakeholder discussion and public feedback. Each recommendation is classified based on its GRADE (Grading of Recommendations Assessment, Development and Evaluation) with regard to its quality of evidence (1-4 based on gradations from randomized studies to clinical

anecdotes) and strength of the recommendation (A or B based on applicability to all patients or only certain patient groups respectively). This complicated process (described on pages 9-15) is likely the reason why it was more than 4 years from the September, 2018 initial CDC expert discussions, which I participated in, of gaps in the 2016 Guideline until publication of the new Guideline in November of 2022. It may also explain why there is so little difference between the new Guideline and the Rules – which were written in late 2017 and 2018. Perhaps most discouraging with regard to the recommendations is the fact that 9 of the 12 recommendations are supported with level 3 or 4 evidence (lacking any quality randomized studies). Below we will compare and contrast each of the 12 CDC recommendations (Grouped into 4 general categories) to the Washington State Rules. As stated above most of the recommendations are covered by the Rules – though often in different detail and not always grouped in the same way as done by the CDC (see Table 1).

Group I – Determining whether or not to initiate opioids for pain.

Recommendation 1:

"Nonopioid therapies are at least as effective as opioids for many common types of acute pain. Clinicians should maximize use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider opioid therapy for acute pain if benefits are anticipated to outweigh risks to the patient. Before prescribing opioid therapy for acute pain, clinicians should discuss with patients the realistic benefits and known risks of opioid therapy (recommendation category: B; evidence type: 3)."

As mentioned above the Rules define acute pain differently than the CDC (6 weeks vs 1 month respectively). Moreover, the Rules but NOT the CDC differentiate between acute nonoperative pain and acute perioperative pain. However, for all acute pain, the Rules, similar to the CDC, encourage preferential nonopioid therapies (WAC 246-919-870), weighing likely benefits and risks before prescribing opioids (WAC 246-919-880, WAC 246-919-885 and WAC 246-919-890) and a discussion of opioid risks with the patient before prescribing (WAC 246-919-865). Also like the CDC (in the supporting text), the Rules state that the prescription for acute pain must not be in a quantity likely to outlast acute pain severe enough to require opioids (WAC 246-919-885, WAC 246-919-890). Finally, the points of discussion with the patient suggested by CDC concerning opioid risks (page 21) are virtually identical to those mandated by the Rules (WAC 246-919-865).

Recommendation 2:

"Nonopioid therapies are preferred for subacute and chronic pain. Clinicians should maximize use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider initiating opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients the realistic benefits and known risks of opioid therapy, should work with patients to establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks (recommendation category: A; evidence type: 2)."

Similar to this recommendation, the Rules encourage the use of nonopioid ("alternative") treatments for pain (WAC 246-919-870). The CDC goes much deeper into the evidence supporting nonopioid pharmacological and nonpharmacological treatments (including interventional treatments) for acute and chronic pain. The distinction between subacute and chronic pain is often blurred by the CDC and "*subacute pain*" is most frequently mentioned in the pairing "*subacute and chronic pain*". In this way, separate assessment and treatment of subacute pain, as distinguished from chronic pain, in the Rules is more clear – complete with examples of acute pain transitioning into subacute pain (WAC 246-919-885 and WAC 246-919-890) and how assessment should change with this transition (WAC 246-919-895 and WAC 246-919-990). On the other hand, the CDC was able to devote more space than the Rules could to detailed discussions of the utility of patient agreements, toxicology screening, prescription drug monitoring program (PDMP) queries and prescriptions for naloxone as mitigation strategies for subacute and chronic pain (pages 23-28). Such discussions could simply not be fleshed out in the limited space allotted in the WAC for the Rules (though all of these mitigation strategies are included in them). On the other hand, a section in the CDC Guideline on the importance of identifying subacute pain in order to look for reversible mechanisms that might cause chronic pain as well as avoiding an unintentional transition to chronic opioid use (page 26) is implied in the Rules (WAC 246-919-895) and is a big improvement from last year's published draft of the Guideline (which did not include any reasons for distinguishing between subacute and chronic pain).

Group II – Selecting opioids and determining opioid dosages.

Recommendation 3:

"*When starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release and long-acting (ER/LA) opioids (recommendation category: A; evidence type: 4).*"

The Rules differ a little with regards to this recommendation. Although ER/LA opioids are clearly stated in the Rules to NOT be indicated for acute pain (WAC 246-919-895 and WAC 246-919-990), instead of warning clinicians away from starting opioid prescribing with ER/LA opioids for subacute and chronic pain (as the CDC does) the Rules focus more on the complex pharmacology of safe prescribing with ER/LA opioids in comparison to immediate release opioids (particularly when starting ER/LA therapy). The Rules suggest a minimum of 4 hours of CME about ER/LA opioids before prescribing these drugs at any stage (initial or otherwise) of prescribing for subacute or chronic pain (WAC 246-919-925). In this regard the Rules mirror the FDA's 7/12 and 6/15 Extended-release (ER) and long-acting (LA) opioid analgesics risk evaluation and mitigation strategy (REMS) (https://www.fda.gov/files/drugs/published/Opioid-Analgesics-Extended-Release-and-Long-Acting.pdf) requiring sponsor paid education and limiting use to, among other things, when immediate release opioids are not sufficient.

Recommendation 4:

"When opioids are initiated for opioid-naïve patients with acute, subacute, or chronic pain, clinicians should prescribe the lowest effective dosage. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage, should carefully evaluate individual benefits and risks when considering increasing dosage, and should avoid increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients (recommendation category: A; evidence type: 3)."

As mentioned above, the 2022 CDC Guideline specifically refrains from naming particular doses in any of their recommendations (stated to be due to inflexible rules by third party payers and state legislatures throughout the country following the 2016 Guideline). Indeed, inflexible reading of the 2022 Guideline, with respect to appropriate doses, is warned against three times in less than a half page (page 30-31) although the same data is discussed and the same doses (i.e., >50 MME/day) are called out as increasing risk/benefit ratios. Critics of the new CDC Guideline argue that there is little evidence that clinicians are skilled at individual risk/benefit analyses required to accomplish this recommendation. I, in contrast, appreciate the advice that "*If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids for chronic pain at any dosage"* - as opposed to the analogous section in the 2016 CDC Guideline (Recommendation 5) which puts the emphasis on dose in stating that the clinician *"should carefully reassess evidence of individual benefits and risks when increasing dosage to >50"* MME/day. The Rules approach the >50 MME/day dose as one of several patient and therapeutic factors contributing to a patient taking chronic opioids as being assessed as transitioning from low to moderate risk of opioid-induced morbidity or mortality (WAC 246-919-852) (with >90 MME/day defined in the same section as "high dose" and contributing to the definition of "high risk"). Low, moderate and high risk categories are used in the Rules (WAC 246-919-920) for determining the frequency of periodic review during the course of treatment - at annual, semi-annual and quarterly frequencies respectively. The Rules also use dose considerations (in keeping with the recommendation from the very first AMDG Guideline in 2007) to mandate >120 MME/day doses as a threshold for obtaining consultation with a pain expert (WAC 246-919-930). Although there are a few exceptions to this mandate (including if the prescriber is tapering the dose or the dose is due to an acute pain escalation, or if the prescriber is a pain specialist for example) (WAC 246-919-935 and WAC-919-940) the CDC has had no such mandatory consultation (in their 2016 or 2022 Guidelines) and, indeed, has never attempted to supply a specific definition for a "pain expert" (2007, 2010 and 2015 AMDG and WAC 246-919-945).

Recommendation 5:

"For patients already receiving opioid therapy, clinicians should carefully weigh benefits and risks and exercise care when changing opioid dosage. If benefits outweigh risks of continued opioid therapy, clinicians should work closely with patients to optimize nonopioid therapies while continuing opioid therapy. If benefits do not outweigh risks of continued opioid therapy, clinicians should optimize other therapies and work closely with patients to gradually taper to lower dosages or, if warranted based on the individual circumstances of the patient, appropriately taper and discontinue opioids. Unless there are indications of a life-threatening

issue such as warning signs of impending overdose (e.g., confusion, sedation, or slurred speech), opioid therapy should not be discontinued abruptly, and clinicians should not rapidly reduce opioid dosages from higher dosages (recommendation category: B; evidence type: 4).”

The indications and strategies for tapering patients on opioids is an expanded focus of the 2022 CDC Guideline in comparison to the 2016. Considerable research has been done in this area and an excellent HHS review of the topic was published in 10/19 (https://www.cms.gov/About-CMS/Story-Page/CDCs-Tapering-Guidance.pdf). The CDC cites these resources liberally in the 6 pages of supporting text for this recommendation. Again, the Rules differ more in detail than in tone concerning tapering of patients on chronic opioids – listing examples when observed risks outweigh benefits and should lead to tapering (WAC 246-919-950). The CDC guidance that not all patients on chronic opioids need to be tapered is more implied than stated in the Rules. The CDC stresses “shared decision making” and “patient-centered treatment” and although these terms largely post-date the 2019 Rules with regard to tapering, the examples given in the Rules are consistent with CDC, HHS and the more recent Bree/AMDG guidance on opioid tapering or lack thereof (https://www.qualityhealth.org/bree/wp-content/uploads/sites/8/2020/05/Bree-Long-Term-Opioid-Use-Recommendations-FINAL-20-05.pdf). The detailed recommendations of how and how fast to taper when deemed appropriate (e.g., lack of abruptness, concern for loss of tolerance if tapering is reversed, close followup during tapering to avoid opioid withdrawal or illicit use, possible need for OUD and/or behavioral consultation, etc.) is, again, not present in the Rules although a simple reference to the 2020 Bree/AMDG Guideline would clarify that tapering is not always necessary and certainly not always fast or easy. One example of chronic opioids stated NOT to require tapering already clarified in the Rules however, is in WAC 246-919-955 (*Patients with chronic pain, including those on high doses of opioids, establishing a relationship with a new physician*) where providers are advised that “*it is normally appropriate for a new physician to initially maintain the patient’s current opioid dose*” and “*Over time, the physician may evaluate if any tapering or other adjustments in the treatment plan can or should be done*”. This section of the Rules concerning tapering is quite consistent with the CDC’s recommendations on the topic.

Group III – Deciding duration of initial prescription and conducting followup.

Recommendation 6:

“When opioids are needed for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids (recommendation category: A; evidence type: 4).”

Again, critics of the 2022 CDC Guideline have expressed unhappiness with taking specific prescription duration guidance from the 2016 CDC Guideline out of this iteration. For example, in the analogous section of the 2016 Guideline (also recommendation 6) the last sentence of the recommendation advises that “*Three days or less will often be sufficient; more than seven days will rarely be needed*”. I would argue that, in addition to attempts to minimize third party payer and legislative inflexibility resulting from dose and duration numbers incorporated into the 2016 Guideline, removal of the specific durations for acute

pain prescribing from the 2022 CDC Guideline may have been driven by the change in scope and audience for this guideline mentioned above. Whereas, the 2016 Guideline was aimed solely towards primary care prescribers, the 2022 version is aimed at all outpatient prescribing for adults in pain. This inclusion of pain after surgical operations for example and the grouping of these patients into the same recommendations with those with much less invasive (or easily treated) acute pain injuries makes specific prescription duration suggestions for opioid prescribing more complex - and perhaps more dangerous. Would it really be appropriate to recommend the same duration of opioids for an acute back sprain and a lung transplant for example? In the Washington State Rules this complexity in acute pain injuries was recognized and different rules were created and implemented for nonperioperative (WAC 246-919-885) and perioperative (WAC 246-919-890) acute pain – with some areas of overlap for all acute pain recognized (WAC 246-919-880 – although this section is mistakenly titled as being about *"Acute nonoperative pain*" only). Within this differential framework of nonoperative and postoperative acute pain more specific maximum duration Rules could be crafted (7 days and 14 days respectively) with allowances for longer durations being possible with documentation of necessity. The distinctions between nonperioperative and perioperative and their maximal durations mirror the 2015 AMDG Guideline (https://amdg.wa.gov/Files/2015AMDGOpioidGuideline.pdf) and the 2018 AMDG supplemental guidance on Prescribing Opioids for Postoperative pain (https://amdg.wa.gov/Files/FinalSupBreeAMDGPostopPain091318wcover.pdf). The latter guideline further differentiated postoperative pain into 3 categories of surgeries based on the patient's expected recovery duration. The Rules appropriately chose the longest duration of recovery in setting its maximal length of opioid prescribing allowed (14 days) without justification documentation (WAC 246-919-890, subsection 3). The CDC, in this, their first, guidance for prescribers outside of primary care, chose not to discriminate between nonoperative and perioperative acute pain; nor did they distinguish between surgeries of different recovery durations. However, similarities can be seen in the supporting text of even this CDC recommendation in that they suggest that prescribers evaluate their patients on opioids for acute pain no less frequently than every 2 weeks (page 38). Although the CDC's definition of a transition from acute to subacute pain at 1 month strikes me as too short for some surgeries and other traumatic injuries, the CDC should be applauded for recommending that even following acute pain opioid tapering may be needed to avoid withdrawal symptoms if opioids have been used continuously for more than a few days (page 40) – a suggestion NOT present in the Rules. Nor is the CDC's reminder to surgeons that, *"When patients are discharged from the hospital after surgery, the course and dosage of any opioid medications administered during hospitalization and before discharge can help predict ongoing pain management needs*" (page 40). Finally the CDC calls for more than just prescriber attention to unexpected long durations of pain requiring opioids - including in the supporting text that: "*To minimize unintended effects on patients, clinicians, practices, and health systems should have mechanisms in place for the subset of patients who experience severe acute pain that continues longer than the expected*

duration. These mechanisms should allow for timely reevaluation to confirm or revise the initial diagnosis and adjust pain management accordingly. Clinicians, practices, and health systems can help minimize disparities in access to and affordability of care and refills by ensuring all patients can obtain and afford additional evaluation and treatment, as needed" (page 40).

Recommendation 7:

"Clinicians should evaluate benefits and risks with patients within 1–4 weeks of starting opioid therapy for subacute or chronic pain or of dosage escalation. Clinicians should regularly reevaluate benefits and risks of continued opioid therapy with patients (recommendation category: A; evidence type: 4)."

The Rules have language most analogous to this with regard to subacute pain, where prescriptions are generally to be of no longer duration than 2 weeks at a time (allowing for re-evaluation at least every two weeks)(WAC 246-919-900, subsection 2). Although the Rules do not directly comment on how soon after starting opioids for chronic pain a patient should be re-evaluated, they do state that, *"When the patient enters the chronic pain phase, the patient shall be reevaluated as if presenting with a new disease*" (WAC 246-919-905*).* This could be interpreted as a prescription duration limit similar to acute pain (7-14 days) but this is NOT explicit. CDC also details in the text the importance of much closer followup (2-7 days) when ERLA opioids are started (page 41) and although this is not specifically addressed in the Rules the requirement of ERLA opioid CME for ERLA prescribers and the statement that "*Special attention should be given to patients who are initiating such treatment"* (WAC 246-919-925) congruent with the idea that these drugs need particularly close monitoring. The Rules are actually clearer in their specifics for periodic review frequency (based on risk level - WAC 246-919-920) with patients at high risk for opioid morbidity to be re-assessed at least quarterly. Similarly, CDC states that, "*Clinicians should reevaluate patients who are at higher risk for opioid use disorder or overdose (e.g., patients with depression or other mental health conditions, a history of substance use disorder, a history of overdose, taking ≥50 MME/day, or taking other central nervous system depressants with opioids) more frequently than every 3 months"* (page 41). Although the periodic re-assessments themselves recommended by the Rules and the CDC Guideline are largely identical (see Recommendation 8), CDC (including page 43) advises use of a screening tool for active substance use disorder (such as the DAST or the AUDIT-C) rather than any still unvalidated tools purported to assess opioid use disorder RISK (such as the ORT). This is somewhat different than the Rules, and importantly, makes the Washington Rule requirement of documenting results of a *"risk assessment tool that is a professionally developed, clinically recommended questionnaire appropriate for characterizing a patient's level of risk for opioid or other substance use disorders"* (WAC 246-919-905, subsection 3d) not yet possible.

Group IV – Assessing risk and addressing potential harms of opioid use.

Recommendation 8:

"Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk for opioid related harms and discuss risk with patients. Clinicians should work with patients to incorporate into the management plan strategies to mitigate risk, including offering naloxone (recommendation category: A; evidence type: 4)."

As mentioned above, the risk factors to be reviewed periodically discussed by the CDC and included in the Rules (WAC 246-919-920) are nearly identical (e.g., mental health conditions, previous overdoses, and substance use disorder). The primary exceptions to this are the opioid overdose risks seen in patients with "*safety critical jobs*"(page 46), "*renal or hepatic insufficiency*" (page 45) and "*sleep-disordered breathing*" (page 44) mentioned by CDC but not in the Rules. The CDC advice to discuss risks of opioid prescribing with patients is detailed in the Rules (WAC 246-919-865) and Washington Department of Health handouts have been created to allow patients to have permanent references to those risk discussions in the setting of opioid prescriptions for acute (nonperioperative and perioperative), subacute and chronic pain. Special populations, including pregnant women and the elderly, and their special risks are discussed by both CDC (pages 45-46) and the Rules (WAC 246-919-960) – although the depth of discussion in both documents at times seem minimally useful. The statement in the Rules that "*The physician shall consider the distinctive needs of patients who are sixty-five years of age or older"* or from the CDC that *"Clinicians should educate older adults receiving opioids to avoid medication-related behaviors that increase risk, such as saving unused medications"* leave the reader wondering why this advice is pertinent only in "special populations". Nonetheless, the CDC offers a good literature review of the pharmacological peculiarities of the pregnant and older patient. Prescribing for children and adolescents is NOT mentioned in the CDC Guideline of course since this guideline refers only to patients 18 years old and over.

A big difference between the CDC Guideline and the Rules is in their approach to written patient agreements. Although the Rules mandate written patient agreements - outlining patient responsibilities in patients prescribed opioids chronically (WAC 246-919-915) - little is said by the CDC about these written agreements. This difference is likely due to a lack of data supporting increased safety for patients that have written patient agreements rather than the CDC attempting to discourage these documents. On page 26 CDC states that, *"Although the clinical evidence reviews did not find studies evaluating the effectiveness of written agreements or treatment plans (7), clinicians and patients who clearly document a treatment plan including specific functional goals in advance of prescribing will clarify expectations about how opioids will be prescribed and monitored with an aim to improve patient safety, health, and well-being".* I would argue, however, that for the reasons noted by CDC the Rules have it right when it comes to written patient agreements being best practice in chronic opioid prescribing. CDC chose NOT to recommend patient agreements, even as part of a recommendation, such as this one, supported by only Type 4 evidence *("clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations"* – page 10*).*

The use of naloxone as a risk mitigation strategy when prescribing opioids for patients at high risk of opioid overdose is emphasized by both the CDC and the Rules – although the specifics of the naloxone use recommendations differ. For example, the CDC includes a patient risk factor indication for naloxone prescribing not mentioned in the Rules; namely, "*patients at risk for returning to a high dose to which they have lost tolerance (e.g., patients undergoing tapering or recently released from prison)*" (page 48). Further, whereas the Rules mandate that the *"opioid prescribing physician shall confirm or provide a current prescription for naloxone when opioids are prescribed to a high-risk patient"* (WAC 246-919-980) the CDC writes that naloxone should be "offered" to patients clarifying that: *"In part because of concerns about cost of naloxone and access for some patients and reports that purchasing of naloxone has in some cases been required to fill opioid prescriptions, including for patients without a way to afford naloxone, this recommendation specifies that naloxone should be offered to patients"* (page 43). A State-wide prescription for naloxone through the Washington Department of Health allows anyone that wants (and can afford) naloxone to get it and would likely fulfill the CDC recommendation. However, the Rules' mandate to "*confirm or provide a current prescription for naloxone*" is likely too difficult for most clinicians to carry out without universal payment for naloxone or a state tracking system for naloxone (such as inclusion in the Prescription Drug Monitoring Program).

Recommendation 9:

"When prescribing initial opioid therapy for acute, subacute, or chronic pain, and periodically during opioid therapy for chronic pain, clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or combinations that put the patient at high risk for overdose (recommendation category: B; evidence type: 4)."

As with naloxone, the PDMP (commonly referred to as the Prescription Monitoring Program or PMP in Washington) is well accepted as an important risk mitigating strategy for opioid prescribing by both the Rules and the CDC. Both agree that ideally PDMP data should be queried before all opioid prescriptions (and in the Rules also when prescribing sedatives that make ongoing opioid treatment more risky – WAC 246-919-985, subsection 3). However, in less than ideal situations the Rules and CDC differ in their minimal PDMP query frequency with the CDC recommending a minimum of PDMP checks before initial opioid prescriptions for any pain and every 3 months thereafter (page 48) and the Rules mandating PDMP checks at the first refill or renewal for acute pain, the time of transition from acute to subacute pain (6 weeks), the transition time from subacute to chronic pains (3 months) and then every 3, 6 or 12 months based on low, moderate and high risk chronic pain patients respectively (WAC 246-919-985). Washington State continues to work towards mandated integration of the PMP with the electronic medical record (EMR) throughout the State (in response to SSB 5380; c.f., WAC 246-470-037 Waiver for integrating electronic health record system with the prescription monitoring program). The Rules already mandate PMP queries for each opioid or sedative prescription within the scope of the rules (WAC 246-919-985, subsection 7) in cases

where the EMR and PMP are integrated. Nonetheless, until full EMR/PMP integration takes place the WMC Rules will not be in accordance with the CDC recommendations.

The CDC spends nearly half of the supporting text for this recommendation suggesting how best to use the data from the PDMP, including considering the data in context, avoiding firing patients based on unexpected query results and the use of other risk mitigation strategies (such as urine toxicology) in concert with the PDMP. Such PDMP data interpretation guides are not included in the Rules.

Recommendation 10:

"*When prescribing opioids for subacute or chronic pain, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances (recommendation category: B; evidence type: 4)."*

Urine toxicology testing is also considered a useful risk mitigation strategy for subacute and chronic opioid prescribing by both the CDC and the Rules. The Rules again use low, moderate or high patient risk assessment to determine the frequency of this assessment (3, 6 and 12 month frequencies respectively - WAC 246-919-920). The CDC suggests toxicology testing before the first subacute or chronic pain opioid prescription and at least annually thereafter (page 50). As in the PDMP supporting text, a large portion of the toxicology supporting text involves the CDC detailing the appropriate use of toxicology testing - including universal application (to avoid bias), discussion of (rather than punishment for) unexpected results and the use of results in the context of other clinical assessments to determine an action plan after unexpected results are obtained. In particular, the CDC advises all prescribing clinicians to understand how to interpret results and identify resources for help in this regard (including the metabolic pathways of certain drugs and the use of confirmatory tests). The CDC Guideline can therefore be seen, not so much as differing from the Rules but instead, as an important resource for Washington State clinicians attempting to follow the Rules in their opioid prescribing practice.

Recommendation 11:

"Clinicians should use particular caution when prescribing opioid pain medication and benzodiazepines concurrently and consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants (recommendation category: B; evidence type: 3)."

The CDC and the Rules also agree on the danger of co-prescribing sedatives and opioids. The CDC describes in the supporting text why they have changed the wording on this recommendation from "*avoid*" (CDC, 2016) to "*use particular caution when*" (CDC, 2022) (page 53). The CDC gives specific examples of when concurrent prescribing might be clinically useful and when tapering, particularly rapid tapering, of sedatives might be dangerous. The Rules expand the sedative co-prescribing concerns beyond benzodiazepines to include barbiturates, carisoprodol and other sedatives and hypnotics (WAC 246-919-970, subsection 1a-e) but place

the onus on the prescriber to document the "medical decision making" as to why the benefits of co-prescribing outweigh the risk for this patient. Indeed, the emphasis on documentation of the risks and benefits of a medical decision rather than simply seeming to prohibit a particular medical decision is found throughout the Rules (and previous AMDG guidelines) and may stem from the fact that the rules (and AMDG guidelines) were primarily the product of medical professionals - rather than legislators, regulators or even researchers.

Recommendation 12:

"Clinicians should offer or arrange treatment with evidence-based medications to treat patients with opioid use disorder. Detoxification on its own, without medications for opioid use disorder, is not recommended for opioid use disorder because of increased risks for resuming drug use, overdose, and overdose death (recommendation category: A; evidence type: 1)."

Ironically this recommendation, the only one labelled as having Category A, type 1 evidence support, for the most part does not really fit within the intent of this "*CDC Clinical Practice Guideline for the Prescribing Opioids for Pain*". Only the last subsection concerns the prescribing of opioids for pain – while the rest is concerned with the treatment of opioid use disorder (OUD) in patients that may or may not have pain – and even this section primarily references an American Society of Addiction Medicine an update of a consensus guideline for the treatment of opioid use disorder (*The ASAM national practice guideline for the treatment of opioid use disorder: 2020 focused update. J Addict Med 2020;14(Suppl 1):1–91).* The Rules, in contrast, are limited to patients with acute pain who come for treatment already receiving OUD pharmacological treatment (labelled as "medication assisted treatment" in the Rules but now more commonly referred to as receiving Medications for Opioid Use Disorder or MOUD) (WAC 246-919-975). The Rules are largely congruent with the CDC's recommendations in this limited patient population (that is, continue MAT/MOUD treatment and DO NOT refuse to treat pain with additional opioids if indicated). On the other hand, the Rules lack the CDC advice on what prescribers should do if a patient with OUD is identified during (or as a result of) their opioid prescribing. CDC encourages all clinicians to be qualified to treat such patients' OUD (page 58) but, failing that, advise that *"Clinicians prescribing opioids should identify treatment resources for opioid use disorder in the community, establish a network of referral options that span the levels of care that patients might need to enable rapid collaboration and referral, when needed, and work together to ensure sufficient treatment capacity for opioid use disorder at the practice level"* (page 55*).* Regardless of who will ultimately provide OUD treatment however, the CDC cautions clinicians that they *"should not dismiss patients from their practice because of opioid use disorder because this can adversely affect patient safety*" (page 54). This valuable advice should go without saying of course but sadly, even today, it may well need to be said.

<u>Summary</u>

Although released almost 4 years after the January 2019 "Washington State Opioid Prescribing Rules", the "2022 CDC Practice Guideline for Opioid Prescribing for Pain" differs

little in any clinically significant way from these Rules despite being almost 4 times as long (96 pages versus 25 pages)(see Table 2. As mentioned, this may be due to the longer and more tortuous trip a new federal guideline needs to make (more than 4 years to release from initial meetings in this case) compared to the shorter route at a state level (less than 18 months from the 1st meeting until implementation). Although one could certainly argue that there are some differences that could be made in the Rules to bring them more in line with the CDC (**Table 1**), most fall into either arbitrary (a 4 week versus a 6 week start for subacute pain) or more detailed (e.g., the science of urine toxicology and opioid prescribing for OUD) difference categories. The biggest difference is definitely that following the CDC Guideline is voluntary and the Rules are largely not. However, in some ways this forced the Rules to be more focused (e.g., more about pain and less about OUD) and flexible (e.g., stressing documentation of medical decision making) which in my opinion avoided some of the inflexibility of interpretations that plagued the 2016 CDC guideline. The biggest advantage that the Rules had that the 2016 CDC Guideline (and even the 2022 version) did not have is almost certainly the long headstart afforded by the 2007, 2010, 2015, 2017 and 2018 AMDG guidelines as well as the 2011 Rules for opioid prescribing for chronic pain (in response to ESHB 2876). For this reason, the 2019 Rules (in response to HB 1427) had less novel terrain to cover. That does not mean that there isn't more work to do in safeguarding Washington's residents from the twin threats of opioid morbidity and unnecessary pain (including improvements in integrating the opioid prescribing Rules into state Electronic Medical Record workflows for example). I would merely question whether in moving forward we want to look back in any detail at what the CDC is doing.

Table 1 - 2022 CDC Guideline/2019 WMC Washington State Rule Recommendation (Rec.) Differences

Section	CDC Opioid Prescribing Guideline	Washington State Opioid Prescribing Rules
General	Voluntary	Many rules are mandatory ("*shall*")
Exemptions	<18 y.o.; Sickle Cell Disease pain	Neither are exempted (although inpatient, cancer pain, palliative and end of life care are exempted by both)
Rec. 1	Acute Pain = <1 month	Acute pain = <6 weeks
Rec. 2	Subacute pain = 1-3 months	Subacute pain = 6 weeks – 3 months
Rec. 3	ER/LA opioids should not be used initially for any pain	a) ER/LA opioids should not be used initially for acute pain b) 4 hours of ER/LA CME are suggested in order to prescribe these drugs
Rec. 4	No stated dose thresholds	Dose thresholds (50, 90 and 120 MMED/d) help define risk (visit and urine toxicology frequency) and mandatory consults
Rec. 5	Detailed "how to" on opioid tapering	No definitive statement that NOT all patients on chronic opioids need to be tapered
Rec. 6	a) No duration/pill numbers mentioned. b) Taper opioids even after acute pain therapy lasting several days b) Use inpatient use to guide outpatient prescribing c) Practices and health systems should have resources to treat unexpectedly long acute pain	Perioperative and nonperioperative distinction for acute pain with maximal nonjustified prescription lengths of 14 or 7 days respectively
Rec. 7	a) Suggests using assessment tools for ongoing substance use disorder rather than unvalidated tools for opioid use disorder risk b) Periodic review frequency for high-risk patients (<3 months)	a) Suggests using "validated tool" for assessing opioid use disorder risk (none currently exist) b) Specifies periodic review frequency for low (1 year) and moderate (6 months) risk patients. Agrees with CDC for high-risk patients.
Rec. 8	Opioid overdose risk specified to include "safety critical jobs", hepatic and renal disease,	a) Includes dose (>90 MMED) as high-risk factor

	sleep-disordered breathing and patients with recent tolerance loss (e.g., from weaning or jail) in risks of opioid overdose	b) Both agree that high-risk is associated with medical and psychological conditions, polypharmacy, aberrant behaviors, current substance use disorder, and any concurrent central nervous system depressants c) Mandates written patient agreements d) Unlike CDC, which specifies "to offer naloxone", mandates "confirm or provide a current prescription for naloxone" to high-risk patients without a mechanism to pay for or track such prescriptions
Rec. 9	Suggests PDMP queries before 1st opioid prescriptions for any pain and then every 3 months	a) PDMP query for acute pain is not required until after a refill is prescribed (query for every controlled drug prescription for EMRs integrated with PMP – almost everyone in the state as of last fall's mandate) b) PDMP queried every 12, 6, or 3 months for low, moderate or high risk patients respectively
Rec. 10	a) Urine toxicology suggested at initial opioid prescription and then annually b) Primer on toxicology result interpretation	Toxicology performed every 12, 6 or 3 months based on low, moderate or high risk patient respectively.
Rec. 11	Discusses examples of when co-prescribing of opioids and benzodiazepines may be needed	Includes other sedatives besides benzodiazepines as opioid co-prescribing concerns
Rec. 12	Discusses the treatment of opioid use disorder (OUD)	Focuses on patients on OUD treatment coming for acute pain treatment

Table 2 – Summary of Recommendation Differences between 2022 CDC Guideline/2019 WMC Washington State Rules

Section	CDC Opioid Prescribing Guideline	Washington State Opioid Prescribing Rules
Exemptions	<18 y.o.; Sickle Cell Disease pain	Neither are exempted
Recommendation 1	Acute Pain defined as <1 month	Acute pain defined as <6 weeks
Recommendation 2	Subacute pain defined as 1-3 months	Subacute pain defined as 6 weeks – 3 months
Recommendation 4	No stated dose thresholds	Dose thresholds (50, 90 and 120 MED/day) help define risk and mandatory consults
General	Long primers on opioid tapering, urine toxicology and treatment of opioid use disorder. Voluntary	Many rules are mandatory (“shall”)

Staff Reports: April 14, 2023

Melanie de Leon, Executive Director

Due to an increase in her practice responsibilities, Dr. Bongmba will resign her appointment on the Commission. Amelia will be actively recruiting to find applicants to fill her position.

Recruitment for my position continues – the job announcement closes on April 16th with the goal of beginning the first round of interviews in late April, early May. Dr. Terry Murphy is managing this process for the Commission.

Micah Matthews, Deputy Executive Director

Recurring: Please submit all Payroll and Travel Reimbursements within 30 days of the time worked or travelled to allow for processing. Request for reimbursement items older than 90 days will be denied. Per Department of Health policy, requests submitted after the cutoff cannot be paid out.

Legislation and Budget

The legislative session is in its final month. As of this writing a few bills have passed that moderately impact the WMC. A bill removing the malpractice insurance requirement for the IMG focused MD CE license was signed by Governor Inslee last week. We do not anticipate a significant impact from that bill. On 4/3/23 the House passed the Senate operating budget. The two chambers will now work to reconcile their differences on the bill. In both versions, the WMC budget request is fully funded, and I do not anticipate amendment negotiations changing that position.

Our current budget outlook remains unchanged from my last report. Collections are steady and overall, we are underspent by roughly three percent as we approach the close of the fiscal year.

Media and Communications Advisory

Due to ongoing court cases, legislation under consideration, and moves by Washington State to procure a state supply of mifepristone, I anticipate higher than normal interest in the WMC's role of regulating reproductive health and gender affirming care from media and other interests. If you receive any of these inquiries, please forward them to media@wmc.wa.gov.

Audit

We received the draft report for technical review, where WMC staff provide suggestions related to factual errors. The next round of review will take into account not only factual issues, but tone and content. Once that feedback is supplied, the report should be published by mid-May with our official response.

Micah Matthews, Deputy Executive Director continued

Joint Operating Agreement

We are in a holding pattern as we wait 30 days for an amendment to consider from the Nursing Commission. Once we receive and review, we will finalize the document to send to the Secretary's office for signature.

Amelia Boyd, Program Manager

Recruitment

We are seeking the following specialties to serve as Pro Tem Members:

- Urology
- Radiology
- Neurosurgery
- General surgeon
- Psychiatry

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.

We began our recruitment for the vacancies we will have on July 1, 2023. We are recruiting for the following positions:

- One physician representing Congressional District 2 – Dr. Lyle's position – eligible for reappointment
- One physician representing Congressional District 4 – Dr. Murphy's position – eligible for reappointment
- One physician representing Congressional District 10 – Dr. Wohns' position – eligible for reappointment
- One Physician-at-Large – Dr. Currie's position – eligible for reappointment
- Two Public Members
    - Michael Bailey – eligible for reappointment
    - Scott Rodgers – eligible for reappointment

All the above Commissioners have been notified that their first term is ending June 30, 2023, they are eligible for reappointment, and they must submit a new application to be considered for reappointment. The application deadline was March 24, 2023.

The following positions expired as of June 30, 2022, and we are awaiting word from the Governor's office staff on the new appointees:

- Public Member – Toni Borlas – not eligible for reappointment
- Public Member – Yanling Yu, PhD – not eligible for reappointment

Mike Hively, Director of Operations and Informatics

Operations & Informatics litigation hold program is currently processing five hold notices and is conducting electronic records search relevant to each hold. The program appears to be working well as processes (i.e., locating, compiling, tracking, transmitting, etc.) become more defined. The team also completed one compulsory request for the Office of Inspector General.

Unit Accomplishments Include:

Digital Archiving:

- 184 Complaints closed BT – folder is current
- 483 Active MD licensing applications
- 546 Active PA licensing applications
- Approximately 2,025 demographic census forms

Data Requests/Changes:

- Approximately 683 open/closed inquiries (individual requests may contain requests)
- Approximately 471 address changes

Demographics:

- Entered approximately 2,025 census forms into the IRLS database and conducted quality checks
- Conducts 781 secondary census contacts via email

Staff recalled approximately ten boxes of records from the records center containing 898 total PA application files which were used to verify existing digitally formatted records. Paper records will be disposed of in accordance with applicable WMC and state policies.

Lastly, we continue to update call center notifications/announcements, so they align with current website information and their respective units.

Morgan Barrett, MD, Medical Consultant, Director of Compliance

Nothing to report.

George Heye, MD, Medical Consultant

Nothing to report.

Rick Glein, Director of Legal Services

Orders Resulting from SOCs:
In re Bernard Mullen, MD, Case No. M2019-359. Agreed Order. On November 16, 2022, the Commission issued a Statement of Charges (SOC) alleging Dr. Mullen underwent a multi-disciplinary evaluation in which staff at Acumen Assessments concluded Dr. Mullen is not fit

to practice medicine. On March 2, 2023, the Commission approved an Agreed Order which indefinitely suspended Dr. Mullen's medical license. Dr. Mullen may petition the Commission to terminate the Agreed Order if the Commission receives a written endorsement from Washington Physicians Health Program (WPHP) that he is safe to practice with reasonable skill and safety.

In re Balamurali Ambati, MD, Case No. M2022-354. Agreed Order. On January 6, 2023, the Commission issued an Ex Parte Order of Summary Restriction which ordered Dr. Ambati restricted from performing all types of eye surgery (including laser, intraocular injections, and any type of surgery involving cutting), performing any experimental and/or off-label procedures, and using non-FDA approved materials pending further disciplinary proceedings by the Commission. The Statement of Charges (SOC) alleges Dr. Ambati practiced experimental medicine that poses a grave risk to patient safety and did so without proper consent. On March 2, 2023, the Commission approved an Agreed Order which reflected the expired credential status of Dr. Ambati's medical license and, upon reactivation of his license, ordered a restriction from performing all types of eye surgery (including laser, intraocular injections, and any type of surgery involving cutting); performing any experimental and/or off-label procedures; and using non-FDA approved materials for a period of not less than three years. Dr. Ambati also agreed, upon reactivation of his medical license, that the Commission may make announced visits to his practice on a bi-annual basis to conduct a compliance audit and will schedule a date to personally appear before the Commission.

In re Paul Thomas, MD, Case No. M2021-378. Agreed Order. On February 10, 2022, the Commission filed a SOC alleging that on or about June 2021 an Interim Stipulated Order was filed with the Oregon Medical Board in which Dr. Thomas agreed to limit his practice to patients requiring acute care; not engage in consultations with parents or patients relating to vaccination protocols, questions, issues, or recommendations; and not perform any research involving patient care. On May 12, 2022, the Washington Medical Commission filed an Interim Stipulated Order mirroring the requirements of the Oregon Interim Stipulated Order. An Amended SOC was issued January 4 additionally alleging that Dr. Thomas agreed to surrender his Oregon medical license. On March 2, 2023, the Commission approved an Agreed Order which indefinitely suspended Dr. Thomas' Washington medical license. Dr. Thomas may petition for reinstatement only after reinstatement of his Oregon medical license. If the Commission does not agree to an order of reinstatement, a hearing may be held on the petition.

In re Steven Pugh, MD, Case No. M2022-611. Agreed Order. On December 22, 2022, the Commission served an Ex Parte Order of Summary Suspension which ordered Dr. Pugh's medical license be suspended pending further disciplinary proceedings. The Statement of Charges (SOC) alleged Dr. Pugh is unable to practice with reasonable skill and safety due to a mental or physical condition. On March 2, 2023, the Commission approved an Agreed Order in which Dr. Pugh's license is indefinitely suspended and he may not practice as a physician and surgeon in the State of Washington for a period of at least one year. Dr. Pugh will maintain satisfactory compliance with Washington Physician Health Program (WPHP) and an

Rick Glein, Director of Legal Services continued

endorsement by WPHP must accompany any petition for reinstatement. Dr. Pugh must also personally appear before the Commission.

Virtual Hearing:
In re Kristine Brecht, MD, Case No. M2022-564. In August 2021, Dr. Brecht entered into an Agreed Order with the Commission which, among other terms, restricted her from performing procedures that require sedation. Separately, in October of 2021, Dr. Brecht admitted to having operated an unlicensed ambulatory surgical facility (ASF) and agreed to cease operating an ASF until she and/or her PLLC received an ASF credential. Despite both agreements and restrictions, on at least ten occasions Dr. Brecht did not comply with Commission orders regarding surgical procedures that require sedation. Between February and April 2022, she carried out multiple documented procedures, several of which were complex including abdominoplasty and breast augmentation. The Statement of Charges (SOC) alleges Dr. Brecht is in violation of RCW 18.130.180 in two sections, including (9) which is "failure to comply with an order issued by a disciplining authority or a stipulation for informal disposition entered into with a disciplining authority." A show cause hearing was convened on October 20, 2022. The resulting Order on Show Cause ordered that the summary suspension remain in effect pending a full adjudication of the allegations. The Commission held a virtual hearing March 30-31, 2023. A Final Order is expected to be issued by the end of June 2023.*

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

Items of Interest:
On March 9-10, 2023, Rick virtually attended the Nursing Commission's Business meeting where they introduced the two finalists for the Nursing Commission's open recruitment for Executive Director. The candidate pool included 44 applicants. Nine people were interviewed, and Alison Bradywood was selected. She has a Doctorate of Nursing Practice, a MPH, and Master's degree in Nursing. Ms. Bradywood will begin working on May 1, 2023.

On March 14, 2023, Rick attended an Interagency Roundtable meeting which brings together various agencies to discuss topics of mutual interest to ensure protection of the public on a broadscale, collaborative effort.

On March 24, 2023, Kyle and Dr. Currie delivered an afternoon CME presentation to the Washington Academy of Family Physicians on the topic of *Abuse of a Patient* (see WAC 246-919-640).

Mike Farrell, Policy Development Manager

Nothing to report that isn't in the policy or legal unit report.

Freda Pace, Director of Investigations

The Investigative Unit has a couple of important recruitment announcements. After serving the agency for 25 years, Complaint Intake Coordinator (HSC1) – Cindy Hamilton retired January 31, 2023. Her position was reallocated to an HSC3 – Case Manager and we've completed the recruitment process to fill this vacancy.

Alex Bielaski has accepted this position and will be joining us on April 16, 2023. Alex has a bachelor's in biology from Saint Martin's University and a master's in public health from Walden University. He has worked the last few years as an HSC 3 Complaint Intake Specialist in a non-permanent/project for the Nursing Commission. We are excited to add Alex to our team!

Complaint Intake Coordinator (HSC1), Jon Anson has accepted a promotional opportunity with the Department of Health – Office of Health Systems Oversight in a project position as an HSC3. We are excited for Jon's advancement opportunity within DOH and wish him the best!

We were fortunate to fill Jon's position with a DOH internal transfer candidate, Tanya Eberly, on March 16th. Tanya was a vaccine engagement specialist in the COVID-19 vaccine program. She has a background in fashion, customer service, and retail management. We are excited to welcome her to the unit!

Lastly, Complaint Intake Support Specialist, Meghan Howell's two consecutive, 1-year non-permanent status with the Commission ended February 28, 2023. We are currently recruiting for this vacancy and the interview selection process is underway.

We are truly grateful for the service and commitment Cindy, Jon, and Meghan gave to the Commission. We wish them all the best!

Off Ramp Process

As we continue to assess the off-ramp process, please make sure to monitor your emails to inform you of any new complaints authorized each week after CMT that may be assigned to you. RCM's must contact the investigator within the two-week time frame to make use of the offramp process, otherwise the investigation will continue as per the normal process. If the assigned RCM wishes to make use of the offramp process, they must complete the offramp memo form and return it to the assigned investigator. If you have any questions or concerns, please reach out directly, freda.pace@wmc.wa.gov.

Reoccurring: CMT Sign-up for 2023

Our CMT sign up slots for 2023 is ready and awaiting your name! Please take some time to check out the 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 (chris.waterman@wmc.wa.gov). This courtesy cancellation notice will allow Chris the opportunity to fill any last-minute vacancy needs.

Jimi Bush, Director of Quality and Engagement

Outreach

Our photo library of commissioners and meetings are grossly out of date. I am going to be taking photos at the April meeting for PowerPoints and the website.

Patient safety awareness week was a great opportunity for engagement. We held 3 webinars regarding patient safety and then 2 Coffee with the Commission(s) in connection with WPHP and legislative affairs. Our joint round table with the nursing commission gathered a lot of buzz and we are working on a joint guidance document for MDs, PAs and Nurses to strengthen their communication based on the topics discussed. It is one of our most viewed videos to date.

Dr. Currie and Kyle Karinen provided a presentation on patient abuse to the Washington Academy of Family Physicians. There has been a lot of positive feedback from the Academy, and they have been in contact with us for additional education.

Thank you to everyone who participated in these outreach efforts.

Mr. Lopez's Newsletter article "I got burned for helping" was the most read article in the Spring 2023 edition of the newsletter with over 1500 views.

Performance

Medical Commission Performance Measures for March Live and FY23 Q3

METRIC NAME	Mar-22	Mar-23	FY22 Q3	FY23 Q3
1.1 PM: Health care credentials issued within 14 days of receiving all documents.	100.00%	100.00%	100.00%	99.89%
2.1 PM: Percent of cases in which the intake and assessment steps are completed within 21 days.	100.00%	98.73%	100.00%	99.51%
2.2 PM: Percent of cases in which the investigation step is completed within 170 days.	87.95%	89.58%	85.03%	86.30%
2.3 PM: Percent of cases in which the case disposition step is completed within 140 days.	80.49%	85.06%	83.61%	78.35%
2.4 PM: Percent of open cases currently in investigations step that are over 170 days.	4.23%	3.97%	4.94%	4.62%
2.5 PM: Percent of open cases currently in the case disposition step that are over 140 days.	13.82%	28.43%	19.28%	32.41%
2.8 PM: Percent of closed cases completed within 360 days	93.65%	95.08%	94.85%	97.38%
3.1 PM: Completed investigations vs. number of investigators.	9.70	5.00	6.83	5.07
Aggregate Performance Measures	92.01%	90.86%	91.32%	89.20%

Jimi Bush, Director of Quality and Engagement continued

Business Practices

The following processes were added, updated, or removed in March.

Administration

- Recruitment

Bridge processes

- Updated – ECMT after the CMT meeting (Legal-Case Management) (Added steps for sending a complainant closure letter)
- Updated – Sending respondent BT closure letters (Investigations-Practitioner Support Program) (Updated ILRS entries)

Licensing

- Updated – SPL redesignation (The qualifiers in step 10 were changed)
- Updated – Verifications (ILRS entries added to step 5)
- Updated – Intake
- Updated – Review

Operations & Informatics

- Updated – Paper records reduction

The next Lean Community of Practice is scheduled for April 25th. We will talk about project charters, scope, and project management plans. Everyone is welcome to attend! If you would like to be added to the Lean mailing list, please let me know.

Marisa Courtney, Licensing Manager

Total licenses issued from 02/22/2023- 04/03/2023= 477

Credential Type	Total Workflow Count
Physician And Surgeon Clinical Experience License	0
Physician And Surgeon Fellowship License	4
Physician And Surgeon Institution License	0
Credential Type	**Total Workflow Count**
Physician And Surgeon License	266

Marisa Courtney, Licensing Manager continued	
Credential Type	**Total Workflow Count**
Physician and Surgeon License Interstate Medical Licensure Compact	131
Physician And Surgeon Residency License	21
Physician And Surgeon Teaching Research License	2
Physician And Surgeon Temporary Permit	0
Physician Assistant Interim Permit	1
Physician Assistant License	51
Physician Assistant Temporary Permit	1
Totals:	**477**

Information on Renewals: February Renewals- 75.66% online renewals

Credential Type	# of Online Renewals	# of Manual Renewals	Total # of Renewals
IMLC	0	49	49
MD	970	291	1261
MDIN	1	0	1
MDTR	1	1	2
PA	175	28	203
	75.66%	**24.34%**	**100.00%**

Information on Renewals: March Renewals- 72.65% online renewals

Credential Type	# of Online Renewals	# of Manual Renewals	Total # of Renewals
IMLC	0	66	66
MD	1088	376	1464
MDIN	1	0	1
MDTR	2	4	6
PA	197	39	236
	72.65%	**27.35%**	**100.00%**

WASHINGTON Medical Commission
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Panel A
Personal Appearance Agenda

Friday, April 14, 2023

Panel Members:	Harlan Gallinger, MD, Panel Chair	Mabel Bongmba, MD	Jimmy Chung, MD	Arlene Dorrough, PA-C
	Anjali D'Souza, MD	Sarah Lyle, MD	Elisha Mvundura, MD	Robert Pullen, Public Member
	Scott Rodgers, Public Member	Richard Wohns, MD	Yanling Yu, PhD, Public Member	
	Janet Barrall, MD, Pro-Tem	Alan Brown, MD, Pro-Tem	Mary Curtis, MD, Pro-Tem	Charlie Browne, MD, Pro-Tem

Compliance Officer: Anthony Elders

10:00 a.m.	**Rajesh Movva, MD** Attorney: Pro Se	M2021-45 (2020-11001) RCM: Anjali D'Souza, MD SA: Joel Defazio
10:45 a.m.	**David P. Shaw, MD** Attorney: Pro Se	M2022-48 (2021-6867) RCM: Sarah Lyle, MD SA: Rick Glein
11:30 a.m.	**Sobia Moghis, MD** Attorney: Carol Sue Janes	M2021-280 (2020-10422 et al.) RCM: Harlan Gallinger, MD SA: Trisha Wolf

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WASHINGTON Medical Commission
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Panel B

Personal Appearance Agenda

Friday, April 14, 2023

Panel Members:	Chair: Terry Murphy, MD	Michael Bailey, Public Member	Christine Blake, Public Member	Toni Borlas, Public Member
	Po-Shen Chang, MD	Diana Currie, MD	Karen Domino, MD	April Jaeger, MD
	Ed Lopez, PA-C	Claire Trescott, MD		
	Theresa Schimmels, PA-C, Pro-Tem	Daniel Flugstad, MD, Pro-Tem	Alden Roberts, MD, Pro-Tem	John Maldon, Public Member, Pro-Tem
	Matthew Kogut, MD			

Compliance Officer: Mike Kramer

10:00 a.m.	**Brian P. Goody, PA-C** Attorney: Katharine Bozzo	M2021-661 (2021-1191) RCM: Christine Blake, Public Member SA: Kelly Elder
10:45 a.m.	**Gerald W. Lee, MD** Attorney: Jennifer Smitrovich	M2018-495 (2018-15154 et al.) RCM: Claire Trescott, MD SA: Trisha Wolf

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