WASHINGTON Medical Commission

Licensing. Accountability. Leadership.

Regular Meeting November 17-18, 2022 1st Revised



2022 Meeting Schedule



Medical Commission Licensing. Accountability. Leadership.

Dates	Location	Meeting Type
January 13-14	Virtual Meeting	Regular Meeting
March 3-4	Virtual Meeting	Regular Meeting
April 14-15	Virtual Options Available Tumwater, WA	Regular Meeting
May 26-27	Virtual Meeting	Regular Meeting
July 14-15	Virtual options available for open sessions for the public Tumwater, WA	Regular Meeting
August 25-26	Virtual options available for open sessions for the public Tumwater, WA	Regular Meeting
October 6	Tentative: Virtual Meeting	Closed Session: Case Reviews
November 17-18	Virtual options available for open sessions for the public Capitol Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater, WA	Regular Meeting
	Association Meetings	

Association Meetings				
Association	Dates	Location		
Federation of State Medical Boards (FSMB) Annual Conference	April 28-30, 2022	New Orleans, LA		
WAPA Spring Conference	April 22-25, 2022	Seattle, WA		
WSMA Annual Meeting	October 1-2, 2022	Spokane, WA		
WAPA Fall Conference	October 27-29, 2022	Cle Elum, WA		
	Other Meetings			
Program	Dates	Location		
Council on Licensure, Enforcement & Regulation (CLEAR) Winter Symposium	January 5, 2022	Virtual Event		
CLEAR Annual Conference	September 14-17, 2022	Louisville, KY		
FSMB Board Attorneys Workshop	November 3-4, 2022	TBD		

2023 Meeting Schedule



WASHINGTON Medical Commission Licensing. Accountability. Leadership.

Dates	Location	Meeting Type
January 12-13	Virtual options available for open sessions for the public Capitol Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater, WA	Regular Meeting
March 2-3	Virtual options available for open sessions for the public Capitol Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater, WA	Regular Meeting
April 13-14	Virtual options available for open sessions for the public Capitol Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater, WA	Regular Meeting
May 25-26	Virtual via GoToWebinar	Regular Meeting
July 13-14	Virtual options available for open sessions for the public Capitol Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater, WA	Regular Meeting
August 24-25	Virtual options available for open sessions for the public 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 for the public Capitol Event Center (ESD 113) 6005 Tyee Drive SW, Tumwater, WA	Regular Meeting

Association Meetings			
Association	Dates	Location	
Federation of State Medical Boards (FSMB) Annual Conference	May 4-6, 2023	Minneapolis, MN	
WAPA Spring Conference	ТВА	ТВА	
WSMA Annual Meeting	September 23-24, 2023	Bellevue, WA	
WAPA Fall Conference	ТВА	ТВА	

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

2024 Meeting Schedule



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	Educational Conference
November 21-22	TBD	Regular Meeting

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Hearing Date	Respondent	Case No.	Location			
	Novembe	r 2022				
NC	NO HEARINGS SCHEDULED THIS MONTH					
	Decembe	r 2022				
NC	HEARINGS SCHED	ULED THIS MON	ITH			
	January	2023				
January 6	Chester C. Hu, MD	M2022-359	TBD			
January 19 through January 20	Rajinder Julta, MD	M2022-438	TBD			
	February	2023				
February 6	Paul Thomas, MD	M2021-378	TBD			
February 27 through March 1	Eric R. Shibley, MD	M2018-443	TBD			
	March 2	2023				
March 16 through March 17	Robert Thompson, MD	M2021-553	TBD			
April 2023						
April 3 through April 7	Richard Wilkinson, MD	M2022-196	TBD			

Commission Meeting Agenda November 17-18, 2022 – 1st Revised

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 November 17, 2022 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 November 18, 2022 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. This is to promote social distancing and the safety of the citizens of Washington State. Registration links can be found below.

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

Time Thursday – November 17, 2022			
Closed Se	ssions		
8:oo am	Case Reviews – Panel A		Pacific
8:oo am	Case Reviews – Panel B	Gi	rays Harbor
Open Ses	sion		
12:30 pm	Lunch & Learn	Т	hurston
	virtually, please register at: <u>https://attendee.gotowebinar.com/</u> gistering, you will receive an email containing a link that is uniqu		
Legislatio	n 101		
Micah Mattl	hews, Deputy Executive Director		
Closed Se	ssions		
1:30 pm	Case Reviews – Panel A		
1:30 pm	Case Reviews – Panel B		
Open Ses	sion		
4:00 pm	Delies Committee Meeting	C -	يرج وأنبحا المريح
	Policy Committee Meeting		,
To atte	end virtually, register at: <u>https://attendee.gotowebinar.com/regi</u>	ster/2039229457902	0 <u>73360</u>
To atte	end virtually, register at: <u>https://attendee.gotowebinar.com/regi</u> egistering, you will receive an email containing a link that is uniqu	ster/2039229457902 he to you to join the w	0 <u>73360</u> vebinar.
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November 17-18, 2022

Revised 11/15/2022

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WASHINGTON

Medical

Accountability, Leadershin,

-	Time	Friday – November 18, 2022	
Open	Sessio	n	
8:	oo am	Business Meeting	Thurston
	After reg	tually, register for this meeting at: <u>https://attendee.gotowebinar.com/rt/5185074</u> istering, you will receive an email containing a link that is unique to you to join th r Calls the Meeting to Order	
2.0	The p this t	ic Comment ublic will have an opportunity to provide comments. <i>If you would like to c</i> <i>ime, please limit your comments to two minutes. Please identify yourself</i> sent, if applicable, when the Chair opens the floor for public comment.	-
3.0	Chai	r Report	
4.0	Cons	ent Agenda	
	ltems and w separ	listed under the Consent Agenda are considered routine agency matters vill be approved by a single motion without separate discussion. If ate discussion is desired, that item will be removed from the Consent da and placed on the regular Business Agenda.	Action
	4.1 M	inutes – Approval of the August 26, 2022 Business Meeting minutes.	Pages 10-13
	4.2 A	genda – Approval of the November 18, 2022 Business Meeting agenda.	Pages 7-9
5.0	Old I	Business	
	5.1	Committee/Workgroup Reports The Chair will call for reports from the Commission's committees and workgroups. Written reports begin on page 14.	Update
		See page 15 for a list of committees and workgroups.	
	5.2	 Rulemaking Activities Rules Progress Report provided on page 16. In addition to the written report, Amelia Boyd, Program Manager, will present the following: Rules petitions from Thomas M. Bertsch. Commissioners must review and decide whether to pursue rulemaking based on the content of each petition. 	Update/Action
		 Petition 1, received October 19, 2022 	Pages 17-63
		 Petitions 2, received October 25, 2022 	Pages 64-87
		 Petition 3, received October 31, 2022 	Pages 88-95
		 Request to rescind medical records rules initiation approval. 	
		 Request to rescind interpretive statements: 	
		 Establishing Approval Criteria for Defining Appropriate Medical Practices for IMG Nomination, <u>INS2022-02</u> 	
		 Requiring the Filing of a Practice Agreement Before Beginning to Practice Under an IMG Limited License, <u>INS2021-01</u> 	
		These two interpretive statements have been incorporated as part of the recently adopted	

November 17-18, 2022

Revised 11/15/2022

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	rules regarding requirements for International Medical Graduates to apply for the new Limited Physician and Surgeon Clinical Experience License.					
	 Exempting Patients in Nursing Homes and Long-Term Acute Care Hospitals from the Opioid Prescribing Rules, <u>INS2019-03</u> – This interpretive statement has been incorporated as part of the recently adopted rules regarding opioid prescribing patient exemptions. 					
		 Request to initiate rulemaking regarding <u>SB 5229</u> – Concerning health equity continuing education for health care professionals 				
	5.3	Open Public Meetings Act Heather Carter, AAG, will provide training regarding the Open Public M <u>chapter 42.30 RCW</u> .	leetings Act,			
6.0	Policy Committee ReportReport/ActionChristine Blake, Public Member, Chair, will report on items discussed at the Policy Committee meeting held on November 17, 2022. See the PolicyReport/Action Begins on page 96 presented.					
7.0		nber Reports Chair will call for reports from Commission members.				
8.0		f Member Reports Chair will call for further reports from staff.	Written reports Pages 113-122			
9.0		G Report her Carter, AAG, may provide a report.	5			
10.0		ournment of Business Meeting				
Open	Open Sessions					
9:45		Personal Appearances – Panel A Page 123	Pacific			
9:45	am	Personal Appearances — Panel B Page 124	Grays Harbor			
Closed	l Sess	ion				
Noon to 1:00 pm Lunch Break						
Open Sessions						
1:00	pm	Personal Appearances – Panel A Page 123	Pacific			

Open Sessions				
1:00 pm	Personal Appearances – Panel A	Page 123	Pacific	
1:00 pm	Personal Appearances – Panel B	Page 124	Grays Harbor	

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Business Meeting Minutes August 26, 2022



Virtual Meeting via GoToWebinar – Link to recording: https://youtu.be/wkK-zQsB wo

Commission Members

Mabel Bongmba, MD – Absent Michael Bailey, Public Member – Absent Christine Blake, Public Member Toni Borlas, Public Member – Absent Po-Shen Chang, MD Jimmy Chung, MD, Chair Diana Currie, MD – Absent Arlene Dorrough, PA-C Anjali D'Souza, MD Karen Domino, MD, Chair Elect Harlan Gallinger, MD

WMC Staff

Colleen Balatbat, Staff Attorney Morgan Barrett, Director of Compliance Amelia Boyd, Program Manager Kayla Bryson, Executive Assistant Jimi Bush, Director of Quality & Engagement Adam Calica, Chief Investigator Marisa Courtney, Licensing Supervisor Melanie de Leon, Executive Director Joel DeFazio, Staff Attorney Kelly Elder, Staff Attorney Mike Farrell, Policy Development Manager

Others in Attendance

Chris Bundy, MD, Executive Medical Director, Washington Physicians Health Program April Jaeger, MD – Absent Ed Lopez, PA-C Sarah Lyle, MD – Absent Terry Murphy, MD, Vice Chair Elisha Mvundura, MD Robert Pullen, Public Member Scott Rodgers, JD, Public Member Claire Trescott, MD – Absent Richard Wohns, MD – Absent Yanling Yu, PhD, Public Member

Rick Glein, Director of Legal Services George Heye, MD, Medical Consultant Mike Hively, Director of Operations & Informatics Ken Imes, Information Liaison Kyle Karinen, Staff Attorney Mike Kramer, Compliance Officer Pam Kohlmeier, MD, JD, Attorney Fatima Mirza, Program Case Manager Micah Matthews, Deputy Executive Director Trisha Wolf, Staff Attorney Gordon Wright, Staff Attorney

Heather Carter, Assistant Attorney General

1.0 Call to Order

Jimmy Chung, MD, Chair, called the meeting of the Washington Medical Commission (WMC) to order at 8:02 a.m. on August 26, 2022.

2.0 Public Comment

Chris Bundy, MD, Executive Medical Director, Washington Physicians Health Program (WPHP), introduced himself. He spoke about the partnership between the WMC and WPHP.

3.0 Chair Report

Jimmy Chung, MD, Chair, welcomed Dr. Elisha Mvundura and Dr. Anjali D'Souza. He then asked each of them to introduce themselves and provide a little of their background.

4.0 Consent Agenda

The Consent Agenda contained the following items for approval:

- 4.1 Minutes from the July 15, 2022 Business Meeting
- **4.2** Agenda for August 26, 2022.

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

5.0 Rules Hearing

International Medical Graduates – Senate Bill 6551 – WSR #22-15-039 New Limited Physician and Surgeon Clinical Experience License.

The revised proposed language was adopted by the Commissioners during this hearing. For more information about the WMC's rules in progress, please visit the Rulemaking page on the website by clicking <u>here</u>.

6.0 New Business

6.1 Reproductive Rights Position Statement

The draft statement was discussed by the panel of Commissioners. Dr. Chung suggested a workgroup be created to work on the language in the document.

Motion: The Chair entertained a motion to table the topic. The motion was seconded and approved unanimously.

7.0 Old Business

7.1 Committee/Workgroup Reports

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

7.2 Rulemaking Activities

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

- Request to rescind Emergency Licensing rules initiation approval.
 - Ms. Boyd stated in 2020 the Commissioners approved initiating emergency rulemaking related to allopathic physician and physician assistant licensing in response to the COVID-19 pandemic. Also in 2020, the Governor instituted a proclamation regarding licensing for these professions that essentially had the same intent as the emergency rulemaking. Ms. Boyd went on to say that the proclamation will be lifted as of October 27, 2022, and that there is no longer a need for this rulemaking. Ms. Boyd asked that the Commissioners vote to rescind their previous approval to initiate emergency rulemaking on this subject.

Motion: The Chair entertained a motion to rescind the approval to initiate emergency rulemaking regarding licensing. The motion was seconded and approved unanimously.

 Informational: ARNP Scope of Practice Rules
 Ms. Boyd stated the Nursing Care Quality Assurance Commission (NCQAC) is required to provide draft language related to ARNP scope of practice to the WMC

Page 2 of 4

for review and comment. She stated the draft language was included in the packet and if a Commissioner has a question or a comment, the contact information for NCQAC was also included in the packet.

7.3 Lists & Labels Request

The following lists and labels request was discussed for possible approval or denial. Approval or denial of this request is based on whether the entity meets the requirements of a "professional association" or an "educational organization" as noted on the application (RCW 42.56.070(9)).

• Washington Physicians Health Program

Motion: The Chair entertained a motion approve the request. The motion was seconded and approved unanimously.

7.4 Open Public Meetings Act

This item was deferred to the November 18, 2022, Business meeting.

8.0 Policy Committee Report

Christine Blake, Public Member, Policy Committee Chair, reported on the items discussed at the Policy Committee meeting held on August 25, 2022:

Guidance Document: Overlapping & Simultaneous Elective Surgeries

Ms. Blake stated the Committee reviewed the changes to the document that had been made since the July 15, 2022, meeting and that the Committee recommended approving the document as revised and provided in the meeting packet.

Procedure: Personal Appearances

Ms. Blake stated that this document is being presented as part of the WMC's established fouryear review schedule. She stated the Committee recommended reaffirming the document. The Commissioners discussed a minor edit to the document.

Motion: The Committee Chair entertained a motion to approve the edit. The motion was approved unanimously.

Delegation of Final Decision-Making to Health Law Judge

Ms. Blake asked Mike Farrell, Policy Development Manager, to report on this document. Mr. Farrell explained the purpose of the document. He then explained there was one error on the document which was provided in the meeting packet. Ms. Blake stated that the Committee recommended approving the amended document as explained by Mr. Farrell.

Motion: The Chair entertained a motion to approve the Committee report as presented. The motion was approved unanimously.

9.0 Member Reports

No Member reports were provided.

10.0 Staff Reports

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

Micah Matthews, Deputy Executive Director, provided an update on the State Auditor's audit of

the Prescription Monitoring Program. He then reported on the proclamations being rescinded in October by Governor Inslee. One of which is Proclamation 20-32 that affects several health professions, including allopathic physicians (MDs) and physician assistants (PAs). Mr. Matthews explained the WMC's plan to educate MDs and PAs on this item. More information about this item can be found on the WMC's website by clicking <u>here</u>.

Mr. Matthews also introduced a new staff member, Fatima Mirza, who is the Program Case Manager.

11.0 AAG Report

Heather Carter, AAG, had nothing to report.

12.0 Adjournment

The Chair called the meeting adjourned at 9:11 am.

Submitted by

Amelia Boyd, Program Manager

Jimmy Chung, MD, Chair Washington Medical Commission

Approved November 18, 2022

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Committee/Workgroup Reports: November 2022

Reduction of Medical Errors Workgroup – Chair: Dr. Chung Staff: Mike Farrell

The workgroup, now called the High Reliability workgroup, last met in August and presented its work to the policy committee. The workgroup will schedule a meeting soon.

Healthcare Disparities Workgroup – Chair: Dr. Currie Staff: Melanie de Leon

Workgroup members working on information for proposed Commission healthcare disparity calendar.

Committees & Workgroups



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

Dr. Chung, Chair
Christine Blake, PM
Dr. Browne
Dr. Chung
Arlene Dorrough, PA-C
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
John Maldon, PM
Dr. Roberts
Dr. Chung
Dr. Jaeger
Christine Blake, PM
Scott Rodgers, PM
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

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
Opioid Prescribing - LTAC, SNF patient exemption	CR-103 filed	10/25/2022	Rule effective November 25, 2022					Complete	Complete	Complete
Collaborative Drug Therapy Agreements (CDTA)	CR-101 filed	7/22/2020	Workshops	TBD				Complete	TBD	TBD
SB 6551 - IMG licensing	CR-103 filed	10/25/2022	Rule effective November 25, 2022					Complete	Complete	Complete
Medical Records	Requesting rescinding of CR- 101 approval	11/18/2022						TBD	TBD	TBD



PETITION FOR ADOPTION, AMENDMENT, OR REPEAL OF A STATE ADMINISTRATIVE RULE

In accordance with <u>RCW 34.05.330</u>, the Office of Financial Management (OFM) created this form for individuals or groups who wish to petition a state agency or institution of higher education to adopt, amend, or repeal an administrative rule. You may use this form to submit your request. You also may contact agencies using other formats, such as a letter or email.

The agency or institution will give full consideration to your petition and will respond to you within 60 days of receiving your petition. For more information on the rule petition process, see Chapter 82-05 of the Washington Administrative Code (WAC) at <u>http://apps.leg.wa.gov/wac/default.aspx?cite=82-05</u>.

CONTACT INFORMATION (please type or print)

Petitioner's Name	Thomas Michael Bertsch	أعمنت			
Name of Organization	N/A				
Mailing Address 1006	N. Park St.				
City Colfax		_ State	WA	Zip Code 99111	
Telephone 509-288-967	0	_ Email	BERTSCH_THO	MAS@YAHOO.COM	

COMPLETING AND SENDING PETITION FORM

- Check all of the boxes that apply.
- Provide relevant examples.
- Include suggested language for a rule, if possible.
- Attach additional pages, if needed.
- Send your petition to the agency with authority to adopt or administer the rule. Here is a list of agencies and their rules coordinators: <u>http://www.leg.wa.gov/CodeReviser/Documents/RClist.htm</u>.

INFORMATION ON RULE PETITION

Agency responsible for adopting or administering the rule:

Washington State Medical Commission

1. NEW RULE - I am requesting the agency to adopt a new rule.

The subject (or purpose) of this rule is:

The rule is needed because:

The new rule would affect the following people or groups:

2 AMEND RULE - I am requesting the agency to char	nge an existing rule.
List rule number (WAC), if known:	
I am requesting the following change:	
This change is needed because:	
The effect of this rule change will be:	
The rule is not clearly or simply stated:	
X 3. REPEAL RULE - I am requesting the agency to elim	ninate an existing rule.
List rule number (WAC), if known: <u>Please see attached l</u>	ISTINGS
(Check one or more boxes)	
$[\mathbf{r}]$ It does not do what it was intended to do.	
PLEASE SEE ATT	ACHED
It is no longer needed because:	
	rached
✓ It imposes unreasonable costs:	
	PLEASE SEE ATTACHED
The agency has no authority to make this rule:	
	PLEASE SEE ATTACHED
It is applied differently to public and private parties:	
 It conflicts with another federal, state, or local law or rule. List conflicting law or rule, if known: 	PLEASE SEE ATTACHED
It duplicates another federal, state or local law or rule. List duplicate law or rule, if known:	
PLEASE SEE ATTACHED	
✓ Other (please explain):	

COVER LETTER

Dear Sirs,

Please allow me this opportunity to introduce myself and explain my current difficulty in obtaing medical care of any kind, for the past two years. I am currently 65 years old.

After 26 years of public service in the Fire Department, I was forced to accept a disability retirement. I had suffered from three on-the-job injuries, and was unable to physically perform the rigors of my job classification. I was forced to realize that not only was I putting my life in more danger, but my inability to physically perform my duties, also placed my fellow firefighters in danger as well. AS a third generation professional firefighter, this was the saddest day of my life.

Upon retiring, I also developed many more physical problems. All of those I suffer from now include: Injuries to my lower back, injuries to my right knee, injuries to my testicular area. I also suffer from Anxiety and Panic Attacks, and at times, suffer from Depressiuon. I have High Blood Pressure, and COPD, have had them for over five years now. I have had my left testical and one half of my Thyroid surgically removed, as well as several Lymph Nodes.

Just before retiring, I began suffering from a sharp pain in my left testicle. Shortly after, it became a sharp, intense, overwhelming, and constant pain. After several years, I elected to have it surgically removed, in an effort to relieve the pain. Surgeons informed me they could not guarantee it would stop the pain, and they were correct. It did not.

I have traveled to Specialists as far away as Salt Lake City, Utah, and Sacramento, California. All of the Physicians claim it is a pinched nerve in my damaged lower back that is manifesting itself as pain in my groin area. It feels like someone is driving a nail threw my left testicle, and I don't even have one! All of those Doctors were unable to help me with my problem. I have had nerve block injections, Physical Therapy, and many other treatments, that offer initial relief, but th epain comes back even worse after these treatments end.

For over the next fifteen years, I was prescribed 7.5mg of Hydrocodone, and .5mg of Xanax. I was presscribed these medications for fifteen years. And this allowed me to function on a day to day basis. Sure I had worse and better days, but I could live life , day to day. My prescriptions were on a non escalating dosage. I never asked for a early refill, used only one Physician, only one Pharmacy. My medical history does not include any problems with drug abuse or diversion, or any mental health issues other thatn the Anxiety/Panic Attacks. I have

no criminal record of any kind.

Then came the "Opioid Crises". I initially was Blackmailed into signing away my Civil Rights and Constitutional Freedoms. Basically giving my health care professional, my permission to violate these rights with discriminatory requirements of drug testing, pill counts, and other strict requirements that other opioid patients were not required to submitt to. I never failed a drug test, and always was compliant with pill counts, and complied with each and every other contract requirements. I felt like I was balckmailed. sign this, or we will not give you your pain medication!

As the DEA ramped up the arrest and convictions of practing Physicians, my health care provider used one of the many tatics used by Doctors today to get rid of their Chronic Pain Patients. Instead of appointmenst every three months, he would now require me to come in each and every month for prescription refills. As I informed him my Insurance (Blue Shield/Blue Cross) would not pay for once a month, he replied it wasn't his problem, and that I would have to pay for the extra three visits pre month by myself.

This started a larger debate, and I was asked to sign a new contract with the new requirements. I refused to sign, and the Doctor refused to refill my prescriptions. Not only the one for Opiods, but my script for High BP, COPD (Inhaler), and my Xanax. That was the last I saw of my Physician of fifteen years. I filed a complaint with the Medical Commission, which was dismissed without any action taken.

Since that day, I have contacted 34 Clinics and private practice Physicials, totaling over 86 Doctors that refused to take me on as a Chronic Pain Patient. I have contacted Palliative Care Facilities as far away as Seattle, who claimed to have Outpatient Palliative Care, all without success. When They did allow me one office visit, I was informed they could not help me. One Doctors said she could be "Fired " if she gave me Hydrocodone and Xanax. I asked her if that meant my previous Physician was in trouble? and she replied no. I walked into one Urgent Care Facility in Idaho, described my extreme debilitation Pain, and was told to return in three weeks for an appointment. Any Doctor who would allow his patient to suffer that long before being treated, is no Doctor of mine.

For over two years now, I have not been able to function on a day to day basis. I have spent my entire life savings in search of medical care. Some days are spent wholly in bed. I cannot even maintain a level of concentration to type this petition. I had to pay someone to clean up the grammar and correct the spelling and re-type this petition.

I now take four to twelve Aleve tablets daily. This reduces my pain about 5%. I have not had

a good nights sleep in years.

All of the above is what led me to the filing of this petition.

I knew when I selected Firefighting as my profession, like my Grandfather, Father, and two older Brothers did, that my life would most certainly be shortened due to the chemicals, smoke, and hazards of the profession. I was prepared to accept that. However I never thought I would be forced to spend my twilight years in pain and agony because of the CDC and the DEA.

Please place all of your attention on this petition, as Chronic Pain Patients in Washington State, like myself, are suffering needlessly in pain and agony, some are being driven to suicide because they have been left without medical care and without hope of any kind. This madness has to end.

With all due respect.

Thomas M. Bertsch

The My Am

THIS PETITION SEEKS THE IMMEDIATE REPEAL OF ALL WASHINGTON STATE LAWS REGARDING CHRONIC PAIN PATIENTS OPIOID PRESCRIBING, PILL COUNTS, DRUG SCREENS, INCLUDING THE REPEAL OF THE REQUIREMENTS OF ENTERING CHRONIC PAIN PATIENTS MEDICAL AND ANY OTHER DATA INTO ANY PRESCRIPTIUON DRUG MONITORING PROGRAM.

THIS PETITION ALSO REQUEST THE REPEAL OF RCW 70.225 (2007) AND WAC 246-470, took effect August 27, 2011

ALSO WAC 246-470, took effect August 27, 2011

THRU 246-919-851

ALSO ANY AND ALL CODES OR LAWS THAT SPECIFICALLY SINGLE OUT CHRONIC PAIN PATIENTS IN A DISCRIMINATORY MANNER.

Il m han

THOMAS M. BERTSCH

WASHINGTON STATE RESIDENT

Dear Sirs,

In accordance with RCW 34.05.330, I wish to submit to you my "Petition" to repeal WAC 246-919-850 through 246-919-985

To: Washington State Medical Commission

From: Thomas M. Bertsch

1006 N. Park St

Colfax, Wa. 99111

Disability Retired Fire Captain

Long Term Chronic Pain Patient

Subject: REPEAL OF WASHINGTON STATE LAWS

This petition contains several articles attached to it. These articles were included with the permission their authors. However thier inclusion does not mean the authors share all of my opions contained herin. Please read and comprehend this petition in it's entirety as the articles are part of my petition. I am soley responsible for the content of this petition.

Us mp

For the following reasons.

Under RCW 34.05.330, the Petitioner is encouraged to address the following issues:

- (a) Whether the rule is authorized;
- (b) Whether the rule is needed;
- (c) Whether the rule conflicts with or duplicates other federal, state, or local laws;
- (d) Whether alternatives to the rule exist that will serve the same purpose at less cost;
- (e) Whether the rule applies differently to public and private entities;
- (f) Whether the rule serves the purposes for which it was adopted;
- (g) Whether the costs imposed by the rule are unreasonable;
- (h) Whether the rule is clearly and simply stated;

(i) Whether the rule is different than a federal law applicable to the same activity or subject matter without adequate justification;

(a) Whether the rule is authorized;

The Washington State Medical Commission, at the time this laws were adopted, ha the responsibility to verify data and it's orgin for actual, factual, information, when considering the adoption of laws and RCW's affecting all of Washington state residents. The CDC 2016 Guidelines were not properly investigated by the previous Commission, and the Commission, at that time, failed to examine it's authors for obvious conflicts of interest.

These "<u>suggested</u>" policies were never intended to be adopted as Laws, Rules, Or Regulations. The author of them, The CDC has specifically stated this fact. This information was never seriously considered by the Washington State Medical Commission, at that time of adoption, before they endorsed their enaction into State Law. Alao, these influencial consultants that advised the CDC are funded by a chain of Drub Rehab companies who stand to gain from the laws.

The previous Washington State Medical Commission errored in recommending these rules be adopted into law by the Washington State Legislature, because the authors of these suggestions clearly stated that these recommendationd were <u>not</u> crrently a Law, a rule, or a regulation, and <u>should not</u> be adopted as such. If the Commission endorsed these guidelines to be admited into law, why did they not take the advice stating they should not be a law, rule, or regulation? They are mearly recommendations compose by the Center for Disease Control. These individuals who have pofited financially, have no business forcing their opinions on the residents of Washington State so that they may enjoy financial gain. The group PROP, is financed by Phoenix House, which owns a chain of rehab centers.

Additionally the governship, creation of. monitoring, testing, advising, and supervision of manufacturing of medications in the Federal Govt fall on the Food and Drug Administratoion, , not the Center for Disease Control, which has no business assuming the duties of the FDA, Nor does it have the executive power to overtake and duties of the FDA. THe FDA has not asked the CDC for advise or assistance in fulfilling their mandate as directed by Federal Laws and Statues.

In fact, the FDA has issued policy letters in direct contradiction to many parts of the CDC guidelines, citing many of those suggestions to policy as dangerous and sometime possibly fatal!

The procedures used when creating the 2016 CDC guidelines, and the policy used when selecting individual members of the Advisory Committee were in violation of the "FEDERAL ADVISORY COMMITTEE ACT".

The Washington State Medical Commission, at that time, had the responsibility to investigate if the published CDC guidelines were created in correspondence with State and Federal laws. Attached documents indicate that as early as December 22nd, 2015, questions by Federal elected officials were publically released indicating a possible violation of the Federal Advisory Committee Act. (Attached)

Among other requirements, this Act states:

(4) standards and uniform procedures should govern the establishment, operation, administration, and duration of advisory committees;

The CDC did not follow this requirement by violating the following:

(5) the Congress and the public should be kept informed with respect to the number, purpose, membership, activities, and cost of advisory committees; and

The CDC did not allow members of the public to be aware of whom was appointed to this advisory committee. (Membership)

) the function of advisory committees should be advisory only, and that all matters under their consideration should be determined, in accordance with law, by the official, agency, or officer involved.

Major portions in the 2016 CDC guidelines, as published, violate Civil Rights, ADA, and Federal Laws currently in effect. (See #3 Below).

(2) require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;

As we now know, this advisory committe was NOT fairly balanced. Most members were historicaly Anti-Opiod, and many had existing Conflicts of Interest.

(3) contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment;

See comment on #2 above

(a)(1) Each advisory committee meeting shall be open to the public.

CDC Advisory Committee meetings were not open to the public and were held in secret.

(3) Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to such reasonable rules or regulations as the Administrator may prescribe.

The attempted compliance with this requirement by the CDC was a joke at best. It had to be rescheduled, expanded, and extended, in their attempt at compliance.

(b) Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

Many groups who represented Chronic Pain Patients, and several Media Organizations requested written documents under the Freedon of Information Act. If the CDC provided ANY documents at all, they were heavily REDACTED, and in some cases, the names of individual comittee members were removed from those released documents, (See attached

Undisclosed Conflicts of Interest by Physicians Creating the CDC Opioid Prescribing Guidelines: Bad Faith or Incompetence?)

(c) Detailed minutes of each meeting of each advisory committee shall be kept and shall contain a record of the persons present, a complete and accurate description of matters discussed and

conclusions reached, and copies of all reports received, issued, or approved by the advisory committee. The accuracy of all minutes shall be certified to by the chairman of the advisory committee.

See Comment above.

§11. Availability of transcripts; "agency proceeding"

(a) Except where prohibited by contractual agreements entered into prior to the effective date of this Act, agencies and advisory committees shall make available to any person, at actual cost of duplication, copies of transcripts of agency proceedings or advisory committee meetings.

See above comments.

The Washinton State Medical Commission stated duties and responsibilities are:

"The mandate of the Washington Medical Commission (WMC) is to protect the public's health and safety and to promote the welfare of the state......"

I believe they had the responsibility to investigate the QUALITY of compliance in the creation of the 2016 CDC guidelines. They Did Not. I also believe they had the responsibility to investigate the "Balance" of appointed members to this committee to be fair and equitable. They did not. And to investigate if any of these appointed members had a "Conflict of Interest" They did not . As we now know, the committee was composed of members who had conflicts of interest and a previous disposition against Opioid prescribing.

The Medical Commission, at that time, suggested and approved these guideline to the State Legislature, and supported their adoption as LAW. should have included a "Professional" investigation of legal compliance and confirmed an unbiased and failry balanced committee membership on the panel that advised the CDC and created these "Guidelines".

(b) Whether the rule is needed;

If ever, this rule is no longer needed as it is innefective. The intended purpose was to reduce opioid availability through diversion and abuse and illicit sales contributing to overdoses, injuries , and deaths. According to statistics, since date of enactment in 2016 and 2021 There has been a 40% reduction in opioids prescribed in Washington State, however there has been an increase in injuries and overdoses indication that monitoring, targeting chronic pain patients with specific rules and regulations, requiring drug tests and pill counts, was ineffective from 2016 to 2021, in reducing overdoses. Since publication of the CDC Guideline for prescribing opioids for chronic pain in 2016, annual opioid-associated deaths have doubled (to 74,000); 84% occur in people using illicit drugs. The Guideline has also created a

5

crisis in the care of the 15–20 million Americans with moderate to severe chronic pain

This proves that there is NO relationshipbetween prescribing opioids, and the rate of opioid overdose deaths. These laws are not needed because they do not fulfill their intended purpose. And have resulted in an increase in Patient Deaths across Washington State. They have had just the opposite effect in relation to overdose death rates!

(c) Whether the rule conflicts with or duplicates other federal, state, or local laws;

This rule violates Federal Americans with Disabilities Act, Section 36 MBLILLL

and the U.S. Constitution specifically the right to be free from unreasonable search and seizure.

Patients who suffer from Chronic Pain have a disability within the meaning of 42 U.S.C. § 12102 and 28 C.F.R. § 36.104. Chronic Pain is an impairment that substantially limits one or more major life activity.

Title III of the Americans with Disabilities Act

When a Chronic Pain Patient refuses to sign a "Pain Contract/Agreement" they are denied further medical care and their prescriptions for Pain Medications.

1.

Denying an individual or class of individuals, (Chronic Pain Patients) on the basis of disability, the ability to participate in or benefit from its goods, services, facilities, privileges, advantages, or accommodations by refusing to provide pain management treatment, in violation of 42 U.S.C. § 12182(b)(1)(A)(i) and 28 C.F.R. § 36.202;

2.

Using standards or criteria or methods of administration that have the effect of discriminating on the basis of disability, is in violation of 42 U.S.C. § 12182(b)(1) (D) and 28 C.F.R. § 36.204;

3.

Imposing or applying eligibility criteria that screen out, or tend to screen out, an individual with a disability or class of individuals with disabilities from fully and equally enjoying any Medical Facilities goods, services, facilities, privileges, advantages, or accommodations, in violation of 42 U.S.C. § 12182(b)(2)(A)(i) and 28 C.F.R. § 36.301(a).

4.

As a result of this Washington State Laws discriminatory conduct, Chronic Pain Patients are suffering physical pain and emotional distress. Chronic Pain Patients and other persons who may have been the victims of these State Laws, and are victims of these discriminatory practices are aggrieved persons under 42 U.S.C. § 12188(b)(2)(B)

When chronic pain patient are singled out as the only patients required to sign pain contracts or agreements, abd they refuse to sign an Agreement, or Contract, when their treatment is cut off and their request to have theri prescriptions refilled, this constitutes discrimination on the basis of disability in violation of the Rehabilitation Act of 1973, §504, 87 Stat. 394,

as amended, 29 U. S. C. §794(a), and the Patient Protection

and Affordable Care Act, §1557, 124 Stat. 260, 42 U. S. C.

<u>§18116.</u>

And when Pain Patients are denied pain medication because of a positive urine drug screen, this also violated Federal Law. The current laws and their interpretation by the State Medical Commission, dictate that if a Pain Patient refuses to sign a Pain Contract or Agreement, his or her Physician is directed to withold treatment, and discontinue filling their current opioid prescriptions. Also, if a Pain Patient has a positive drug test, in accordance with Washington State Medical Commission regulations and Laws adopted at the beheast of same, their physician is to withold their opioid prescriptions, and/or treatment.

I call your attention to:

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR PART 35

Nondiscrimination on the Basis of Disability in State and Local Government Services

AGENCY: Department of Justice.

ACTION: Final rule.

Paragraph (b) of {35.131 Illegal use of drugs. provides a limited exception to the exclusion of current illegal users of drugs from the protections of the Act. It prohibits denial of health services, or services provided in connection with drug rehabilitation to an individual on the basis of current illegal use of drugs, if the individual is otherwise entitled to such services. A health care facility, such as a hospital or clinic, may not refuse treatment to an individual in need of the services it provides on the grounds that the individual is illegally using drugs, but it is not required by this section to provide services that it does not ordinarily provide. For example, a health care facility that specializes in a particular type of treatment, such as care of burn victims, is not required to provide drug rehabilitation services, but it cannot refuse to treat a individual's burns on the grounds that the individual is illegally using drugs.

(d) Whether alternatives to the rule exist that will serve the same purpose at less cost;

The best alternative would be the immediate repeal of all discriminatory laws that single out Chronic Pain Patients from other patients who receive opioid medications. Thus ending the discriminatory practices now in effect. The pain and anguish that Chronicx Pain Patients, is as real as any pain suffered by other individuals.

An alternative would be the adoption of rules requiring all Health Care Employees, and staff at Assisted Living Facilities and Rest Homes, and Hospitals and Clinics to provide urine samples for drug screening each and every month. Residents of all of these facilities are now exempt from the rigors of current law. Given 6% to 12% of Physicians will have a drug problem sometime in their profession., perhaps they too can be drug tested. Nurses and CNA's also could be tested . Currently, 6% to 20% of Nurses and nursing staff, have a problem with drug addictions and theft of medications. And one in five employees currenly employed in Washington State at Rest Homes and Assisted Living Facilities have at least one criminal record. These individuals have more of an opportunity to steal and divert drugs, as they have the opportunity to divert or steal them on a daily basis

A perfect option would be to enact a rule requiring ANYONE seeking health and or dental care to be required to submit to drug screening. And to require Medical Doctors, Dentists, Nurses, Nursing Assistants, CNA's, and everyone, even Janitors who work with or in the medical or DRUG MANUFACTIURING industry. Let also Drug Test Law Enforcement Officials, who, on a daily basis, have unhindered access to illicit drugs. People who make important life and death decisions that affect us all, Senators, Congressmen, Legislative Representatives, Judges, and even the President and his Staff. Lets not forget Military personnel!

Perhaps we could go Door to Door and drug test EVERYONE in the State. This would surely put an end to drug abuse and diversion. But I do not see this happeneing soon. Because we are guaranteed certain rights and freedoms, BY LAW!

(e) Whether the rule applies differently to public and private entities;

Many washington patients receive Opioid Medications in washington state, but only long term Chronic Pain Patients are required to sign contracts, respond to "Pill Counts", provide urine samples for Drug Screens, and agree to other terms and conditions in said contracts, that other patients who receive opioid medications are <u>not</u> subjected to.

<u>Only</u> long term Chronic Pain Patients are required to comply with the adopted rules, regulaions and laws, specifically encated regarding the prescribing of opiods in Washington State. Thousands of patients receive opioid medications, buy only chronic pain patients must comply with additional terms, conditions, and regulations, in order to receive the SAME medications and medical treatment.

These Laws affect a "Protected Class" of Washington residents. Disabled chronic Pain Patients are singled out and are required to comply with requirements that effect them, and only them.And require them and only them , to meet certain requirements and submit to drug tests and the recording of personal health information. ONLY CHRONIC PAIN PATIENTS ARE REQUIRED TO SIGN PAIN CONTRACTS AND SUBMIT TO DRUG TESTING. Any and all other patients who receive opioid pain medications, are EXEMPT from said Laws. This singles out Chronic Pain Patients, requiring them to be subjected to additional rules and regulations, that other opioid patients do not have to comply with, and discriminates against them by establishing laws that affect them, and only them. Other opioid patients, are treated differently and receive their medications without the numerous additional requirements

(f) Whether the rule serves the purposes for which it was adopted;

These laws were created and adopted in response to the increased overdose death rate for opioids. And were adopted with the intent of lowering Washington State opioid overdose death rates. However, as Prescribing for opioids has fallen 40% TO 60%, overdose rates for opioids have risen over 70%. This proves that there is NO corrolation between prescribing opioids, and the rate of opioid overdose deaths. These laws are not needed because they do not fulfill their intended purpose. And have resulted in an increase in Patient Deaths across Washington State. They have had just the opposite effect in relation to overdose death rates!

This rule has <u>not</u> reduced opioid overdose in Washington State from date of enaction 2016 to peresent date of 2021. And the Overdose rate has risen dramatically. Chronic Pain Patients are suffering needlessly, daily, driving some to suicide.

(g) Whether the costs imposed by the rule are unreasonable;

The costs associated with the existing rules are inhumane and immoral. Long term Chronic Pain Patients are improperly and illegaly having their opioid medication reduced, tapered, and cut off, resulting in pain, agaony, and suffering, Some resorting to suicide as their only alternative to their lack of proper Medcal Care.

These rules were NOT adopted according to all applicable provisions of law because, it is apparent to me that it was never examined by legal staff of Washinton State Medical Commission to see if it conflicted with Federal laws, the ADA laws, HIPPA Laws and/or the Constitution of the United States of America

(h) Whether the rule is clearly and simply stated;

This rule is not clearly and simply stated because it does not specifically atate that a Physician is to cut off and/or reduce opioid prescribing for existing opioid patients, but the threat of prosecution by Law Enforcement <u>implies</u> this action under the direction of the Washington State Medical Commission. This rule does not specificall state that a Physician is to cut off the existing opioid medcicatios of an existing aptient of that patient refuses to sign a pain contract or agreement. But the WSMC implies and advises Physicians to do so.

(i) Whether the rule is different than a federal law applicable to the same activity or subject matter without adequate justification;

This law is different from Federal Laws which state clearly that a patient may not be denied medical care because that person is currently using illicit drugs.

(j) Whether the rule was adopted according to all applicable provisions of law.

These rules were NOT adopted according to all applicable provisions of law because, it is apparent to me that it was never examined by legal staff of the previous Washinton State Medical Commission to see if it conflicted with Federal laws, the ADA laws, HIPPA Laws and/or the Constitution of the United States.

When the CDC drafted these 'SUGGESTIONS", it violated the "Federal Advisory Committee Act". The Washington State Medical Commission, before suggesting these "Suggested Guidelines" be enacted into Law, had the responsibility to investigate the proper creation of these "Guidelines". As you can see in the attached "Congress Investigating CDC's Opioid Guidelines" this information was available to the Commission as far back as December 22, 2015, before these laws were created.

PLEASE SEE ATTACHED: Congress Investigating CDC's Opioid Guidelines

Please read and consider this attachment, as it is a part of my petition.

This article was attached with the permission of it's author, but does not indicate that author shares all of my opinions regarding this petition.

Additionally, several key members in the creation of these guidelines, reside in Washington State , and have benefited financially from their becoming Law.

Please see attached: "Undisclosed Conflicts of Interest by Physicians Creating the CDC Opioid Prescribing Guidelines: Bad Faith or Incompetence?" Please read and consider this attachment, as it is a part of my petition.

This article was attached with the permission of it's author, but does not indicate that author shares all of my opinions regarding this petition.

THE AUTHORS AND THE MANAGEMENT OF THE CDC HAVE PUBLICALLY STATED THAT THEIR "SUGGESTED RULES" OF 2016 WERE NEVER INTENDED TO BE ADOPTED AS LAWS.

THEY HAVE ACKNOWLEDGED THAT:

THE CDC HAS ACKNOWLEDGED THAT THEIR "SUGGESTED" GUIDELINES ARE BEING MISINTERPRETED BY MOST PHYSICIANS

THE PRESCRIBING OF OPIOID MEDICATION HAS FALLEN OVER 40%

THE OVERDOSE RATE HAS RISEN SUBSTANTIALLY

THAT CHRONIC PAIN PATIENTS ARE BEING ABANDONED

THAT CHRONIC PAIN PATIENTS ARE UNABLE TO FIND DOCTORS TO TREAT THEM

SOME PAIN PATIENTS HAVE BEEN DRIVEN TO SUICIDE BECAUSE OF THEIR UNTREATED PAIN

DOCTORS ARE REFUSING TO ACCEPT PAIN PATIENTS BECAUSE OF THESE LAWS

PATIENTS HAVE HAD THEIR PRESCRIPTIONS CUT OFF SUDDENLY WITHOUT TAPERING

UNTREATED CHRONIC PAIN LEADS TO OTHER SIGNIFICANT HEALTH CONCERNS

THEIR ORIGINAL DATA , DECLARING AN "OPIOID CRISES" WAS FLAWED, AND COMBINED ILLICIT STREET DRUGS WITH PRESCRIPTION OPIOID MEDICATIONS WHICH RESULTED IN THEIR INITIAL CONCLUSION A CRISES WAS OCCURRING

Prescription opioid were counted togeter wight herion, and fentanal deaths. Most ovewrdose deaths were a ressult of a combination of drugs, not just one specific prescribed medication. Coroners do not administer specific tests to seperate those attributed to heroin, fentanal, xanax, and/or prescription opioid medications/. The actiual number of diverted opion medications legally prescribed in Washinton State is unknow by the CDC, FDA or the DEA.

The CDC now admits they over estimated the overdoses attributed to prescriptions by about 100 % and the actual number of deaths where just a prescription opioid drug, and wherre a

combination of a prescribed opid medication and othe illicit drug , are one half of it's original and published estimations.

ADDITIONAL FACTS:

1. CHRONIC PAIN PATIENTS ARE SUFFERING NEEDLESSLY IN PAIN AND AGONY, DRIVING SOME TO SUICIDE.

2. THE LAWS HAVE RESULTED IN MILLIONS OF CHRONIC PAIN PATIENTS WITHOUT MEDICAL CARE OF ANY KIND.

3. THE COMPILING AND RECORDING OF SENSATIVE, PROTECTED HEALTH INFORMATION IS BEING RECORDED, AS REQUIRED BY THESE LAWS, IN DIRECT VIOLATION OF FEDERAL LAWS AND HIPPA LAWS. IN MOST STATES, CAN BE ACCESSED BY LAW ENFORCEMENT WITHOUT A SUPEONA OR COURT ORDER, IN VIOLATION OF CIVIL RIGHTS LAWS, AND CONSTITUTIONAL LAW PROTECTING INDIVIDUALS FROM UNREASONABLE SEARCH AND SEIZURE WITHOUT PROBABLE CAUSE. AND ARE AN INVASION OF PRIVACY.

4. CHRONIC PAIN PATIENTS ARE "BLACKMAILED" INTO SIGNING THESE CONTRACTS/AGREEMENTS. SIGN THIS DOCUMENT OR WE WILL WITHHOLD YOUR CURRENT PAIN MEDICATIONS. LAST TIME I CHECKED, BLACKMAIL WAS AGAINST THE LAW IN MOST STATES.

5. It has been six years since the adoption of the CDC's suggested guidelines, and despite all of the harm it has caused chronic pain patients, nothing has been done to remedy the current situation, resulting in the thousands of Washington States Chronic pain patients suffering needlessly.

6. Taking into account of the above, the actual deaths from prescribed opioid medication has never risen above an actual and expected increase due to normal increases in medication abuse across the country.

7. The CDCw was advise by a group know as PROP, Physicians for Responsible Opioid Prescribing. DR Chow was on the initial panel which drafted the Guidelines, and is now on the panel to ammend said guidelines. He is not a member of the CDC, the FDA, or the DEA. These are not Govt officials action in an official capacity as a govt employee. they are members of a private, non elected, and non appointed private group that has comflicts of interest as they receive monies for speaking out against the prescribing of opioids.

OPINION

It's Time to Undo the Harm the CDC Has Done to Pain Patients | Opinion

JEFFREY A. SINGER AND JOSH BLOOM , SENIOR FELLOW AT THE CATO INSTITUTE; DIRECTOR OF CHEMICAL AND PHARMACEUTICAL SCIENCE AT THE AMERICAN COUNCIL ON SCIENCE AND HEALTH

ON 9/21/22 AT 2:13 PM

After the U.S. Centers for Disease Control suggested dosage thresholds for patients receiving pain medication in 2016, 38 states rushed to pass legal limits on opioid prescribing and dispensing. Even though the CDC insisted the guidance was "voluntary, rather than prescriptive standards," states wanted to signal they were being tough on opioids. So they enacted tougher laws, even though CDC guidelines recommended dosing thresholds based upon the "morphine milligram equivalents" (MMEs) of the various opioids, a metric that never made sense, was not evidence-based, and amounted to "junk science."

Learning that its guidelines were being misinterpreted and misapplied, the CDC published an advisory in 2019, emphasizing that it never intended doctors to abruptly taper their patients from their pain medications, some of whom had been flourishing on high-dose opioid therapy for years, to its "approved" MME metrics.

But the advisory was too little too late for doctors and patients in states where legislation was already in place.

When a government agency "recommends" a policy, it's akin to a recommendation from Tony Soprano; it is inevitably interpreted as a mandate, obeyed by state and federal agencies, health insurers, and even pharmacies.

Over the past several months, lawmakers around America have begun re-examining existing state laws that have strictly limited and prescribed how health care practitioners can treat pain, which is a clear violation of both physicians' and patient's rights.

In Minnesota, for instance, a new law that went into effect Aug. 1 protects health care practitioners from disciplinary action if, based upon their good-faith professional judgment, they prescribe opioids to patients with intractable pain, regardless of the dose. Arizona and Alabama have also put in place some incremental reforms this year, although they have yet to enact significant revisions to the opioid prescribing regulations passed based on the CDC's recommendations.

<u>Those "recommendations" caused millions of patients to suffer. Some, unable to acquire adequate</u> <u>amounts of medication, sought relief in the dangerous black market, where they inadvertently</u> <u>purchased deadly illicit fentanyl. Others were driven to suicide, and some to homicide. Many in the U.S.</u> <u>became so-called "pain refugees," unable to find any doctors to help them. As an unintended</u> <u>consequence, patients are now under-treated for acute, even postoperative pain—ridiculous and cruel</u> by any measure.
To justify these cruel policies, we're often told that prescribing opioids to pain patients caused the overdose crisis. And yet, this "fact"—the basis of the CDC's advice—turned out to be a fallacy. There turns out to be no correlation between the number of opioid prescriptions and the non-medical use of or addiction to prescription pain killers. Data from the National Survey on Drug Use and Health shows that the addiction rate among persons aged 18 and above has remained essentially unchanged throughout the 21st century, despite prescription rates surging to record highs in the early 2000s and then, after 2012, dropping 60 percent.

Despite a huge decrease in opioid prescribing, the overdose rate continues to skyrocket, and modelers predict it will soon dramatically accelerate, as illegal drugs become more potent and deadly.

Responding to complaints by patient advocacy groups, medical scholars, and the American Medical Association, the CDC decided it will publish a revised opioid prescribing guideline by the end of this year. It requested comments on a draft proposal made public last February. We both submitted comments. But no matter how much the CDC stresses that the 2022 revision is merely a recommendation, ill-advised laws will be difficult to overturn.

Minnesota lawmakers deserve high marks in undoing some of the harms that the CDC has inflicted on pain patients and their physicians, and hopefully the state's actions will soon be followed by others. But until the CDC gets out of the business of telling doctors how to practice medicine, none of us can feel safe.

The following information is a part of my Petition. Please read and comprehend their content. These articles are included in my petition with the permission of the Authors. The inclusion of these articles does not imply that the Authors share my personal opinions included in my petition. I am soly responsible for that content.

THE FULL PRINTING OF THESE STORIES, INCLUDING PHOTOS, REFERENCES, AND FOOTNOTES, CAN BE FOUND:

https://www.painnewsnetwork.org/stories/2015/9/18/cdc-maintains-secrecyover-opioid-guidelines

AND

https://www.painnewsnetwork.org/stories/2015/12/21/congressinvestigating-cdcs-opioid-guidelines? fbclid=IwAR0dHncOVM8Ok9AeXI8yRgcmzOy0qLB08wnVIc7-8Dm4KEQz0QmjMf OKyZA

AND

https://www.frontiersin.org/articles/10.3389/fpain.2022.884674/full

Congress Investigating CDC's Opioid Guidelines

December 22, 2015

By Pat Anson, Editor

A congressional committee has launched an investigation into efforts by the Centers for Disease Control and Prevention (CDC) to develop new guidelines for the prescribing of opioid pain medication. The controversial draft guidelines discourage primary care physicians from prescribing opioids for chronic pain. As many as 11 million Americans take opioids daily for long term, chronic pain.

In a letter to CDC director Thomas Frieden, the chairman of the House Committee on Oversight and Government Reform questioned whether the agency broke federal law by appointing a biased advisory panel and refusing to disclose the identities of its members. Rep. Jason Chaffetz (R-Utah) asked Frieden to supply documents and information about the guidelines process "as soon as possible."

At issue is the "Core Expert Group," a panel composed of 17 members, most of them health researchers, state regulators and addiction treatment specialists. Although the CDC never publicly disclosed who was on the panel, their identities were leaked to Pain News Network and other websites. Critics charged that some members had conflicts of interests and strong biases against opioids. No patients or active pain management physicians are on the panel.

"Some groups have raised concern that the proposed guidelines may be insufficient to treat those suffering from chronic pain," wrote Rep. Jason Chaffetz (R-Utah). "We expect CDC's guidelines drafting process to seek an appropriate balance between the risk of addiction and the need to address chronic pain. The CDC has utilized a 'Core Expert Group' in the drafting and development of opioid prescribing guidelines, raising questions as to whether CDC is complying with FACA (Federal Advisory Committee Act)."

Chaffetz's letter was co-signed by five other committee members; Rep. Elijah Cummings (D-Maryland), Rep. Jim Jordan (R-Ohio), Rep. Matt Cartwright (D-Pennsylvania), Rep. Mark Meadows (R-North Carolina), and Rep. Gerald Connolly (D-Virginia).

Two members of the Core Expert Group are Jane Ballantyne, MD, and Gary Franklin, MD, who are the President and Vice-President, respectively, of Physicians for Responsible Opioid Prescribing (PROP), an advocacy group funded by Phoenix House, which runs a chain of addiction treatment centers.

Ballantyne and Franklin, who have been vocal critics of opioid prescribing, played key roles in the development of opioid regulations in Washington State, which has some of the toughest prescribing laws in the nation.

Ballantyne has served as a paid consultant to a law firm that is suing pharmaceutical companies over their opioid marketing practices. She also recently came under fire for co-authoring an article in the New England Journal of Medicine that said reducing pain intensity

should not be the goal of doctors that treat chronic pain.

In all, five PROP board members are advising the CDC in different capacities, including its founder, Andrew Kolodny, MD, who has called opioid pain relievers "heroin pills."

Another member of the Core Expert Group is Lewis Nelson, MD, an emergency physician and toxicologist at New York University Langone Medical Center. Nelson has also compared prescription opioids to heroin and said the risks of taking them outweigh the benefits.

"As a civilization we somehow managed to survive for 50,000 years without OxyContin and I think we will continue to survive," Nelson recently told the Associated Press.

In his letter to Frieden, Chaffetz asked the CDC to provide all documents related to the selection of the Core Expert Group, as well as any documentation related to their meetings or advice they gave to the agency. They asked Frieden to provide the information by January 8th.

"CDC has received the letter and is complying with the request," a spokesperson for the agency told PNN.

The CDC recently announced it would delay implementing the guidelines, reopen a public comment period, and have the guidelines reviewed by its scientific advisory committee. As Pain News Network has reported, the agency also said the Core Expert Group and other outside advisers are expected to continue advising the CDC.

Fed Panel 'Appalled' by Guidelines

Some of the sharpest criticism of the CDC has come from officials in other federal agencies, such as the Food and Drug Administration, which normally plays a lead role in setting guidelines for prescription drugs.

"I think we need to recognize that CDC wants to substantially limit opioid prescribing. Period," said Sharon Hertz, director of the FDA's Division of Anesthesia, Analgesia and Addiction Products, at a recent meeting of a federal pain research panel.

Hertz said the evidence cited to support the guidelines was "low to very low and that's a problem." She also told the National Institute of Health's Interagency Pain Research Coordinating Committee that the FDA "did have an opportunity to look at the product and comment," but otherwise was not involved in its development.

Other panel members expressed alarm that, although "voluntary" and meant for primary

care physicians, the guidelines could quickly become policy throughout the country.

"I see how our state health department looks at CDC. They really take direction from CDC. CDC has a great name for good reason. They've done incredibly good work in many areas," one panel member said. "And I have to say this has really diminished my respect for CDC. I have to say that this process was horrible. I'm appalled, appalled at the process CDC used to develop these in secrecy, not allowing input from the pain community and pain physicians."

"I think we cannot for one minute be naïve enough to imagine that these will be seen as recommendations and that state medical societies, boards of healing arts, legislators, will not jump all over this," said Myra Christopher, of the Center for Practical Bioethics.

"This is a ridiculous recommendation from my perspective. Very low quality of evidence, yet a strong recommendation. How do you possibly do that?" asked Richard Ricciardi, PhD, of the Agency for Healthcare Research and Quality.

"I would be remiss and I'm certain so would many of my government colleagues if I didn't go back to my director and say there's a report coming out of the CDC that has very low quality of evidence and there's a strong recommendation. That's an embarrassment to the government."

The CDC's own briefing papers make clear that the agency's ultimate goal is for the guidelines to be widely adopted.

"Efforts are required to disseminate the guideline and achieve widespread adoption and implementation of the recommendations in clinical settings," the agency says in documents obtained by Pain News Network. "CDC is dedicated to translating this guideline into userfriendly materials for distribution and use by health systems, medical professional societies, insurers, public health departments, health information technology developers, and providers, and engaging in dissemination efforts."

Even though the guidelines may be several months away from being finalized, Congress last week passed and President Obama signed into law a federal spending bill that requires the Veterans Administration to adopt the CDC's guidelines as official policy when VA doctors treat veterans suffering from chronic pain.

Undisclosed Conflicts of Interest by Physicians Creating the CDC

Opioid Prescribing Guidelines: Bad Faith or Incompetence? by Chad D. Kollas, MD, Beverly Schechtman and Carrie Judy

Introduction

In May 2021, Pallimed published our commentary that described the inappropriate and disproportionate influence given to the advocacy group, Physicians for Responsible Opioid Prescribing (PROP, also known as Health Professionals for Responsible Opioid Prescribing) during the creation process of the Centers for Disease Control and Prevention (CDC) 2016 Guideline for Prescribing Opioids for Chronic Pain, hereafter the 2016 Guideline (1-3). In September 2021, Pallimed published our second commentary, which focused on the astonishing disclosure of an important conflict-of-interest (COI) by Dr. Roger Chou (5), who co-authored the 2016 Guideline, calling its integrity into question (4, 5).

This commentary, the final in our trilogy, expands on these articles to quantify and clarify the extent of Chou's COI. We also explore additional COIs from the 2016 Guideline's creation group before the final release of the updated CDC 2022 Clinical Practice Guideline on Prescribing Opioids for pain, hereafter the 2022 Draft Guideline (6,7). Our results suggest that advocates for unfocused reductions in opioid prescribing propagated a false narrative that physician overprescribing drove increases in overdose deaths over the last two decades. Using this false narrative, these advocates facilitated a corresponding moral panic that produced flawed national opioid policy that has increased drug overdose deaths and harmed patients in pain but has also served the competing financial and intellectual interests of the CDC, health insurers, mass tort litigation attorneys, state attorneys general and anti-opioid stakeholders.

Background/Chronology

"Just because you're paranoid doesn't mean they aren't after you (8)."

In a moral panic, a group of people are portrayed as posing a threat to themselves or society, thereby "justify[ing] intolerance and unfair treatment" of that group, while the "evidentiary standard" for treating them that way is lowered (9, 10). A moral panic can effectively sway public opinion to force a shift in public policy (9-11). "Moral entrepreneurs... crusade for making and enforcing rules that benefit their own interests by bringing them to the attention of the public and those in positions of power and authority under the guise of righting a society [sic] evil " created by those causing the threat (9, 11). Medicine is not immune to such

moral panics, and in the case of opioid policy, patients using opioid analgesics - whether to treat pain or opioid use disorder - became the group posing a "threat to society (9)," while physician advocates for unfocused reductions in opioid prescribing became moral entrepreneurs (9, 10).

How Did the Media Contribute to this Moral Panic?

In November 2003, the Orlando Sentinel published a series of articles on OxyContin, exemplifying the media's moral panic about opioids (12). The series garnered national attention and culminated in the scheduling of a Congressional hearing on the dangers of OxyContin, popularizing the concept of "The Opioid Crisis (13, 14)." Suspicions about the veracity of the articles' sources triggered an internal investigation, which led to the author's resignation (15-17), but the series had created a foundation for a false narrative: duped by pharmaceutical companies' deceptive marketing, physicians allegedly overprescribed opioids to patients with mild pain inappropriately, who eventually died from overdoses after becoming addicted to prescription medications.

Moral Entrepreneurs Seize the Opportunity

Opioid prescribing increased during the mid-1990s after widespread calls to improve pain management, particularly at the end of life (18-21). This unexpectedly and undesirably increased health insurers' medication costs, including Medicare and Medicaid (22). Responding to an underfunded Medicaid program in 2003, Washington State's Prescription Drug Preferred Drug List "steered people with state-subsidized health care — Medicaid patients, injured workers and state employees — to methadone" as a money-saving choice versus other opioid analgesics (23-25). By 2007, the Washington State Agency Medical Directors Group (AMDG), which included several eventual PROP members (23), published an "Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain (26) that introduced the concept of hard dosing thresholds for opioid analgesics, which was later incorporated into the 2016 Guideline (2, 3). Although this reduced Washington state's Medicaid costs, it contributed "to the deaths of at least 2,173 people between 2003 and late 2011 (23, 25)."

Despite these deaths, the false narrative gained traction and clarity when it was advanced by Andrew Kolodny, who co-authored a 2011 article with Roger Chou which announced the formation of the physician advocacy group, Physicians for Responsible Opioid Prescribing or PROP (26). Kolodny further asserted that physicians "contributed to an epidemic of overdose deaths and addiction by overprescribing opioids (27, 28)." PROP and Chou petitioned the Food and Drug Administration (FDA) to change opioid labeling in July 2012 (29, 30), but FDA rejected PROP's call for a maximum daily dose of opioid analgesia of 100 morphine milligram equivalents (MME) based on a lack of supporting data (31).

The 2016 Guideline, Its Misapplication and Patient Harms

In the CDC, PROP found a more willing collaborator than FDA during the formation of the 2016 Guideline, prompting numerous concerns about the transparency and flawed integrity of its creation process (1, 4, 32-34). For example, in late 2015, Washington Legal Foundation alleged that one of the members of CDC's Core Expert Group (later identified as PROP member, Jane Ballantyne) had "served as a paid consultant to a law firm planning multi-district litigation against opioid manufacturers (4, 33, 34)." WLF's complaint compelled the CDC to re-open a second open comment period for the public, lasting 30 days in duration, rather than the two-day period for comment which CDC had originally presented via a September 2015 webinar (4, 35).

Despite transparency concerns and worries about conflicted interests on the part of the Guideline's creators by key stakeholders (36-39), CDC published its 2016 Guideline on March 18, 2016 (2-4). That same month, Kolodny – who had served as a Stakeholder Reviewer for the 2016 Guideline - deflected concerns about PROP members' relationships with law firms suing opioid manufacturers (34) and instead characterized key stakeholders' open comments to CDC as driven by "financial relationships with opioid manufacturers (40)."

By November 2018, misapplication of the 2016 Guideline had begun to cause serious patient harms, including diminished access to medically appropriate opioid analgesia (41). Moreover, a group of CDC scientists publicly questioned the accuracy of CDC data on drug overdose deaths, which had not accounted for deaths involving illicit fentanyl (42). In response, the American Medical Association (AMA) called against widespread misapplication of the 2016 Guideline, including its embrace of hard dosing thresholds (1, 43). Other stakeholders quickly joined AMA's call against misapplying the 2016 Guideline (44-47), and in April 2019, the Guideline's co-authors acknowledged its widespread, including "inflexible application of recommended dosage and duration thresholds and policies that encourage[d] hard limits and abrupt tapering of drug dosages, resulting in sudden opioid discontinuation or dismissal of patients from a physician's practice (48, 49)." That same month, FDA posted a public safety announcement warning against sudden discontinuation of opioid medications (1, 50), supplemented by a podcast warning against rapid opioid tapers (51). CDC issued another public warning against misapplication of the 2016 Guideline on April 24, 2019 (52).

Moral Entrepreneurs Undermine a Call for Balanced Opioid Policy

Just a few months earlier, a new hope for balanced opioid policy had emerged via the U.S.

Department of Health and Human Services (HHS) Inter-Agency Task Force Draft Report on Pain Management Best Practices (53, 54). Pain management experts felt that the HHS Draft Report would "improve the access to pain care and remove the stigma, providing patients and providers with appropriate education, training, risk assessment, and evaluation (55)."

Opposing that view, however, the National Association of Attorneys General (NAAG) sent comments to HHS Assistant Secretary for Health, Dr. Vanila Singh, encouraging HHS not to move away "from key components of the CDC Guideline for Prescribing Opioids for Chronic Pain," citing concerns that doing so "would undermine ongoing legislative initiatives [and] refinements to standards of medical care (56)." PROP hypocritically criticized the HHS Draft Report, noting that "HHS should have excluded individuals and organizations with financial ties to opioid manufacturers from serving on the HHS Pain Management Task Force (57)." The HHS Draft Report on Pain Management Best Practices quietly faded into obscurity.

Reassessing the 2016 Guideline; Creating the 2022 Opioid Guideline

As part of a planned assessment process, CDC opened a docket for public comments on its 2016 Guideline in April 2020 (58). Key stakeholders again expressed concerns about growing patient harms arising from the Guideline's misapplication, especially from nonconsensual opioid tapers and denials for pain care, which amplified calls to rescind hard dosing thresholds (59, 60). In contrast, PROP predicted "the downward trends in new starts of chronic opioid treatment achieved by the 2016 guideline should be seen as a positive development that will encourage people to find alternative means of controlling chronic pain, which... will ultimately result in better outcomes and less distress (61)." Despite PROP's optimism, CDC observed that "age-adjusted overdose death rates involving synthetic opioids, psychostimulants, cocaine, heroin, and prescription opioids during 2013–2019" increased 1,040%, largely as the result of illicit fentalogues (62-64). PROP deflected this news by criticizing AMA's opioid policy as tainted by contributions from the pharmaceutical industry (65, 66).

When Roger Chou unexpectedly disclosed his conflict of interest (COI) from receiving "funding to conduct reviews on opioids (4, 5)," evidence of harms from misapplications of 2016 Guideline had become more apparent (67-73). In the wake of Chou's admission, the CDC 2022 Opioid Work Group (OWG) expressed additional concerns about the 2022 Draft Guideline, including that it was "not balanced and missing key studies" about potential opioid benefits and contained a constant tension between "public health benefits [versus] patient benefits (74)." The OWG also cited concerns about "including specific opioid dose thresholds in the recommendations" in the 2022 Draft Guideline (74). In light of the OWG's concerns, we explored the depth of Chou's COI disclosure (4, 5) and sought to uncover any

other relevant, unreported COIs by those who created the 2016 Guideline and shaped current U.S. opioid policy.

Methodology

We qualitatively explored undisclosed or omitted conflicts of interests (COIs) from journal articles authored by the group of physicians who had advocated publicly, mainly through their PROP-related activities, for reduced opioid prescribing before their selection into the creation group of the 2016 Guideline. We examined whether they excluded disclosures of relevant COIs in publications that could influence opioid policy, emphasizing articles that might have prejudiced the creation process for the 2022 Draft Guideline.

We identified relevant publications via a query of PubMed (via the website link, <u>https://pubmed.ncbi.nlm.nih.gov/</u>) using the authors' names and the search terms "CDC," "Tapers," "MME," "Opioid Treatment," or "Opioid Epidemic" for the period between September 1, 2015 and June 30, 2022. This start date reflected the timing of CDC's webinar for its intended release of its 2016 Guideline (2, 3), while the end date preceded a decision by CDC on the final form for its 2022 Revised Opioid Guideline (6, 7). We included articles that articulated policy positions or recommendations relevant to either the 2016 Guideline or 2022 Draft Guideline. These articles contained key themes arising from discourse about the Guidelines, including but not limited to opioid tapering, MME, dosing thresholds and/or opioid prescribing recommendations. We called articles that met these inclusion criteria, "qualifying policy articles (QPAs)." Articles that focused on opioid use disorder or its treatment, acute pain management, or that made no recommendations about opioid treatment or U.S. policy were excluded from the analysis.

We defined "conflict of interest" using the methodology used by CDC itself in its creation of the 2016 Guideline, which "asked potential experts to reveal possible conflicts of interest such as financial relationships with industry, intellectual preconceptions, or previously stated public positions (2)." This included financial and non-financial or intellectual conflicts or competing interests. It also called for the exclusion of any experts that had "conflicts that might have a direct and predictable effect on the recommendations (2, italics ours)," such as taking a public position (such as signing a petition) or making recommendations intended to affect opioid policy. Additionally, we defined the authors' role within relevant advocacy organizations based on their own statements of membership, or by virtue of their authorship of, or signature on, a supporting a policy document advocating for an opioid policy position.

Results

Table 1 summarizes the undisclosed or omitted conflicts of interest of the study group physicians, who advocated for reduced opioid prescribing prior to their involvement in the creation of the 2016 Guideline (2, 3). In sixty-three of 87 QPAs (72%), these physicians omitted or failed to disclose conflicts of interest (COIs) as defined by the 2016 Guideline (5). Three of these physicians (GF, DT and LN) failed to disclose relevant COIs in all their QPAs, and one physician (JB), failed to disclose COIs in 84% of her QPAs. Only one physician (RC) fully disclosed all COIs in more than half of his QPAs.

Table 2 lists the physicians' most frequently cited QPAs and relevant conflicts of interest. As a group, four of six physicians (67%) omitted or failed to disclose both financial and intellectual (non-financial) COIs, while two of six physicians had intellectual COIs only. At the time of their selection to the 2016 Guideline creation group, each of the six physicians had an existing intellectual COI (4, 27, 29, 33) and two (RC and JB) had existing financial COIs (3, 4, 33, 34), although these COIs were identified only after they had contributed to the Guideline's creation process.

Discussion

Conflict Overview, Ethics and CDC's Guiding Principles

The Institute of Medicine (IOM) has defined a conflict of interest as "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest (107)." IOM has noted that "expert judgment based on clinical experience remains a significant element in the development of evidencebased practice guidelines," and recommended that "groups that develop clinical practice guidelines should generally exclude as panel members individuals with conflicts of interest (107)." The American College of Physicians (ACP) recently echoed this sentiment, noting, "One of the hallmarks of a trustworthy clinical guideline or guidance statement is a comprehensive process for disclosure of interests (DOI) and management of conflicts of interest (COIs) (108)." ACP also emphasized that participants creating clinical guidelines should "disclose all active and inactive financial and intellectual interests related to health care," noting that intellectual COIs "may leave a clinical guideline vulnerable to cognitive biases and may result in indirect financial benefit related to career advancement (108, 109)." Additionally, a Guideline Panel Review working group commissioned by the British Medical Journal (BMJ) identified "red flags" to raise "substantial skepticism" about clinical guidelines' credibility (110). These "red flags" include any financial conflict by the committee chair, multiple panel members with financial conflicts and "any suggestion of committee stacking

that would pre-ordain a recommendation regarding a controversial topic (110)."

Taking these position statements into account, our results suggest that the physicians from this study group have undermined the integrity of both the 2016 Guideline and 2022 Draft Guideline through their PROP- and MDL-related undisclosed or omitted COIs. We have applied CDC's own ethics and guiding principles to identify these COIs, beginning with its definition of COIs from rules for creating the 2016 Guideline (2, 3). CDC has asserted that "users of guidelines and recommendations need to feel confident that those participating in the development process were not unduly influenced by personal interests. Minimizing competing interests among members of steering committees and technical groups improves guideline acceptability, credibility, and scientific rigor (111)." CDC acknowledged that "a participant with a competing interest might be excluded from participating in the development of the final recommendation statement (111)," and that "guideline developers should make every effort to either eliminate or manage financial, intellectual, or professional interests that compete with the goals of producing an evidence-based guideline (111)." Furthermore, CDC policy states that "reviewers must provide written assurance that their reviews are free of real or perceived conflicts of interest (112)", and "scientists having real or perceived conflicts of interest with the applications under review may not attend or participate in initial peer review or secondary review meetings (112; italics ours)." Since HHS ethical rules allow obtaining a waiver if an "individual's services [to an advisory committee] outweigh the potential for a conflict of interest created by the particular financial interest involved (113)," we have submitted a Freedom of Information Act (FOIA) request to CDC to view the waivers of the members of study group (JB, RC, DJ and AK) with financial COIs (see Table 2), the outcome of which is pending at this time (114).

COI Overview and Key Individual Conflicts

All authors should disclose all relevant financial and non-financial or intellectual COIs when creating clinical guidelines intended to influence health policy. In a 2012 study of 114 clinical guidelines created by medical specialty societies (115), COIs were disclosed for 71% of committee chairpersons and 91% of co-chairpersons, which still led to criticism about their trustworthiness for falling short of complete disclosure (116). The physicians in this study group had an overall COI disclosure rate of just 28% in QPAs, which should raise serious concerns about their credibility in matters of health care policy.

While Roger Chou omitted COIs in just 40% of QPAs in this study, he omitted disqualifying financial and intellectual conflicts at the time of his co-authorship of both the 2016 Guideline and the 2022 Draft Guideline (3, 27, 29, 85-91). At the time of his authorship of the 2016 Guideline, Chou did not disclose his pending funding from the Agency for Healthcare

Research and Quality (AHRQ) for writing systemic reviews on opioid prescribing, although the grant award was not announced publicly until after its publication (85-91). The National Foundation for the Centers for Disease Control and Prevention, also known as the CDC Foundation, "an independent, private, nonprofit organization chartered by Congress in 1995 and classified as a 501(c)(3) public charity (117)," and AHRQ have both received funding from Group Health that supported Chou's systemic reviews of opioids (4, 23). Chou's competing interests should have mandated restriction "from further involvement in development of the clinical guideline... [including] participation in discussions, voting on recommendations, and authorship, or he or she may resign from the committee (108)." Chou did not resign from either the 2016 Guideline or 2022 Draft Guideline creation groups, nor did he step away from authorship, even after disclosing his financial COI publicly (4,5). Several stakeholders commented on these disqualifying COIs during the Open Period for comments on the 2022 Draft Guideline (118-121), but CDC created confusion by redacting Chou's identity from many of these comments (122) despite public knowledge of his co-authorship of both Guidelines (122).

In addition to Chou's egregious funding omission, Jane Ballantyne failed to report COIs in 84% of QPAs, while serving as a section editor for a well-known medical journal (123). As an editor, she understood well the ethical principles for reporting competing interests in medical journals (123-125). Furthermore, Ballantyne's PROP colleague and frequent coauthor, Mark Sullivan, recently failed to report his opioid litigation expert witness work as a COI in articles about opioid tapering policies in the journal which she serves as an editor (81, 126), including an article on which she "provided comments on an earlier draft (127)." When notified about the COI in a submitted editorial letter, the journal's editor-in-chief pledged to publish a correction, but rejected the letter for publication, avoiding publicization of Ballantyne's ethical violation (128). This correction has not been posted to date (126, 127). Similarly, Sullivan failed to disclose the same conflict in a letter to a medical journal that he co-authored with Ballantyne in March 2021 (129). Rather than publishing an editorial letter identifying the undisclosed COI, however, the article was updated to include the previously unreported competing interest (130). To date, identifying Ballantyne's failure to disclose these omitted COIs has not affected her status as a section editor for the journal (123).

By contrast, Andrew Kolodny has published three QPAs since September 2019 (131-133), after he corrected his COI disclosures for JAMA articles from 2017 and 2018 (102-105). In more recent QPAs, Kolodny has consistently disclosed COIs arising from his PROP membership and expert witness work for multidistrict litigation (MDL) against opioid manufacturers and distributors (131-133). Unlike Ballantyne's case, Annals of Internal Medicine posted a comment that revealed that a co-author on one of Kolodny's QPAs (99) failed to disclose a relevant COI in an opioid policy article (134-136). While Kolodny's recent reappointment as the president of PROP suggests that disclosing his more recent COIs has not restricted his aggressive advocacy (137), it is unclear whether that has affected the outcome of two recent MDL cases in which he testified for the plaintiffs (138, 139).

Does Disclosing COIs Matter?

The lack of consequences for omitting relevant COIs from QPAs in our study and the failure of many clinical practice guidelines to conform to standards for disclosing COIs (107-117) begs the question of whether disclosing COIs in medical journal articles even matters. Again, the answer comes from the CDC itself: "Guidelines, unlike some types of policies, are not mandatory. In health care and public health, guidelines are not meant to enforce but rather to recommend programs or practices based on the best evidence available. Often, however, CDC and others' guidelines become 'the standards of practice,' unintentionally acquiring the force of policy (111). Users of guidelines and recommendations need to feel confident that those participating in the development process were not unduly influenced by personal interests. Minimizing competing interests among members of steering committees and technical groups improves guideline might have a lasting impact on clinical and public health practice. Guidelines may be converted to policy, implying widespread implementation by a broad range of groups. Guidelines may be even converted into law, entailing subsequent regulatory enforcement (111; italics ours)."

Ironically, Roger Chou lamented this conversion of the 2016 Guideline into law because of its misapplication in the very same article in which he failed to disclose his funding for writing the systemic reviews upon which he based the both the Guidelines (4, 5, 23, 48, 85, 86). Accurate disclosures of COIs matter because the "public trust in the scientific process and the credibility of published articles depend[s] in part on how transparently an author's relationships and activities, directly or topically related to a work, are handled during the planning, implementation, writing, peer review, editing, and publication of scientific work (125)."

Following the Money

Advocates for reduced opioid prescribing have enjoyed an advantage from the failure of regulatory agencies and medical journals to identify and publicize relevant COIs, thereby propagating moral panic and the false narrative that overprescribing drives the opioid overdose deaths (27, 28). These deaths arose from an epidemic of poisonings from multiple illicit substances, including counterfeit drugs and ethanol, rather than from prescription

opioids (42, 140-145). Knowing this, why have federal regulatory agencies and advocates for reduced opioid prescribing cling to a demonstrably false narrative about overprescribing?

As the saying goes, "Follow the money (146)." We described above how changes in opioid policy aimed at reducing Washington State's Medicaid and Workers Compensation costs contributed to an increase in methadone deaths between 2003 and late 2014 (23-25). Focusing on similar cost reductions, the Centers for Medicare and Medicaid Services (CMS) proposed rules for 2019 including several directives intended to reduce "Opioid Overutilization," including adoption of the "90 morphine milligram equivalent (MME) threshold cited by the 2016 CDC Opioid Guideline (147, 148). Simply put, reduced prescribing reduces costs for prescribed medications.

Chou received research funding to write systemic reviews of opioid analgesics that shaped both Guidelines, but largely ignored opioids' potential benefits; he again failed to cite that funding when writing an article bemoaning early harms from the 2016 Guideline's misapplication (3-5, 48, 74, 85-91). Employing a model created by the tobacco settlements of the 1990s (149), state, federal and local governments have successfully used the 2016 Guideline to justify their legal arguments in settlements of multidistrict litigation (MDL) suits against opioid manufacturers and distributors (150-153). Legal experts' concerns about Ballantyne's and Kolodny's participation in the Guideline's creation, during which they received financial compensation for MDL-related expert witness work (4, 23, 33, 34, 81-84, 99-105), proved correct when plaintiffs used the 2016 Guideline as a tool to support MDL lawsuits (37, 38, 154).). Andrew Kolodny openly anticipated making \$500,000 from his expert witness work on Oklahoma's lawsuit against opioid manufacturers and distributors (137, 155), while Ballantyne has never disclosed the amount of her personal fees from Motley Rice LLP, "one of the Nation's Largest Plaintiffs' Litigation Firms" and an MDL litigant (156, 157).

As of July 31, 2022, awards from opioid MDL lawsuits settlements had totaled more than \$36 billion, with more suits still pending nationwide (158). Many policymakers have called for this settlement money to be spent fortifying public health (159), but tensions have emerged about "what interventions and treatments should be funded (160)." While it remains unclear how much the public will benefit from these settlements, it is very clear that plaintiff expert witnesses from our study group comprise one of the major financial beneficiaries of the MDL lawsuits.

Limitations and Criticisms

When creating our methodology, we purposely borrowed from Kolodny's methodology (40) to disarm anticipated criticism by PROP and its allies. Similarly, when seeking publication, we

received confidential criticism that we self-referenced our prior works in the same way that the study group's references one another's work to justify their opioid policy positions. To this we reply, "Turnabout is fair play (161)." Our study examines only physician advocates who served a role in creating the 2016 Guideline. Many more physicians have advocated for open-ended reductions in opioid prescribing and have omitted COIs in journal articles involving opioid policies (126-130, 132, 135), but have not been included in this commentary, because of our intentional limitation on its scope. Finally, we did not identify any participants in the creation process of the 2016 Guideline who possessed "conflicts that might have a direct and predictable effect on the recommendations" related to policy positions supporting medically appropriate opioid prescribing.

Concluding Recommendations

Our results strongly suggest that CDC disregarded or disobeyed its own rules and ethical guidelines (111-113) by allowing PROP members and allies to help create the 2016 Guideline, thereby compromising its ethical integrity (1, 4, 23, 34, 36, 119-123). Those physicians acted entrepreneurially to facilitate a moral panic (9-11) about opioid-involved overdose deaths, using a false narrative about overprescribing that successfully changed opioid policy nationally. These policies have unacceptably increased risks of harm for patients in pain (43-45, 48-52, 67-73). Unfortunately, abolishing or repealing the 2016 Guideline and 2022 Draft Guideline, while ethically justifiable, now seems like an impossible task. The federal government has invested too much time and too many resources into the Guidelines to abandon them, especially while MDL suits against opioid manufacturers and distributers are still pending.

What can be done to undo the harms created by the 2016 Guideline and prevent further harm from the 2022 Draft Guideline? We strongly recommend abolishing hard dosing thresholds from the 2022 Draft Guideline, because their misapplication has emboldened involuntary and/or rapid opioid tapers, contributing to patient harms (43-45, 48-52, 67-73). These hard dosing thresholds have been improperly translated into "mandatory policies and laws throughout the country, becoming, in effect a standard of care used by states, payers, pharmacy benefit plans, health care systems and providers (162)." Next, while the 2022 Draft Guideline offers some improved language toward that goal, CDC must unequivocally denounce the false narrative that overprescribing still drives the opioid crisis, as "the particular focus around reduced opioid prescribing has met with limited success and contributed to subsequent waves of the crisis (163)." CDC's Opioid Workgroup for the 2022 Draft Guideline cited similar concerns about hard dosing thresholds, but also acknowledged the inherent tension between patient versus public or societal health benefits (74). In addition, we call on policymakers to correct the current policy imbalance between patients' medical autonomy and society's benefit, acknowledging that physicians have an individualized, fiduciary duty to act in their patients' best interests which may sometimes reasonably conflicts with public health goals (164). Patients are not monoliths, and physicians cannot treat them individually using a broad policy brush. Physicians' primary responsibility is to attend the individualized needs of the patients they are treating. Thus, we envision creating an ethics-based, education-focused informed consent process that allows patients to weigh treatment risks versus potential benefits collaboratively to enhance opioid prescribing safety (165).

Furthermore, we identified a 72% rate of nondisclosure of COIs in our study group, which we find ethically unacceptable, considering the purported importance of transparency when creating clinical guidelines (107-110). CDC itself has acknowledged this moral imperative, but hasn't adhered to its own ethical rules (111-113). Given the apparent inability of the study group authors and the CDC to transparently self-regulate the conflict disclosure process, we encourage medical journals to become more vigilant about identifying authors' financial and intellectual COIs in submitted manuscripts about opioid policies. This includes holding editors accountable when they deliberately ignore relevant competing interests (123, 126-128).

Finally, if these recommendations fail to restore balanced U.S. opioid policy, we call upon the U.S. House Committee on Oversight and Government Reform to convene a hearing to scrutinize CDC's use of a Core Expert Group to write its opioid guidelines instead of complying with the supervisory requirements of Federal Advisory Committee Act (166). Alternatively, we would invite the U.S. Department of Justice to investigate why CDC has repeatedly violated internal rules and ethical policies while creating the 2016 Guideline and 2022 Draft Guideline (111-113). Permitting ongoing patients harms from these Guidelines desecrates the sacred trust between prescribing physicians and patients afflicted by chronic pain.

Dedication:

This commentary is dedicated to the memory of Dr. Terri Lewis, a beloved colleague and tireless advocate for patients with disabilities and chronic pain.

About the Authors:

Lead author, Chad Kollas, serves as the Medical Director for Palliative and Supportive Care at the Orlando Health Cancer Institute in Orlando, FL. He can be reached by e-mail at chad.kollas@orlandohealth.com or via Twitter at @ChadKollasMD.

Bev Schechtman is a patient with chronic illness and pain who has spent the last five years volunteering as a patient advocate. She is currently the Vice-president of The Doctor Patient Forum, and she has been with the volunteer organization, Don't Punish Pain, since its inception in 2017. She is a passionate researcher and advocate who hopes to give a voice to those in pain.

Carrie Judy is an unpaid contributor and researcher at The Doctor Patient Forum.

Competing Interests: Dr. Kollas recently served as Secretary on the Board of Directors of the American Academy of Hospice and Palliative Medicine (AAHPM). He also serves as the AAHPM Delegate to the American Medical Association (AMA) House of Delegates, where he is the Chair of the AMA Pain and Palliative Medicine Specialty Section Council and a member of the AMA Substance Use and Pain Care Task Force. Dr. Kollas provided testimony at a 2004 Congressional Hearing on OxyContin. Dr. Kollas has served as a medical expert witness in cases involving opinions regarding the standard of care in internal medicine and hospice and palliative medicine. He has received educational research grants from the AMA Education and Research Foundation, Geisinger Clinic and M. D. Anderson Cancer Center Orlando. He serves as the editor for the Advocacy section of AAHPM Quarterly and is a member of the Editorial Advisory Board and review for the Journal of Pain and Symptoms Management. He has also served as a reviewer for the Journal of Palliative Medicine, Annals of Internal Medicine, Journal of General Internal Medicine, Journal of Graduate Medical Education, and the Educational Clearinghouse for Internal Medicine.

Ms. Schechtman serves as the Vice-president of The Patient Doctor Forum, which accepts donations as a registered 501(c)(3) non-profit organization.

Ms. Judy serves as a volunteer researchist for The Doctor Patient Forum.

Overdose, opioid treatment admissions and prescription opioid pain reliever relationships: United States, 2010–2019

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Background: "As part of the U.S. government's urgent response to the epidemic of overdose deaths (1)" the United States Centers for Disease Control and Prevention (CDC) issued the "CDC Guideline for Prescribing Opioids for Chronic Pain-United States, 2016 (2)" (guideline) followed by the "CDC Clinical Practice Guideline for Prescribing Opioids–United States, 2022 (3) (guideline update). " The guideline and guideline update cite a direct correlation between prescription opioids sales (POS) and opioid treatment admissions (OTA) and prescription opioid deaths (POD), which was based on data from 1999 to 2010. This paper updates those relationships and includes the correlations between prescription opioid sales (POS) and opioid treatment prescription opioid sales (POS) and any opioid deaths (AOD) and total overdose deaths (TOD) from 2010 to 2019.

Methods: Linear regression models were fit to each response separately. Opioid sales (measured as MME (morphine milligram equivalent) per capita) was the independent variable. Total overdose deaths (TOD), any opioid overdose deaths (AOD), prescription opioid overdose deaths (POD) and opioid treatment admissions (OTA) were the dependent, response variables. The models were assessed using three criteria: the statistical significance of the model (Overall P-Value), the quality of the fit (R2), and the sign of the slope coefficient (positive or negative).

Results: The analyses revealed that the direct correlations (i.e., significant, positive slopes) reported by the CDC based on data from 1999 to 2010 no longer exist. Based on data from 2010 to 2019, the relationships either have reversed (i.e., significant, negative slopes) or are non-existent (i.e., no significant model).

Conclusions: The guideline, guideline update, CDC's public, medical profession, and intergovernmental communications should be corrected/updated to state no direct correlation has existed between POS to OTA, POD, AOD, and TOD since 2010. Individualized patient care and public health policy should be amended accordingly.

Background and rationale

Direct correlations that existed between Prescription Opioid Deaths (POD), Opioid Treatment Admissions/addiction (OTA) and Prescription Opioid Sales (POS) from 1999 to 2010 (4) (see Figure 1) led the CDC to conclude that POS are the determinant for POD, any opioid overdose deaths (AOD), Total overdose deaths (TOD), and OTA (1–14).

Figure 1

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FIGURE 1. CDC chart 1999–2010, February 28, 2018, Congressional testimony "Combatting the Opioid Crisis," made before the Committee on Energy and Commerce, Subcommittee on Health U.S. House of Representatives (5): "The CDC has shown that a sharp increase in prescriptions for opioids resulted in a corresponding rise in addiction and overdose deaths. This is a CDC graph. The green line represents opioid prescribing, the red line represents opioid deaths, and the blue line represents opioid addiction. The green line went up as opioid prescriptions started to soar, it led to parallel increases in addiction and overdose deaths (6)".

The U.S. Department of Health and Human Services (HHS) declared in 2015 "There is a clear correlation between opioid prescribing rates and overdose death rates in the United States (7)." With the guideline's release, then CDC Director Tom Frieden stated, "Overprescribing opioids—largely for chronic pain—is a key driver of America's drug-overdose epidemic (1)."

Cutting POS has been CDC's, DEA's, legislative policy makers', healthcare system providers and practitioners' solution to cut overdose deaths and OTA (1–18).

The impact of the CDC guideline has been systemic. Long term opioid therapy patients are not accepted as new patients by over 40% of primary pain clinics (18). 2021 MME per capita use declined to 309 (19), a level last seen in 2000, while the over 55 population with its agerelated health conditions increased by 40 million since then and COVID care has required "high demand." "Forty-seven states and the District of Columbia have laws that set time or dosage limits for controlled substances (20)." "All 50 states have established prescription drug monitoring programs (PDMPs) (21)" to collect and surveil doctor, patient, and dispensed medication information. Since 2009, U.S. morphine milligram equivalents per 1,000 inhabitants per day (MID) declined by 48% from second in the world (22) to third in 2019 (23).

The American Medical Association (AMA) reports "72% of pain medicine specialists said that they—or their patients—have been required to reduce the quantity or dose of medication they have prescribed (24)" as a result of the guideline.

The objective of the guideline was to cut opioid addiction and overdose deaths while ensuring to first do no harm. Considering "The epidemic of overdose deaths in the USA has been growing, inexorably and exponentially, for four decades" per the U.S. Drug Enforcement Administration (DEA) (25), an increase in U.S. overdose deaths of nearly 70% from 2016 to 2021, and an annual overdose cost of \$1 trillion in the United States (26)," it is critical that public health policy and individual patient care not be based on out-of-date or misleading information.

The 2022 guideline update revises and expands upon the recommendations of the 2016 guideline considering a substantial amount of more recent data. However, it continues to cite the positive relationship between opioid prescribing rates and overdose deaths between 1999 and 2010 but makes no mention of the fact that those relationships have not existed for more than a decade. It is important that both clinical practice and regulatory policy be based on as much valid data as is readily available. This paper is intended to augment the new information contained in the guideline update to address the current relationships between POS and OTA, POD, AOD, and TOD.

The direct correlation of POS with OTA, POD, AOD and TOD has been cited in communications of public health policy, individual patient care and doctor conduct by HHS and CDC, referenced in congressional testimony, intergovernmental communications, and legal proceedings, thereby making these correlations a critical material fact. The analyses presented in this paper covering the period from 2010 to 2019 updates these material facts to avoid misrepresentation or omission of relevant evidence.

Methods

Description of data sources

Data limitations

Data limitations have the potential for over or underestimating overdose deaths. The authors of a 2018 report "Quantifying the Epidemic of Prescription Opioid Overdose Deaths," with the CDC, acknowledged that systemic errors and omissions in the source data along with the CDC's methodology for compiling drug-related mortality data "could significantly inflate (27)" prescription opioid overdose death estimates (27, 28). In 2018, the CDC cut their estimates of prescription opioid deaths from 1999 to 2016 by 48,000 or 19.5%, with the 2016 estimates cut by more than 15,000 or 47.3% (27, 28).

Confounding factors impacting the accuracy of overdose deaths are that "multiple drugs are often involved" (27), the source of opioids detected in postmortem blood toxicity screens is not known (e.g., legally prescribed vs. illicitly obtained), among other issues (27, 28). With this occurrence and/or when multiple conditions resulted in an overdose death a single sequence/cause will be documented based on the physician's "best medical opinion (29)."

The same data sources that the CDC guideline appears to be based upon were used for this

paper. As such, the results of analyses presented here are at least as reliable and subject to the same limitations as what the CDC obtained from their own analyses of 1999–2010 and if they chose to undertake them for the most recent decade of 2010–2019. Thus, the following sources have been applied.

Drug Overdose Deaths (National); Total Overdose Deaths, Any Opioid Overdose Deaths and Prescription Opioid Overdose Deaths (30): 1999–2019 data accessed from Drugabuse.gov., Published 2021. Deaths are classified according to the International Classification of Diseases, 10th Revision. Drug overdose deaths are identified with underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14. The following multiple cause-of-death codes were used to identify specific drug types: T40.2 for natural and semisynthetic opioid analgesics, T40.3 for methadone, and T40.4 for synthetic opioid analgesics other than methadone. Accessed January 10, 2021 <u>https://www.drugabuse.gov/sites/default/files/Overdose_data_ 1999-2019.xlsx</u>.

Opioid Overdose Death Crude Rates (U.S. States) (31): 1999–2019 data accessed from CDC, National Center for Health Statistics. Underlying Cause of Death, 1999–2019 were sourced from CDC WONDER Online Database, released in 2020. Data are from the Multiple Cause of Death Files, 1999–2019, as compiled from data provided by 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Identified using underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14. Accessed Feb 7, 2021, 12:01:39 PM from <u>http://wonder.cdc.gov/ucd-icd10.html</u>.

Opiate/Opioid Treatment Admissions (National) (32): 2006–2008 data accessed from Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, "Treatment Episode Data Set (TEDS): 2000–2010". National Admissions to Substance Abuse Treatment Services. DASIS Series S-61, HHS Publication No. (SMA) 12-4701. Rockville, MD: Substance Abuse and Mental Health Services Administration (samhsa.gov), 2012. P. 43. Accessed April 18, 2021 from Treatment Episode Data Set (TEDS) 2000–2010 (samhsa.gov).

Opiate/Opioid Treatment Admissions (National) (33): 2008–2018 data accessed from Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, "Treatment Episode Data Set (TEDS): 2018." Admissions to and Discharges from Publicly Funded Substance Use Treatment. Rockville, MD: 2018 TEDS Annual Report. Substance Abuse and Mental Health Services Administration (samhsa.gov), 2020. Table 1.1a. Accessed April 18, 2021 from

https://www.samhsa.gov/data/sites/default/files/reports/rpt31097/2018_TEDS/2018

<u>TEDS.html#PSU</u>. 2018 TEDS Annual Report (samhsa.gov).

Opioid Prescribing; MME per Capita (National) (34): 2006–2013 data accessed from CDC," Annual Surveillance Report of Drug-Related Risks and Outcomes—United States Surveillance Special Report" 0.2019 CDC, U.S. Department of Health and Human Services. Published November 1, 2019. P. 115. Accessed January 10, 2021 from <u>https://www.cdc.gov/drugoverdose/pdf/pubs/2019-cdc-drug-surveillance-report.pdf</u>.

Opioid Prescribing; MME per Capita (National) (35): 2014–2018 data accessed from Statista," Annual morphine milligram equivalents (MME) dispensed per capita in the U.S. from 2014 to 2018", MME per capita U.S. 2014–2018. Statista. May 28, 2021. Accessed July 8, 2021 from https://www.statista.com/statistics/753284/number-of-mme-dispensed-per-capita-in-us/.

Opioid Prescribing; MME per Capita (National) (36): 2019 data accessed from The IQVIA Institute, "Prescription Opioid Trends in the United States," Institute Report, Dec 16, 2020. P.4. Accessed January 10, 2021 from <u>https://www.iqvia.com/insights/the-iqvia-</u> <u>institute/reports/prescription-opioid-trends-in-the-united-states</u>.

Opioid Prescribing; Opioid Dispensing Rates per 100 (U.S. States) (37): 2006–2019 data accessed from CDC, "U.S. Opioid Dispensing Rate Maps, Drug Overdose," CDC Injury Center. Accessed February 9, 2021 from <u>https://www.cdc.gov/drugoverdose/rxrate-maps/index.html</u>.

Opioid Sales kg/10,000 (National): For the period from 2006 through 2018/2019, these data were not known to be publicly available. We instead examined Opioid Prescribing by separately computing MME per Capita.

Statistical methodology

Objective 1: Evaluate MME per capita as a legitimate alternative measure of annual prescription opioid sales

The CDC used Annual Prescription Opioid Sales to support the guideline (Figure 1). Data on Annual Prescription Opioid Sales are not readily available since 2010. However, MME per Capita data are available from 2006 to 2019 and offer a reasonable surrogate. Annual Sales data from the CDC chart were visually extracted and correlated with MME per Capita data, using simple linear regression analysis. The goal of the analysis was to evaluate MME per Capita as a legitimate alternative measure of Annual Prescription Opioid Sales.

Objective 2: Assess the strength and nature of the relationships between total overdose deaths, any opioid overdose deaths, prescription opioid overdose deaths and opioid

treatment admissions and opioid sales/MME per capita

Consistent with the methods used by the CDC, simple linear regression models were fit to the data. Separate models were fit to each of the four dependent variables (TOD, AOD, POD, and OTA) using Annual Opioid Sales (i.e., MME per Capita) as the independent variable. Two models were fit to each dependent variable. One model covered the years presented in the original CDC chart (for which MME per Capita data were available) (2006–2010) and the second model covered the years since the published CDC chart (2010–2019).

For both objectives, the strength and nature of relationships in all the regression models were assessed using three criteria:

1) significance of the regression model (overall P-Value),

2) the quality of the model's fit (R2), and

3) the sign of the linear slope coefficient (+ or –).

All models were fit using PROC REG from SAS/STAT software Version 9.4.

Results and discussion

Data from CDC's original chart was reconstructed using graphical analysis. The reconstructed Annual Prescription Opioid Sales values from the original CDC chart are highly correlated with publicly available MME per Capita values (R2 = 94%). MME per Capita, which are available for more recent years than the data originally used by the CDC, is thus used in place of Annual Prescription Opioid Sales for all subsequent analyses.

For the years covered in the CDC's original chart (for which MME per Capita data are available, i.e., 2006–2010), the CDC's claim of positive/direct relationships between TOD, AOD, POD, and OTA and Annual Prescription Opioid Sales (i.e., MME per Capita) were validated (91% < R2 <97%), with statistically significant, positive slopes.

For more recent years (i.e., 2010–2019), however, the CDC's assertion of continued direct relationships is not valid. The relationships between TOD, AOD, POD, and OTA and Annual Prescription Opioid Sales (i.e., MME per Capita) are either non-existent or significantly negative/inverse (Figures 2, 3).

Figure 2

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FIGURE 2. 2010–2019 update. The green line represents opioid prescribing (POS, MME/capita); the red lines are opioid deaths (POD, AOD, and TOD); the blue line represents opioid addiction (OTA). Over the past decade, as the green line (prescription opioids) declined by +50%, prescription opioid deaths remained flat while opioid addiction, any opioid and total overdose deaths continued increasing "exponentially (9)".

Figure 3

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FIGURE 3. 2010–2019 regression models: Illustrates the regression of OTA, POD, AOD, and TOD as functions of POS. Significant, negative relationships were found for OTA, AOD, and TOD. No significant relationship exists between POD and POS.

Results for all regression models are presented in Table 1.

Table 1

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TABLE 1. Summary of national regression models fit in the paper.

National trends since 2010 are paralleled in a strong majority of states. Between 2010 and 2019 inclusive, there was a statistically significant negative correlation (95% confidence level) between AOD and Annual Prescription Opioid Sales in 38 states, with significant positive correlations occurring in only 2 states. Ten (5) states did not exhibit a significant (95% confidence level) relationships between overdose deaths and prescription opioid sales during the 2010–2019 time period (Table 2).

Table 2

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TABLE 2. Summary of regression models by state, any opioid overdose death by opioid precribing rate/100 people.

The guideline emphasized to clinicians that opioid dosages should be limited to no more than 90 MME/day based on the "evidence regarding the association of opioid dosage and overdose risk" in that "overdose risk is increased at higher opioid dosages" (2).

This recommendation is not supported by the available data. Regression analyses of TOD,

AOD, and OTA on POS from 2010 to 2019 among patients receiving doses of at least 90 MME/day show significant negative relationships, indicating that lower POS in this high-dosage cohort do not correspond to lower death rates. As with the national results, the relationship between POD and POS in this cohort is not significant (Table 3).

Table 3

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TABLE 3. Summary of > 90 MME regression models.

Conclusions

The direct correlations used to justify the CDC guideline and guideline update that existed from 1999 to 2010 are no longer present. Starting in 2010, opioid MME per Capita (POS) does not have a "clear correlation" (7) or move "in parallel" (2) or "in lockstep" (8) with OTA, POD, AOD or TOD. The relationships changed from direct to inverse in 2010. These results hold on a national level, in a large majority of states, and even among patients receiving opioid dosages greater than the recommended maximum dosage in the guideline (much less the reduced maximum dosage recommended in the guideline update). Based on the results presented in this paper and the current trends in opioid deaths, the policies of cutting POS to reduce TOD, AOD, POD, and OTA as presented in the guideline and the guideline update are unfounded and ineffective.

In 2019, the DEA concluded "Without effective new interventions, this overall pattern of predictable exponential growth is likely to continue into the future" (25). Government resources should be allocated to identify the root cause of drug addiction and overdose mortality and then applied to an effective approach that will consistently reduce addiction and overdose deaths.

Reasonable judgment would dictate tracking and reporting of chronic pain patient outcomes (deaths, suicides, returns in benefits, reported pain, function, etc.) for individuals since the guideline or the guideline update. However, there appears to be no publicly available evidence that a monitoring process is required or is planned to measure and confirm outcomes. PDMP records may provide a basis for contact and to survey a random sample of long-term opioid therapy patients to confirm consent, check their status and to evaluate the effectiveness of policy to date.

The results of the analyses presented here help to inform the public, legislators, and the medical community that since 2010 there has been no direct correlation of POS to OTA, POD,

AOD, and TOD. The basis for the guideline, the guideline update, communications of public health policy, individual patient care, doctor conduct, congressional testimony, and intergovernmental communication that state and/or imply a direct correlation of POS to OTA, POD, AOD, and TOD are not valid. Based on the current relationships that have existed for a decade the guideline, guideline update and public health policy should be corrected/updated along with an acknowledgment of this material information to avoid misrepresentation or omission of relevant evidence.

Author contributions

LA obtained all of the data used in the manuscript. BC analyzed the data using regression analysis. Both authors contributed equally to the drafting of the manuscript.

Conflict of interest

Author BC was employed by Carr Consulting, United States.

The remaining author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Disclaimer: All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article or claim that may be made by its manufacturer is not guaranteed or endorsed by the publisher. Dear Sirs,

In accordance with RCW 34.05.330, I wish to submit to you my "Petition" to repeal WAC 246-919-850 through 246-919-985

To: Washington State Medical Commission

From: Thomas M. Bertsch

1006 N. Park St

Colfax, Wa. 99111

Disability Retired Fire Captain

Long Term Chronic Pain Patient

Subject: REPEAL OF WASHINGTON STATE LAWS

This petition contains several articles attached to it. These articles were included with the permission their authors. However thier inclusion does not mean the authors share all of my opions contained herin. Please read and comprehend this petition in it's entirety as the articles are part of my petition. I am soley responsible for the content of this petition.

the mp

For the following reasons.

Under RCW 34.05.330, the Petitioner is encouraged to address the following issues:

(a) Whether the rule is authorized;

(b) Whether the rule is needed;

(c) Whether the rule conflicts with or duplicates other federal, state, or local laws;

(d) Whether alternatives to the rule exist that will serve the same purpose at less cost;

(e) Whether the rule applies differently to public and private entities;

(f) Whether the rule serves the purposes for which it was adopted;

- (g) Whether the costs imposed by the rule are unreasonable;
- (h) Whether the rule is clearly and simply stated;

(i) Whether the rule is different than a federal law applicable to the same activity or subject matter without adequate justification;

(a) Whether the rule is authorized;

The Washington State Medical Commission, at the time this laws were adopted, ha the responsibility to verify data and it's orgin for actual, factual, information, when considering the adoption of laws and RCW's affecting all of Washington state residents. The CDC 2016 Guidelines were not properly investigated by the previous Commission, and the Commission, at that time, failed to examine it's authors for obvious conflicts of interest.

These "<u>suggested</u>" policies were never intended to be adopted as Laws , Rules, Or Regulations. The author of them, The CDC has specifically stated this fact. This information was never seriously considered by the Washington State Medical Commission, at that time of adoption, before they endorsed their enaction into State Law. Alao, these influencial consultants that advised the CDC are funded by a chain of Drub Rehab companies who stand to gain from the laws.

The previous Washington State Medical Commission errored in recommending these rules be adopted into law by the Washington State Legislature, because the authors of these suggestions clearly stated that these recommendationd were <u>not</u> crrently a Law, a rule, or a regulation, and <u>should not</u> be adopted as such. If the Commission endorsed these guidelines

to be admited into law, why did they not take the advice stating they should not be a law, rule, or regulation? They are mearly recommendations compose by tthe Center for Disease Control. These individuals who have posited financially, have no business forcing their opinions on the residents of Washington State so that they may enjoy financial gain. The group PROP, is financed by Phoenix House, which owns a chain of rehab centers.

Additionally the governship, creation of. monitoring, testing, advising, and supervision of manufacturing of medications in the Federal Govt fall on the Food and Drug Administratoion, , not the Center for Disease Control, which has no business assuming the duties of the FDA, Nor does it have the executive power to overtake and duties of the FDA. THe FDA has not asked the CDC for advise or assistance in fulfilling their mandate as directed by Federal Laws and Statues.

In fact, the FDA has issued policy letters in direct contradiction to many parts of the CDC guidelines, citing many of those suggestions to policy as dangerous and sometime possibly fatal!

The procedures used when creating the 2016 CDC guidelines, and the policy used when selecting individual members of the Advisory Committee were in violation of the "FEDERAL ADVISORY COMMITTEE ACT".

The Washington State Medical Commission, at that time, had the responsibility to investigate if the published CDC guidelines were created in correspondence with State and Federal laws. Attached documents indicate that as early as December 22nd, 2015, questions by Federal elected officials were publically released indicating a possible violation of the Federal Advisory Committee Act. (Attached)

Among other requirements, this Act states:

(4) standards and uniform procedures should govern the establishment, operation, administration, and duration of advisory committees;

The CDC did not follow this requirement by violating the following:

(5) the Congress and the public should be kept informed with respect to the number, purpose, membership, activities, and cost of advisory committees; and

The CDC did not allow members of the public to be aware of whom was appointed to this advisory committee. (Membership)

) the function of advisory committees should be advisory only, and that all matters under their consideration should be determined, in accordance with law, by the official, agency, or officer involved.

Major portions in the 2016 CDC guidelines, as published, violate Civil Rights, ADA, and Federal Laws currently in effect. (See #3 Below).

(2) require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;

As we now know, this advisory committe was NOT fairly balanced. Most members were historicaly Anti-Opiod, and many had existing Conflicts of Interest.

(3) contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment;

See comment on #2 above

(a)(1) Each advisory committee meeting shall be open to the public.

CDC Advisory Committee meetings were not open to the public and were held in secret.

(3) Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to such reasonable rules or regulations as the Administrator may prescribe.

The attempted compliance with this requirement by the CDC was a joke at best. It had to be rescheduled, expanded, and extended, in their attempt at compliance.

(b) Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

Many groups who represented Chronic Pain Patients, and several Media Organizations requested written documents under the Freedon of Information Act. If the CDC provided ANY documents at all, they were heavily REDACTED, and in some cases, the names of individual comittee members were removed from those released documents, (See attached

Undisclosed Conflicts of Interest by Physicians Creating the CDC Opioid Prescribing Guidelines: Bad Faith or Incompetence?)

(c) Detailed minutes of each meeting of each advisory committee shall be kept and shall contain a record of the persons present, a complete and accurate description of matters discussed and

conclusions reached, and copies of all reports received, issued, or approved by the advisory committee. The accuracy of all minutes shall be certified to by the chairman of the advisory committee.

See Comment above.

§11. Availability of transcripts; "agency proceeding"

(a) Except where prohibited by contractual agreements entered into prior to the effective date of this Act, agencies and advisory committees shall make available to any person, at actual cost of duplication, copies of transcripts of agency proceedings or advisory committee meetings.

See above comments.

The Washinton State Medical Commission stated duties and responsibilities are:

"The mandate of the Washington Medical Commission (WMC) is to protect the public's health and safety and to promote the welfare of the state......"

I believe they had the responsibility to investigate the QUALITY of compliance in the creation of the 2016 CDC guidelines. They Did Not. I also believe they had the responsibility to investigate the "Balance" of appointed members to this committee to be fair and equitable. They did not. And to investigate if any of these appointed members had a "Conflict of Interest" They did not . As we now know, the committee was composed of members who had conflicts of interest and a previous disposition against Opioid prescribing.

The Medical Commission, at that time, suggested and approved these guideline to the State Legislature, and supported their adoption as LAW. should have included a "Professional" investigation of legal compliance and confirmed an unbiased and failry balanced committee membership on the panel that advised the CDC and created these "Guidelines".

(b) Whether the rule is needed;

If ever, this rule is no longer needed as it is innefective. The intended purpose was to reduce opioid availability through diversion and abuse and illicit sales contributing to overdoses, injuries , and deaths. According to statistics, since date of enactment in 2016 and 2021 There has been a 40% reduction in opioids prescribed in Washington State, however there has been an increase in injuries and overdoses indication that monitoring, targeting chronic pain patients with specific rules and regulations, requiring drug tests and pill counts, was ineffective from 2016 to 2021, in reducing overdoses. Since publication of the CDC Guideline for prescribing opioids for chronic pain in 2016, annual opioid-associated deaths have doubled (to 74,000); 84% occur in people using illicit drugs. The Guideline has also created a

crisis in the care of the 15–20 million Americans with moderate to severe chronic pain

This proves that there is NO relationshipbetween prescribing opioids, and the rate of opioid overdose deaths. These laws are not needed because they do not fulfill their intended purpose. And have resulted in an increase in Patient Deaths across Washington State. They have had just the opposite effect in relation to overdose death rates!

(c) Whether the rule conflicts with or duplicates other federal, state, or local laws;

This rule violates Federal Americans with Disabilities Act, Section 36 MBLIILLL

and the U.S. Constitution specifically the right to be free from unreasonable search and seizure.

Patients who suffer from Chronic Pain have a disability within the meaning of 42 U.S.C. § 12102 and 28 C.F.R. § 36.104. Chronic Pain is an impairment that substantially limits one or more major life activity.

Title III of the Americans with Disabilities Act

When a Chronic Pain Patient refuses to sign a "Pain Contract/Agreement" they are denied further medical care and their prescriptions for Pain Medications.

1.

Denying an individual or class of individuals, (Chronic Pain Patients) on the basis of disability, the ability to participate in or benefit from its goods, services, facilities, privileges, advantages, or accommodations by refusing to provide pain management treatment, in violation of 42 U.S.C. § 12182(b)(1)(A)(i) and 28 C.F.R. § 36.202;

2.

Using standards or criteria or methods of administration that have the effect of discriminating on the basis of disability, is in violation of 42 U.S.C. § 12182(b)(1) (D) and 28 C.F.R. § 36.204;

Imposing or applying eligibility criteria that screen out, or tend to screen out, an individual with a disability or class of individuals with disabilities from fully and equally enjoying any Medical Facilities goods, services, facilities, privileges, advantages, or accommodations, in violation of 42 U.S.C. § 12182(b)(2)(A)(i) and 28 C.F.R. § 36.301(a).

4.

As a result of this Washington State Laws discriminatory conduct, Chronic Pain Patients are suffering physical pain and emotional distress. Chronic Pain Patients and other persons who may have been the victims of these State Laws, and are victims of these discriminatory practices are aggrieved persons under 42 U.S.C. § 12188(b)(2)(B)

When chronic pain patient are singled out as the only patients required to sign pain contracts or agreements, abd they refuse to sign an Agreement, or Contract, when their treatment is cut off and their request to have theri prescriptions refilled, this constitutes discrimination on the basis of disability in violation of the Rehabilitation Act of 1973, §504, 87 Stat. 394,

as amended, 29 U. S. C. §794(a), and the Patient Protection

and Affordable Care Act, §1557, 124 Stat. 260, 42 U. S. C.

<u>§18116.</u>

And when Pain Patients are denied pain medication because of a positive urine drug screen, this also violated Federal Law. The current laws and their interpretation by the State Medical Commission, dictate that if a Pain Patient refuses to sign a Pain Contract or Agreement, his or her Physician is directed to withold treatment, and discontinue filling their current opioid prescriptions. Also, if a Pain Patient has a positive drug test, in accordance with Washington State Medical Commission regulations and Laws adopted at the beheast of same, their physician is to withold their opioid prescriptions, and/or treatment.

I call your attention to:

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR PART 35

Nondiscrimination on the Basis of Disability in State and Local Government Services

AGENCY: Department of Justice.

ACTION: Final rule.

Paragraph (b) of {35.131 Illegal use of drugs. provides a limited exception to the exclusion of current illegal users of drugs from the protections of the Act. It prohibits denial of health services, or services provided in connection with drug rehabilitation to an individual on the basis of current illegal use of drugs, if the individual is otherwise entitled to such services. A health care facility, such as a hospital or clinic, may not refuse treatment to an individual in need of the services it provides on the grounds that the individual is illegally using drugs, but it is not required by this section to provide services that it does not ordinarily provide. For example, a health care facility that specializes in a particular type of treatment, such as care of burn victims, is not required to provide drug rehabilitation services, but it cannot refuse to treat a individual's burns on the grounds that the individual is illegally using drugs.

(d) Whether alternatives to the rule exist that will serve the same purpose at less cost;

The best alternative would be the immediate repeal of all discriminatory laws that single out Chronic Pain Patients from other patients who receive opioid medications. Thus ending the discriminatory practices now in effect. The pain and anguish that Chronicx Pain Patients, is as real as any pain suffered by other individuals.

An alternative would be the adoption of rules requiring all Health Care Employees, and staff at Assisted Living Facilities and Rest Homes, and Hospitals and Clinics to provide urine samples for drug screening each and every month. Residents of all of these facilities are now exempt from the rigors of current law. Given 6% to 12% of Physicians will have a drug problem sometime in their profession., perhaps they too can be drug tested. Nurses and CNA's also could be tested . Currently, 6% to 20% of Nurses and nursing staff, have a problem with drug addictions and theft of medications. And one in five employees currenly employed in Washington State at Rest Homes and Assisted Living Facilities have at least one criminal record. These individuals have more of an opportunity to steal and divert drugs, as they have the opportunity to divert or steal them on a daily basis

A perfect option would be to enact a rule requiring ANYONE seeking health and or dental care to be required to submit to drug screening. And to require Medical Doctors, Dentists, Nurses, Nursing Assistants, CNA's, and everyone, even Janitors who work with or in the medical or DRUG MANUFACTIURING industry. Let also Drug Test Law Enforcement Officials, who, on a daily basis, have unhindered access to illicit drugs. People who make important life and death decisions that affect us all, Senators, Congressmen, Legislative Representatives, Judges, and even the President and his Staff. Lets not forget Military personnel!

Perhaps we could go Door to Door and drug test EVERYONE in the State. This would surely put an end to drug abuse and diversion. But I do not see this happeneing soon. Because we are guaranteed certain rights and freedoms, BY LAW!

(e) Whether the rule applies differently to public and private entities;

Many washington patients receive Opioid Medications in washington state, but only long term Chronic Pain Patients are required to sign contracts, respond to "Pill Counts", provide urine samples for Drug Screens, and agree to other terms and conditions in said contracts, that other patients who receive opioid medications are <u>not</u> subjected to.

<u>Only</u> long term Chronic Pain Patients are required to comply with the adopted rules, regulaions and laws, specifically encated regarding the prescribing of opiods in Washington State. Thousands of patients receive opioid medications, buy only chronic pain patients must comply with additional terms, conditions, and regulations, in order to receive the SAME medications and medical treatment.

These Laws affect a "Protected Class" of Washington residents. Disabled chronic Pain Patients are singled out and are required to comply with requirements that effect them, and only them.And require them and only them, to meet certain requirements and submit to drug tests and the recording of personal health information. ONLY CHRONIC PAIN PATIENTS ARE REQUIRED TO SIGN PAIN CONTRACTS AND SUBMIT TO DRUG TESTING. Any and all other patients who receive opioid pain medications, are EXEMPT from said Laws. This singles out Chronic Pain Patients, requiring them to be subjected to additional rules and regulations, that other opioid patients do not have to comply with, and discriminates against them by establishing laws that affect them, and only them. Other opioid patients, are treated differently and receive their medications without the numerous additional requirements
(f) Whether the rule serves the purposes for which it was adopted;

These laws were created and adopted in response to the increased overdose death rate for opioids. And were adopted with the intent of lowering Washington State opioid overdose death rates. However, as Prescribing for opioids has fallen 40% TO 60%, overdose rates for opioids have risen over 70%. This proves that there is NO corrolation between prescribing opioids, and the rate of opioid overdose deaths. These laws are not needed because they do not fulfill their intended purpose. And have resulted in an increase in Patient Deaths across Washington State. They have had just the opposite effect in relation to overdose death rates!

This rule has <u>not</u> reduced opioid overdose in Washington State from date of enaction 2016 toperesent date of 2021. And the Overdose rate has risen dramatically. Chronic Pain Patients are suffering needlessly, daily, driving some to suicide.

(g) Whether the costs imposed by the rule are unreasonable;

The costs associated with the existing rules are inhumane and immoral. Long term Chronic Pain Patients are improperly and illegaly having their opioid medication reduced, tapered, and cut off, resulting in pain, agaony, and suffering, Some resorting to suicide as their only alternative to their lack of proper Medcal Care.

These rules were NOT adopted according to all applicable provisions of law because, it is apparent to me that it was never examined by legal staff of Washinton State Medical Commission to see if it conflicted with Federal laws, the ADA laws, HIPPA Laws and/or the Constitution of the United States of America

(h) Whether the rule is clearly and simply stated;

This rule is not clearly and simply stated because it does not specifically atate that a Physician is to cut off and/or reduce opioid prescribing for existing opioid patients, but the threat of prosecution by Law Enforcement <u>implies</u> this action under the direction of the Washington State Medical Commission. This rule does not specificall state that a Physician is to cut off the existing opioid medcicatios of an existing aptient of that patient refuses to sign a pain contract or agreement. But the WSMC implies and advises Physicians to do so.

(i) Whether the rule is different than a federal law applicable to the same activity or subject matter without adequate justification;

This law is different from Federal Laws which state clearly that a patient may not be denied medical care because that person is currently using illicit drugs.

(j) Whether the rule was adopted according to all applicable provisions of law.

These rules were NOT adopted according to all applicable provisions of law because, it is apparent to me that it was never examined by legal staff of the previous Washinton State Medical Commission to see if it conflicted with Federal laws, the ADA laws, HIPPA Laws and/or the Constitution of the United States.

When the CDC drafted these 'SUGGESTIONS", it violated the "Federal Advisory Committee Act". The Washington State Medical Commission, before suggesting these "Suggested Guidelines" be enacted into Law, had the responsibility to investigate the proper creation of these "Guidelines". As you can see in the attached "Congress Investigating CDC's Opioid Guidelines" this information was available to the Commission as far back as December 22, 2015, before these laws were created.

PLEASE SEE ATTACHED: Congress Investigating CDC's Opioid Guidelines

Please read and consider this attachment, as it is a part of my petition.

This article was attached with the permission of it's author, but does not indicate that author shares all of my opinions regarding this petition.

Additionally, several key members in the creation of these guidelines, reside in Washington State , and have benefited financially from their becoming Law.

Please see attached: "Undisclosed Conflicts of Interest by Physicians Creating the CDC Opioid Prescribing Guidelines: Bad Faith or Incompetence?" Please read and consider this attachment, as it is a part of my petition.

This article was attached with the permission of it's author, but does not indicate that author shares all of my opinions regarding this petition.

THE AUTHORS AND THE MANAGEMENT OF THE CDC HAVE PUBLICALLY STATED THAT THEIR "SUGGESTED RULES" OF 2016 WERE NEVER INTENDED TO BE ADOPTED AS LAWS.

THEY HAVE ACKNOWLEDGED THAT:

THE CDC HAS ACKNOWLEDGED THAT THEIR "SUGGESTED" GUIDELINES ARE BEING MISINTERPRETED BY MOST PHYSICIANS

THE PRESCRIBING OF OPIOID MEDICATION HAS FALLEN OVER 40%

THE OVERDOSE RATE HAS RISEN SUBSTANTIALLY

THAT CHRONIC PAIN PATIENTS ARE BEING ABANDONED

THAT CHRONIC PAIN PATIENTS ARE UNABLE TO FIND DOCTORS TO TREAT THEM

SOME PAIN PATIENTS HAVE BEEN DRIVEN TO SUICIDE BECAUSE OF THEIR UNTREATED PAIN

DOCTORS ARE REFUSING TO ACCEPT PAIN PATIENTS BECAUSE OF THESE LAWS

PATIENTS HAVE HAD THEIR PRESCRIPTIONS CUT OFF SUDDENLY WITHOUT TAPERING

UNTREATED CHRONIC PAIN LEADS TO OTHER SIGNIFICANT HEALTH CONCERNS

THEIR ORIGINAL DATA , DECLARING AN "OPIOID CRISES" WAS FLAWED, AND COMBINED ILLICIT STREET DRUGS WITH PRESCRIPTION OPIOID MEDICATIONS WHICH RESULTED IN THEIR INITIAL CONCLUSION A CRISES WAS OCCURRING

Prescription opioid were counted togetter wight herion, and fentanal deaths. Most ovewrdose deaths were a ressult of a combination of drugs, not just one specific prescribed medication. Coroners do not administer specific tests to seperate those attributed to heroin, fentanal, xanax, and/or prescription opioid medications/. The actiual number of diverted opion medications legally prescribed in Washinton State is unknow by the CDC, FDA or the DEA.

The CDC now admits they over estimated the overdoses attributed to prescriptions by about 100 % and the actual number of deaths where just a prescription opioid drug, and wherre a

combination of a prescribed opid medication and othe illicit drug , are one half of it's original and published estimations.

ADDITIONAL FACTS:

1. CHRONIC PAIN PATIENTS ARE SUFFERING NEEDLESSLY IN PAIN AND AGONY, DRIVING SOME TO SUICIDE.

2. THE LAWS HAVE RESULTED IN MILLIONS OF CHRONIC PAIN PATIENTS WITHOUT MEDICAL CARE OF ANY KIND.

3. THE COMPILING AND RECORDING OF SENSATIVE, PROTECTED HEALTH INFORMATION IS BEING RECORDED, AS REQUIRED BY THESE LAWS, IN DIRECT VIOLATION OF FEDERAL LAWS AND HIPPA LAWS. IN MOST STATES, CAN BE ACCESSED BY LAW ENFORCEMENT WITHOUT A SUPEONA OR COURT ORDER, IN VIOLATION OF CIVIL RIGHTS LAWS, AND CONSTITUTIONAL LAW PROTECTING INDIVIDUALS FROM UNREASONABLE SEARCH AND SEIZURE WITHOUT PROBABLE CAUSE. AND ARE AN INVASION OF PRIVACY.

4. CHRONIC PAIN PATIENTS ARE "BLACKMAILED" INTO SIGNING THESE CONTRACTS/AGREEMENTS. SIGN THIS DOCUMENT OR WE WILL WITHHOLD YOUR CURRENT PAIN MEDICATIONS. LAST TIME I CHECKED, BLACKMAIL WAS AGAINST THE LAW IN MOST STATES.

5. It has been six years since the adoption of the CDC's suggested guidelines, and despite all of the harm it has caused chronic pain patients, nothing has been done to remedy the current situation, resulting in the thousands of Washington States Chronic pain patients suffering needlessly.

6. Taking into account of the above, the actual deaths from prescribed opioid medication has never risen above an actual and expected increase due to normal increases in medication abuse across the country.

7. The CDCw was advise by a group know as PROP, Physicians for Responsible Opioid Prescribing. DR Chow was on the initial panel which drafted the Guidelines, and is now on the panel to ammend said guidelines. He is not a member of the CDC, the FDA, or the DEA. These are not Govt officials action in an official capacity as a govt employee. they are members of a private, non elected, and non appointed private group that has comflicts of interest as they receive monies for speaking out against the prescribing of opioids.

OPINION

It's Time to Undo the Harm the CDC Has Done to Pain Patients | Opinion

JEFFREY A. SINGER AND JOSH BLOOM , SENIOR FELLOW AT THE CATO INSTITUTE; DIRECTOR OF CHEMICAL AND PHARMACEUTICAL SCIENCE AT THE AMERICAN COUNCIL ON SCIENCE AND HEALTH

ON 9/21/22 AT 2:13 PM

After the U.S. Centers for Disease Control suggested dosage thresholds for patients receiving pain medication in 2016, 38 states rushed to pass legal limits on opioid prescribing and dispensing. Even though the CDC insisted the guidance was "voluntary, rather than prescriptive standards," states wanted to signal they were being tough on opioids. So they enacted tougher laws, even though CDC guidelines recommended dosing thresholds based upon the "morphine milligram equivalents" (MMEs) of the various opioids, a metric that never made sense, was not evidence-based, and amounted to "junk science."

Learning that its guidelines were being misinterpreted and misapplied, the CDC published an advisory in 2019, emphasizing that it never intended doctors to abruptly taper their patients from their pain medications, some of whom had been flourishing on high-dose opioid therapy for years, to its "approved" MME metrics.

But the advisory was too little too late for doctors and patients in states where legislation was already in place.

When a government agency "recommends" a policy, it's akin to a recommendation from Tony Soprano; it is inevitably interpreted as a mandate, obeyed by state and federal agencies, health insurers, and even pharmacies.

Over the past several months, lawmakers around America have begun re-examining existing state laws that have strictly limited and prescribed how health care practitioners can treat pain, which is a clear violation of both physicians' and patient's rights.

In Minnesota, for instance, a new law that went into effect Aug. 1 protects health care practitioners from disciplinary action if, based upon their good-faith professional judgment, they prescribe opioids to patients with intractable pain, regardless of the dose. Arizona and Alabama have also put in place some incremental reforms this year, although they have yet to enact significant revisions to the opioid prescribing regulations passed based on the CDC's recommendations.

<u>Those "recommendations" caused millions of patients to suffer. Some, unable to acquire adequate</u> <u>amounts of medication, sought relief in the dangerous black market, where they inadvertently</u> <u>purchased deadly illicit fentanyl. Others were driven to suicide, and some to homicide. Many in the U.S.</u> <u>became so-called "pain refugees," unable to find any doctors to help them. As an unintended</u> <u>consequence, patients are now under-treated for acute, even postoperative pain—ridiculous and cruel</u> by any measure. To justify these cruel policies, we're often told that prescribing opioids to pain patients caused the overdose crisis. And yet, this "fact"—the basis of the CDC's advice—turned out to be a fallacy. There turns out to be no correlation between the number of opioid prescriptions and the non-medical use of or addiction to prescription pain killers. Data from the National Survey on Drug Use and Health shows that the addiction rate among persons aged 18 and above has remained essentially unchanged throughout the 21st century, despite prescription rates surging to record highs in the early 2000s and then, after 2012, dropping 60 percent.

Despite a huge decrease in opioid prescribing, the overdose rate continues to skyrocket, and modelers predict it will soon dramatically accelerate, as illegal drugs become more potent and deadly.

Responding to complaints by patient advocacy groups, medical scholars, and the American Medical Association, the CDC decided it will publish a revised opioid prescribing guideline by the end of this year. It requested comments on a draft proposal made public last February. We both submitted comments. But no matter how much the CDC stresses that the 2022 revision is merely a recommendation, ill-advised laws will be difficult to overturn.

Minnesota lawmakers deserve high marks in undoing some of the harms that the CDC has inflicted on pain patients and their physicians, and hopefully the state's actions will soon be followed by others. But until the CDC gets out of the business of telling doctors how to practice medicine, none of us can feel safe.

TO:

Washington State Medical Association Emergency Nurses Association Washington State Hospital Association American College of Emergency Physicians, Washington Chapter Washington State Department of Health Washington State Department of Social and Health Services Washington Department of Labor and Industries Washington Poison Center Washington Pain Physicians

Dear Sirs,

Please be advised that somje of your "opioid Prescribing Guidelines" are in violation of Federal Law.

Your publically stated rules say:

Washington Emergency Department Opioid Prescribing Guidelines

"Urine drug testing for illicit and prescribed substances requires a working knowledge of the potential forfalse positive and false negative results and the need for confirmatory testing. A discussion on thelimitations of urine testing is beyond the scope of this guideline. Other chronic pain guidelines address urine drug testing in detail6. <u>Urine drug testing has to potential to identify patients using illicit</u> <u>drugs or not taking medications they report being prescribed. Both of these situations are grounds for denying further opioid prescriptions.</u> Clinicians knowledgeable at interpreting the results of the urine drug testing are encouraged to perform urine drug testing before prescribing opioids for exacerbations of chronic pain.

You cannot deny a patient opioid medications because they are currently using illicit drugs.

It conflicts with another federal, state, or local law

This rule violates Federal Americans with Disabilities Act, Section 36 MBLILLL

and the U.S. Constitution.

Patients who suffer from Chronic Pain have a disability within the meaning of 42 U.S.C. § 12102 and 28 C.F.R. § 36.104. Chronic Pain is an impairment that substantially limits one or more major life activity.

Title III of the Americans with Disabilities Act

When a Chronic Pain Patient refuses to sign a "Pain Contract/Agreement" they are denied further medical care and their prescriptions for Pain Medications.

1.

Denying an individual or class of individuals, (Chronic Pain Patients) on the basis of disability, the ability to participate in or benefit from its goods, services, facilities, privileges, advantages, or accommodations by refusing to provide pain management treatment, in violation of 42 U.S.C. § 12182(b)(1)(A)(i) and 28 C.F.R. § 36.202;

2.

Using standards or criteria or methods of administration that have the effect of discriminating on the basis of disability, is in violation of 42 U.S.C. § 12182(b)(1) (D) and 28 C.F.R. § 36.204;

3.

Imposing or applying eligibility criteria that screen out, or tend to screen out, an individual with a disability or class of individuals with disabilities from fully and equally enjoying any Medical Facilities goods, services, facilities, privileges, advantages, or accommodations, in violation of 42 U.S.C. § 12182(b)(2)(A)(i) and

28 C.F.R. § 36.301(a).

4.

As a result of this Washington State Laws discriminatory conduct, Chronic Pain Patients are suffering physical pain and emotional distress. Chronic Pain Patients and other persons who may have been the victims of these State Laws, and are victims of these discriminatory practices are aggrieved persons under 42 U.S.C. § 12188(b)(2)(B)

And when Pain Patients are denied pain medication because of a positive urine drug screen, this also violated Federal Law. The current laws and their interpretation by the State Medical Commission, dictate that if a Pain Patient refuses to sign a Pain Contract or Agreement, his or her Physician is directed to withold treatment, and discontinue filling their current opioid prescriptions. Also, if a Pain Patient has a positive drug test, in accordance with Washington State Medical Commission regulations and Laws adopted at the beheast of same, their physician is to withold their opioid prescriptions, and/or treatment.

<u>I call your attention to:</u>

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR PART 35

Nondiscrimination on the Basis of Disability in State and Local Government Services

AGENCY: Department of Justice.

ACTION: Final rule.

Paragraph (b) of {35.131 Illegal use of drugs. provides a limited exception to the exclusion of current illegal users of drugs from the protections of the Act. It prohibits denial of health services, or services provided in connection with drug rehabilitation to an individual on the basis of current illegal use of drugs, if the individual is otherwise entitled to such services. A health care facility, such as a hospital or clinic, may not refuse treatment to an individual in need of the services it provides on the grounds that the individual is illegally using drugs, but it is not required by this section to provide services that it does not ordinarily provide. For example, a health care facility that specializes in a particular type of treatment, such as care of burn victims, is not required to provide drug rehabilitation services, but it cannot refuse to treat a individual's burns on the grounds that the individual is illegally using drugs.

PAIN CONTRACTS UNLAWFUL

WAC 162-26-140

Unfair to request or require waiver of rights.

This section is intended to prohibit waivers on the basis of disability, but is not intended to preclude waivers required on a nondiscriminatory basis.

(1) It is an unfair practice for any person to request or require another person to waive rights or hold anyone harmless as a condition of the use or enjoyment of a place of public accommodation by a disabled person.

(2) It is an unfair practice to request or require another person to waive rights or hold anyone harmless as a condition of the use or enjoyment of a place of public accommodation by a disabled person using a dog guide or service animal.

WAC 162-26-120

Requirements of other law.

(1) Guidance. Failure to meet requirements of related law protecting persons with disabilities in places of public accommodation may be evidence of an unfair practice under RCW 49.60.215. The commission may refer to standards established in related law for guidance in determining whether an unfair practice under RCW 49.60.215 has occurred.

(2) References to selected laws. Related law may include, but is not limited to:

(a) Chapter 28A.13 RCW (education for handicapped children);

(b) Sections 503 and 504 of the United States Rehabilitation Act of 1973, 29 U.S.C. §§793 and 794;

- (c) Chapter 70.84 RCW, the "white cane law";
- (d) Chapter 2.42 RCW (Interpreters in legal proceedings);
- (e) The Washington State Building Code;
- (f) The Americans with Disabilities Act of 1990;
- (g) The Individuals with Disabilities Education Act;
- (h) The Air Carriers Access Act;
- (i) The Federal Fair Housing Act.

Washington State Legislature

PrintRCWs > Title 49 > Chapter 49.60 > Section 49.60.215

49.60.214 << 49.60.215 >> 49.60.220

RCW 49.60.215

Unfair practices of places of public resort, accommodation, assemblage, amusement—Trained dog guides and service animals.

It shall be an unfair practice for any person or the person's agent or employee to commit an act which directly or indirectly results in any distinction, restriction, or discrimination, or the requiring of any person to pay a larger sum than the uniform rates charged other persons, or the refusing or withholding from any person the admission, patronage, custom, presence, frequenting, dwelling, staying, or lodging in any place of public resort, accommodation, assemblage, or amusement, except for conditions and limitations established by law <u>and applicable to all persons</u>, regardless of race, creed, color, national origin, citizenship or immigration status, sexual orientation, sex, honorably discharged veteran or military status, status as a mother breastfeeding her child, the presence of any sensory, mental, or physical disability, or the use of a trained dog guide or service animal by a person with a disability: PROVIDED, That this section shall not be construed to require structural changes, modifications, or additions to make any place accessible to a person with a disability except as otherwise required by law: PROVIDED, That behavior or actions constituting a risk to property or other persons can be grounds for refusal and shall not constitute an unfair practice.

Washington State Legislature

WACs > Title 162 > Chapter 162-26 > Section 162-26-120

HTML has links - PDF has AuthenticationPrint This Page

162-26-110 << 162-26-120 >> 162-26-130

No agency filings affecting this section since 2003

WAC 162-26-120

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- (h) The Air Carriers Access Act;
- (i) The Federal Fair Housing Act.

Washington State Legislature

PrintRCWs > Title 49 > Chapter 49.60 > Section 49.60.030

49.60.020 << 49.60.030 >> 49.60.040

RCW 49.60.030

Freedom from discrimination—Declaration of civil rights.

(1) The right to be free from discrimination because of race, creed, color, national origin, citizenship or immigration status, sex, honorably discharged veteran or military status, sexual orientation, or the presence of any sensory, mental, or physical disability or the use of a trained dog guide or service animal by a person with a disability is recognized as and declared to be a civil right. This right shall include, but not be limited to:

(a) The right to obtain and hold employment without discrimination;

(b) The right to the full enjoyment of any of the accommodations, advantages, facilities, or privileges of any place of public resort, accommodation, assemblage, or amusement;

(c) The right to engage in real estate transactions without discrimination, including discrimination against families with children;

(d) The right to engage in credit transactions without discrimination;

(e) The right to engage in insurance transactions or transactions with health maintenance organizations without discrimination: PROVIDED, That a practice which is not unlawful under RCW 48.30.300, 48.44.220, or 48.46.370 does not constitute an unfair practice for the purposes of this subparagraph;

(f) The right to engage in commerce free from any discriminatory boycotts or blacklists. Discriminatory boycotts or blacklists for purposes of this section shall be defined as the formation or execution of any express or implied agreement, understanding, policy or contractual arrangement for economic benefit between any persons which is not specifically authorized by the laws of the United States and which is required or imposed, either directly or indirectly, overtly or covertly, by a foreign government or foreign person in order to restrict, condition, prohibit, or interfere with or in order to exclude any person or persons from any business relationship on the basis of race, color, creed, religion, sex, honorably discharged veteran or military status, sexual orientation, the presence of any sensory, mental, or physical disability, or the use of a trained dog guide or service animal by a person with a disability, or national origin, citizenship or immigration status, or lawful business relationship: PROVIDED HOWEVER, That nothing herein contained shall prohibit the use of boycotts as authorized by law pertaining to labor

disputes and unfair labor practices; and

(g) The right of a mother to breastfeed her child in any place of public resort, accommodation, assemblage, or amusement.

(2) Any person deeming himself or herself injured by any act in violation of this chapter shall have a civil action in a court of competent jurisdiction to enjoin further violations, or to recover the actual damages sustained by the person, or both, together with the cost of suit including reasonable attorneys' fees or any other appropriate remedy authorized by this chapter or the United States Civil Rights Act of 1964 as amended, or the Federal Fair Housing Amendments Act of 1988 (42 U.S.C. Sec. 3601 et seq.).

(3) Except for any unfair practice committed by an employer against an employee or a prospective employee, or any unfair practice in a real estate transaction which is the basis for relief specified in the amendments to RCW 49.60.225 contained in chapter 69, Laws of 1993, any unfair practice prohibited by this chapter which is committed in the course of trade or commerce as defined in the Consumer Protection Act, chapter 19.86 RCW, is, for the purpose of applying that chapter, a matter affecting the public interest, is not reasonable in relation to the development and preservation of business, and is an unfair or deceptive act in trade or commerce.

Washington State Legislature

PrintRCWs > Title 49 > Chapter 49.60 > Section 49.60.010

Beginning of Chapter << 49.60.010 >> 49.60.020

RCW 49.60.010

Purpose of chapter.

This chapter shall be known as the "law against discrimination." It is an exercise of the police power of the state for the protection of the public welfare, health, and peace of the people of this state, and in fulfillment of the provisions of the Constitution of this state concerning civil rights. The legislature hereby finds and declares that practices of discrimination against any of its inhabitants because of race, creed, color, national origin, citizenship or immigration status, families with children, sex, marital status, sexual orientation, age, honorably discharged veteran or military status, or the presence of any sensory, mental, or physical disability or the use of a trained dog guide or service animal by a person with a

disability are a matter of state concern, that such discrimination threatens not only the rights and proper privileges of its inhabitants but menaces the institutions and foundation of a free democratic state. A state agency is herein created with powers with respect to elimination and prevention of discrimination in employment, in credit and insurance transactions, in places of public resort, accommodation, or amusement, and in real property transactions because of race, creed, color, national origin, citizenship or immigration status, families with children, sex, marital status, sexual orientation, age, honorably discharged veteran or military status, or the presence of any sensory, mental, or physical disability or the use of a trained dog guide or service animal by a person with a disability; and the commission established hereunder is hereby given general jurisdiction and power for such purposes.

To single out chronic pain patients and deny them medical care because they are currently using illicit drugs, is a violation of Federal and Constitutional Law.

I was wondering, do you require urine drug tests for ANYONE seeking ANY medical care? If you do not, this is a discriminatory practice!

I suggest you immediently repeal any and all rules or guidelines that are discriminatory against pain patients.

YOU HAVE BEE SO ADVISED.

I nRd

Thomas M. Bertsch Captain Cal-Fire Disability Retired Long Term Chronic Pain Patient

RECEIVED

OCT 31 2022

TO: WASHINGTON STATE MEDICAL COMMISSION

MEDICAL COMMISSION

FROM: THOMAS M. BERTSCH

SUBJEST: AMMENDMENT REQUEST OF CURRENT LAW.

Dear Sirs,

In accordance with RCW 34.05.330, please find my enclosed Petition to AMMEND a Washington State Law.

Sincerely,

Sham Ba

Thomas M. Bertsch



PETITION FOR ADOPTION, AMENDMENT, OR REPEAL OF A STATE ADMINISTRATIVE RULE

In accordance with <u>RCW 34.05.330</u>, the Office of Financial Management (OFM) created this form for individuals or groups who wish to petition a state agency or institution of higher education to adopt, amend, or repeal an administrative rule. You may use this form to submit your request. You also may contact agencies using other formats, such as a letter or email.

The agency or institution will give full consideration to your petition and will respond to you within 60 days of receiving your petition. For more information on the rule petition process, see Chapter 82-05 of the Washington Administrative Code (WAC) at <u>http://apps.leg.wa.gov/wac/default.aspx?cite=82-05</u>.

CONTACT INFORMATION (please type or print)

Petitioner's Name	Thomas M. Bertsch			
Name of Organization	VARIOUS CHRONIC PAIN SOCIAL PL	ATFORM GR	OUPS	
Mailing Address 1006	N. PARK ST			
City <u>COLFAX</u>		State <u>wa</u>	Zip Code	99111
Telephone 509-288-967	70	Email BERTSCH_THOMAS@YAHOO.COM		

COMPLETING AND SENDING PETITION FORM

- Check all of the boxes that apply.
- Provide relevant examples.
- Include suggested language for a rule, if possible.
- Attach additional pages, if needed.
- Send your petition to the agency with authority to adopt or administer the rule. Here is a list of agencies and their rules coordinators: <u>http://www.leg.wa.gov/CodeReviser/Documents/RClist.htm</u>.

INFORMATION ON RULE PETITION

Agency responsible for adopting or administering the rule:

1. NEW RULE - I am requesting the agency to adopt a new rule.

The subject (or purpose) of this rule is:

The rule is needed because:

The new rule would affect the following people or groups:

List rule number (WAC), if known: <u>WAC 246</u>	-918-801 EXCLUSIONS
	6) The treatment of chronic pain patients who are 65 years of age, or older, who have been previously prescribed opioid medications at any time in their medical history.
S	EE ATTACHED
This change is needed because:	
	SEE ATTACHED
The effect of this rule change will be:	
The rule is not clearly or simply stated:	
3. REPEAL RULE - I am requesting the a	gency to eliminate an existing rule.
List rule number (WAC), if known:	
(Check one or more boxes)	
It does not do what it was intended to do).
It is no longer needed because:	
It imposes unreasonable costs:	
The agency has no authority to make the	iis rule:
It is applied differently to public and priv	vate parties:
It conflicts with another federal, state, o rule. List conflicting law or rule, if know	
It duplicates another federal, state or lo List duplicate law or rule, if known:	cal law or rule.
Other (please explain):	

Thomas M. Bertsch

Captain Cal-Fire

Disability Retired

1006 N. Park St. Colfax, WA. 99111 509-288-9670

10/21/2022

Dear Sirs,

Please find enclosed, my "Petition" to AMEND

WAC 246-918-801 EXCLUSIONS

WAC 246-918-800 THROUGH WAC 246-918-935 do not apply to:

My request is that this rule be ammended as follows:

ADD:

(6) The treatment of chronic pain patients who are 65 years of age, or older, who have been previously prescribed opioid medications at any time in their medical history.

If this accomodation and ammedment can be achieved, I would withdraw my previous request for the repeal of several laws regarding the prescribing of opioids in Washington State. Attached are my reasons for requesting this ammendment.

Sincerely,

Ab m an

Thomas M. Bertsch

Captain

Cal-Fire

Disability Retired

10/21/2002 SUBMITTED BY THOMAS M. BERTSCH

GENERAL DISCUSSION

Long Term Chronioc Pain patients suffer REAL pain. THeir pain is as real as any Cancers Patients pain. Their pain is as real as anyone living in an Assisted Living Facility, anyone living in a Nursing Home, anyone living in a Long Term Acute Care Hospital, anyone who lives in a Residential Treatment Facility, anyone who lives in a Residential Habilitation Center, anyone who lives in a Psychiatric Hospital, anyone living in a Acute Care Hospital.

To exclude the prescribing of Opioids to Patients who do not reside in these types of Facilities, is Discriminatory , Immoral, and Inhumane, and violates several ADA and Federal Laws.

Because a Pain Patient chooses to live his or her final years in their own residence, should not preclude them from receiving adequate and continued medical care for their Pain.

I understand the intent of ESHB 1427, ENACTED IN 2017 WAS TO REDUCE OVERDOSE DEATHS AND THE DIVERSION OF OPIOIDS FROM LEGALLY OBTAINED PRESCRIPTIONS. To omit my suggested Ammendment, is to accuse Chronic Pain Patients of being responsible for the Overdose Crises. Opioid prescribing has fallen over 40% in Washinton State, yet the Overdose rates continue to climb. Indicating that prescription Opioids have no bearing on Overdose Death rates.

To omit my suggested ammendment would "BlackMail" Chronic Pain Patients into taking up residence in one of those listed Facilities. Live here or we will not allow you Pain Medications, at the very least, we will require you meets certain terms and conditions not applied to other Patients who receive opioid medications on a regular basis.

It is my belief that many opioid medications are "Diverted" from Assisted Living Facilities and other residential locations that you have previously Exempted from these requirements. Perhaps you should reexamine those Exemptions.

Also., the Fact that the Medical Professionals do not have the ability to "CURE" the pain of Chronic Pain Patients, should not preclude them from receiving adequate pain relief. Especially if they are elderly and have been previously prescribed opioids.

10/21/2002 SUBMITTED BY THOMAS M. BERTSCH

Why this ammendment is needed

The CDC and the AMA have acknowledged that the CDC Guidelines are being misapplied. The CDC has acknowledged that many Chronic Pain Patients are being left without mMedical Care of ANY kind because of these misapplications of the 2016 and the 2022 CDC guidelines. The CDC expressly stated that5 these "Guidelines" were NEVER intended to become Laws. Yet every State adopted them as such.

Some Chronic Pain Patients are being driven to Suicide, because of the lack of sufficient pain relief. Many others aredriven to purchase their medications off the street or blackmarket, to allieve their pain and suffering.

In addition to their pain medications cut off, these chronic pain patients feel they can no longer trust their providers, and as such never return for healthcare for their many other ailments. Leaving these chronic pain patients without medical care of any kind.

Abandoned Chronic Pain Patients are unable to find Medical Care, as 40% of Doctors surveyed claim they will not accept new Pain Patients because they fear Prosecution by the DEA and other Law Enforcement Agencies. Pain Management Physicians are leavingthis field in excessive numbers, for the same reasons.

Would this ammendment violate other laws

This ammendment would corerect the current laws violations of Federall and ADA laws. Chronic Pain Patients would not be singled out and discriminated against , becasue of their disability and where they choose to reside.

Respectfully Submitted,

the mBL

Thomas M. Bertsch



Medical Marijuana (Cannabis) Authorization Guidelines

1.1 PURPOSE

To improve patient safety and maintain the dignity of healthcare practitioners, the regulating boards and commissions adopted professional practice standards expected of authorizing healthcare practitioners who recommend medical marijuana under Washington State law.

1.2 DEFINITIONS

Authorization. A form developed by the Department of Health that is completed and signed by a healthcare practitioner and printed on tamper-resistant paper containing the RCW 69.51A.030 logo. An authorization is not a prescription as defined in RCW 69.50.101. A patient with a valid authorization is allowed to grow up to four plants within their domicile under RCW 69.51A.210.

Authorizing healthcare practitioner. The following types of healthcare practitioners licensed in Washington State are allowed to authorize the use of marijuana to medical patients:

- Medical doctor (MD) licensed under chapter 18.71 RCW •
- Physician assistant (PA) licensed under chapter 18.71A RCW •
- Osteopathic physician (DO) licensed under chapter 18.57 RCW •
- Osteopathic physician assistant (OPA) – licensed under <u>chapter 18.57A RCW</u>
- Naturopathic physician (ND) licensed under chapter 18.36A RCW •
- Advanced registered nurse practitioner (ARNP)– licensed under chapter 18.79 RCW ٠

Certified Medical Marijuana Consultant. A person who has completed a 20-hour state-approved Medical Marijuana Consultant Certification training program and holds a valid medical marijuana consultant certificate issued by the Department of Health - WAC 246-72-010. A certified consultant works in a licensed marijuana retail store that has a medical endorsement. A certified consultant's role is to assist a patient with registration into the medical marijuana authorization database, create and issue a recognition card to the patient and assist the patient with the selection of marijuana products that may benefit the patient's medical condition - WAC 246-72-030.

Designated provider. A person who is twenty-one years of age or older and is the parent or guardian of a qualifying patient who is under the age of eighteen; or has been designated by the qualifying patient to purchase, provide or grow marijuana for the patient and has an authorization from the patient's healthcare practitioner. A designated provider can only serve one patient at any one time - RCW69.51A.010(4).

Medical marijuana authorization database. A secure and confidential database administered by the Department of Health and used by medically-endorsed marijuana retail stores to register, issue and verify recognition cards to qualifying patients and their designated providers (if any); and, used by healthcare practitioners to access health care information on their patients for the purpose of providing medical and pharmaceutical care as established under <u>RCW 69.51A.230</u>.

Medically-endorsed marijuana retail store. A marijuana retailer that has been issued a medical marijuana endorsement by the state liquor and cannabis board pursuant to <u>RCW 69.50.375</u>.

Qualifying patient. A person who is a patient of a healthcare practitioner; has been diagnosed by that practitioner as having a terminal or debilitating medical condition defined under <u>RCW 69.51A.010(24)</u>; is a resident of Washington; has been advised by that practitioner about the risks and benefits of the medical use of marijuana; has been advised by that practitioner that they may benefit from the medical use of marijuana; and has an authorization from his or her healthcare practitioner to use marijuana for medical purposes – <u>RCW 69.51A.010(17)</u>.

Recognition card. A card issued to qualifying patients and designated providers by a marijuana retailer with a medical marijuana endorsement that has entered them into the medical marijuana authorization database – <u>RCW 69.51A.010(20)</u>. With a recognition card a patient can purchase up to three times the recreational amount of product, is allowed to grow up to six plants (or up to 15 plants upon their practitioner's additional plant recommendation), and can purchase sales tax free from a medically endorsed marijuana retail store – <u>RCW 69.51A.210</u>.

Tamper-resistant paper. Paper that meets industry-recognized security features to copying, erasure or modification of information on the paper, and to prevent the use of counterfeit authorization – $\frac{\text{RCW}}{69.514.010(23)}$.

Terminal or debilitating medical condition. Means a condition severe enough to significantly interfere with the patient's activities of daily living and ability to function, which can be objectively assessed and evaluated and limited to the conditions outlined under <u>RCW 69.51A.010(24)</u>.

Compassionate Care Renewal. A renewal of an authorization by a health care practitioner through the use of telemedicine if the health care practitioner determines that requiring the qualifying patient to attend an in-person physical examination would likely result in severe hardship to the qualifying patient because of the qualifying patient's physical or emotional condition. A compassionate care renewal of a qualifying patient's registration and recognition card also allows the qualifying patient's designated provider to renew the qualifying patient's registration in the database and recognition card without the qualifying patient being physically present at a retailer and without a new photograph being taken per WAC 246-71-010(2).

Telemedicine. Has the same meaning as the definition of that term adopted by the authorizing health care practitioner's disciplining authority, whether defined in rule or policy per WAC 246-71-010(15).

1.3 HEALTHCARE PRACTITIONER STATUTORY LIMITATIONS

The healthcare practitioner shall not (RCW 69.51A.030):

- a. Accept, solicit, or offer any form of pecuniary remuneration from or to a marijuana retailer, marijuana processor, or marijuana producer;
- b. Offer a discount or any other thing of value to a qualifying patient who is a customer of, or agrees to be a customer of, a particular marijuana retailer;

- c. Examine or offer to examine a patient for purposes of diagnosing a terminal or debilitating medical condition at a location where marijuana is produced, processed, or sold;
- d. Have a business or practice which consists primarily of authorizing the medical use of marijuana or authorize the medical use of marijuana at any location other than his or her practice's permanent physical location;
- e. Except as provided in <u>RCW 69.51A.280</u>, sell, or provide at no charge, marijuana concentrates, marijuana-infused products, or useable marijuana to a qualifying patient or designated provider; or
- f. Hold an economic interest in an enterprise that produces, processes, or sells marijuana if the health care professional authorizes the medical use of marijuana.

1.4 AUTHORIZATION PRACTICE GUIDELINES

A healthcare practitioner may provide valid documentation to authorize medical marijuana (cannabis) to a qualifying patient under <u>Chapter 69.51A RCW</u> under the following conditions:

SECTION 1: PATIENT EVALUATION

A healthcare practitioner should obtain, evaluate, and document the patient's health history and physical examination in the health record prior to treating for a terminal or debilitating condition.

- a. The patient's health history should include:
 - i. Current and past treatments for the terminal or debilitating condition;
 - ii. Comorbidities; and
 - iii. Any history of substance misuse or abuse using a risk assessment tool.
- b. The healthcare practitioner should:
 - i. Complete an initial physical examination as appropriate based on the patient's condition and medical history; and
 - ii. Check of the Prescription Drug Monitoring Program database for the patient's receipt of controlled substances
 - iii. Review the patient's medications including indication(s), date, type, dosage, and quantity prescribed.
 - Provide the qualifying patient and their designated provider (if any) each with a medical marijuana authorization form printed on tamper-resistant paper containing the RCW 69.51A.030 logo as required under <u>WAC 246-71-010</u>.

SECTION 2: TREATMENT PLAN

A healthcare practitioner should document a written treatment plan that includes:

- a. Review of other measures attempted to treat the terminal or debilitating medical condition that do not involve the medical use of marijuana;
- b. Advice about other options for treating the terminal or debilitating medical condition;
- c. Determination that the patient may benefit from treatment of the terminal or debilitating medical condition with medical use of marijuana
- d. Advice about the potential risks of the medical use of marijuana to include: The variability of quality and concentration of medical marijuana;
 - i. Adverse events, including falls or fractures;
 - ii. The unknown short-term and long-term effects in minors, as more fully explained in Section 4, below;
 - iii. Use of marijuana during pregnancy or breast feeding; and,
 - iv. The need to safeguard all marijuana and marijuana-infused products from children and pets or domestic animals.
 - v. Additional diagnostic evaluations or other planned treatments;
- e. A specific duration for the medical marijuana authorization for a period no longer than 12 months for adults (age 18 and over) and 6 months for minors (under age 18); and,
- f. A specific ongoing treatment plan as medically appropriate.

SECTION 3: ONGOING TREATMENT

A healthcare practitioner should conduct ongoing treatment and assessment as medically appropriate to review the course of the patient's treatment, to include:

- a. Any change in the medical condition;
- b. Any change in physical or psychosocial function;
- c. Any new information about the patient's terminal or debilitating medical condition; and
- d. An authorization may be renewed upon completion of an in-person physical examination.
- e. Following an in-person physical examination, evaluate patient eligibility for a compassionate care renewal of their authorization per RCW 69.51A.030(2)(c)(iii).

SECTION 4: TREATING MINOR PATIENTS OR PATIENTS WITHOUT DECISION MAKING CAPACITY

The risks of marijuana use in minors are substantial, particularly given its well-documented adverse effects on the developing brain. ¹ While research demonstrates that the use of marijuana can be helpful for adults with specific debilitating conditions, there are no published studies on the use of medical

¹ <u>https://pediatrics.aappublications.org/content/135/3/584</u>

marijuana for minors. A health care practitioner should strongly consider limiting the authorization of marijuana to minors in palliative pediatric care when short-term symptom relief outweighs long-term risks. The most common symptoms that may justify the use of medical marijuana for minors are pain, nausea, vomiting, seizures, and agitation.²

Under <u>RCW 69.51A.220</u> and <u>RCW 69.51A.230(4)</u>, a healthcare practitioner considering authorizing marijuana to a patient under the age of 18 or without decision making capacity must:

- a. Ensure the patient's parent, guardian, or surrogate participates in the treatment and agrees to the medical use of marijuana;
- b. Evaluate and document history of substance misuse or abuse using a risk assessment tool; ³
- c. Consult with other healthcare practitioners involved in the patient's treatment, as medically indicated and as agreed to by the patient's parent, guardian, or surrogate, before authorization or reauthorization of the medical use of marijuana; and
- d. Include a follow-up discussion with the minor's parent or patient surrogate to ensure the parent or patient surrogate continues to participate in the treatment;
- e. Ensure the patient's parent, guardian, or surrogate acts as the designated provider; and
- f. Reexamine the minor at least once every six months or more frequently as medically indicated.

Additional requirements to note when treating minor patients:

- a. Qualifying patients (adult or minor) can only have one designated provider under <u>RCW</u> <u>69.51A.010</u>. This can be challenging for minor patients who live in divorced families.
 - School districts must permit a designated provider (parent/legal guardian) to administer marijuana-infused product to a minor qualifying patient (under age 18) in accordance with school policy at the request of a parent – <u>RCW 69.51A.225</u>
 - b. The minor may not grow plants or purchase marijuana (cannabis) RCW 69.51A.220.

https://pediatrics.aappublications.org/content/138/1/e20161210

² The federal Food and Drug Administration (FDA) has approved medications related to marijuana that are available in pharmaceutical grade by prescription for rare conditions. One of the medications is approved for the treatment of seizures associated with Lennox-Gastut syndrome or Dravet syndrome in patients over two years of age. This medication is not considered medical marijuana and is not available at marijuana dispensaries. This medication is prescribed by subspecialists with expertise in these conditions.

³ The use of a risk assessment tool is particularly important in the treatment of minors. The American Academy of Pediatrics developed a guide to help providers incorporate screening, brief intervention, and referral for the use of alcohol, tobacco, marijuana and other drugs among adolescent patients.

c. Both the minor and the minor's parent or guardian who is acting as the designated provider must be entered in the medical marijuana authorization database and hold a recognition card - <u>RCW 69.51A.220</u>.

SECTION 5: MAINTENANCE OF HEALTH RECORDS

A healthcare practitioner should maintain the patient's health record in an accessible manner, readily available for review, and include:

- a. The diagnosis, treatment plan, and therapeutic objectives;
- b. Documentation of the presence of one or more recognized terminal or debilitating medical conditions identified in <u>RCW 69.51A.010(24)</u>.
- c. Documentation of other measures attempted to treat the terminal or debilitating medical condition that do not involve the medical use of marijuana;
- d. A copy of the signed authorization form for both the patient and their designated provider (if any);
- e. Results of ongoing treatment; and
- f. The healthcare practitioner's instructions to the patient.

SECTION 6: CONTINUING EDUCATION

A healthcare practitioner issuing authorizations or valid documentation for the medical use of marijuana on or after the effective date of these guidelines, should complete a minimum of three hours of continuing education related to medical marijuana.

Such program should explain the proper use of marijuana (cannabis), including the pharmacology and effects of marijuana (e.g., distinction between cannabidiol (CBD) and tetrahydrocannabinol (THC); methods of administration; and potential side effects or risks).

1.5 Resources

Washington State Department of Health Medical Marijuana Program

Guidance Document



Introduction

Purpose

The Washington Medical Commission (Commission) provides this guidance to assist physicians and physician assistants (collectively "practitioners") who have been out of practice a period of time due to a suspended license to demonstrate that they have the knowledge and skills to successfully reenter the practice of medicine.

WASHINGTON

Medica

Licensing. Accountability. Leadership.

Background

To protect public health, the Commission may find it necessary to suspend the license of a physician or physician assistant. The suspension may be the result of unprofessional conduct or a physical or mental impairment. At some point the practitioner may seek reinstatement of his or her license to practice. In addition to fully satisfying the requirements of the disciplinary order, the practitioner may have to demonstrate that he or she has the knowledge and skills necessary to practice medicine with reasonable skill and safety. Evidence shows that practitioners who have been out of practice for a period of time experience a decline in their medical knowledge and skills.

Guidance

The Commission may require a practitioner with a suspended license to demonstrate clinical competence by completing a reentry program prior to entering clinical practice. When determining whether completion of a reentry program is required, the Commission will carefully review all the circumstances in each individual case.

The length, activities and cost of reentry programs vary. Reentry programs should be comprehensive but practical and flexible enough to address a variety of situations and specialties. Reentry programs should be evidence-based and consistent with lifelong learning expectations for all practitioners. At the very least, reentry programs should include reflective self-assessment, assessment of knowledge and skills, and performance in practice.

Practitioners should be aware that some reentry programs will not admit practitioners with licenses under suspension or discipline. <u>A list of reentry programs can be found at the end of this guidance</u> <u>document under Resources.</u>

The Commission will have complete discretion to determine whether the practitioner has satisfactorily completed a reentry program and is competent to reenter clinical practice. If the Commission permits a practitioner to reenter clinical practice, the Commission may impose additional restrictions or limitations on the practitioner's practice to protect the public, including approval of practice monitors.

The Commission recognizes that reentry programs may be expensive and that funding will likely be borne by the practitioner, presenting a barrier for some practitioners. The Commission encourages academic medical centers to look for ways to cover some of the cost of reentry programs through research opportunities and generation of revenue. Federal, state and local funding driven by physician shortages may become a funding source. Potential employers, including community hospitals and large group practices, may be willing to offset individual physician reentry costs in exchange for later service. Practitioners with disabilities may consider the State of Washington Department of Social and Health Services, Division of Vocational Rehabilitation, as another potential source of funding.

Resources

American Medical Association Resources for Physicians Returning to Clinical Practice Drexel University College of Medicine Physician Refresher/Re-Entry Program Physician Retraining & Reentry at UC San Diego School of Medicine The Center for Personalized Education for Physicians (CPEP) Reentry to Clinical Practice Program CPEP Reentry to Clinical Practice KSTAR/Texas A&M Rural and Community Health Institute Lifequard Re-Entry/Reinstatement at Foundation of the Pennsylvania Medical Society

Number:	GUI2019-02
Date of Adoption:	April 12, 2019
Reaffirmed / Updated:	N/A
Supersedes:	Reentry to Practice for Suspended Licenses, MD2015-11, November 6, 2015

Guideline Document



Reentry to Practice

Introduction

Purpose

To help ensure and advance patient safety and quality of care, the Washington Medical Commission (Commission) provides this guideline to assist physicians and physician assistants who take a temporary leave from practice <u>to</u> successfully reenter the safe practice of medicine

Background

A growing number of physicians and physician assistants (collectively "practitioners") take a leave from the clinical practice of medicine at some point in their careers. The break from practice may be for any number of reasons, the most common being the birth of a child, child care, caring for an ill family member, personal health, military service, humanitarian leave, and a change in career path. This issue cuts across genders and specialties, but may affect women more than men. With the projected national physician shortage and considering the public's investment in education and training physicians, practitioner reentry is becoming increasingly important to the health care delivery system.

While reentry can be complex and challenging, there is evidence that practitioners who participate in a supportive structured educational program were generally successful in returning to practice.¹ Successful reentry to the safe practice of medicine requires the combined efforts of various stakeholders, such as regulators, specialty boards, hospitals, health plans, potential employers and preceptors. Recognizing that reentry to the practice of medicine is becoming an increasingly common part of a practitioner's career, the Commission creates this guideline to assist practitioners to successfully navigate a return to the practice of medicine in the state of Washington.

Definition(s)

Practitioner reentry is defined as the return to clinical practice in an area or scope of practice for which one has been trained, certified or licensed after an extended period of time away from clinical practice. A practitioner returning to clinical practice in an area or scope of practice in which he or she has not been previously trained or certified or in which he or she has not had an extensive work history is not considered a reentry practitioner for the purpose of this guideline.

¹ Grace ES, Korinek EJ, Weitzel LB, Wentz DK. Physicians reentering clinical practice: Characteristics and clinical abilities. Journal of Continuing Education in the Health Professions. 2011;31(1):49-55.

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

Guid<u>ance</u>eline

Planning ahead before leaving clinical practice

A practitioner considering taking a temporary leave from clinical practice should consider taking some or all of the following steps to help ease the transition back to the practice of medicine.

- Maintain an active license;
- Maintain board certification;
- Keep up with continuing medical education activities; and

• Take advantage of opportunities to stay involved in practice in a limited context. This can include part-time volunteer medical work during the leave from practice.

Reentering Clinical Practice

The Commission encourages practitioners who have been inactive for 24 months or more to complete a reentry program prior to entering clinical practice. Practitioners who are inactive for 12 to 24 months should consider completing an informal reentry program.

Reentry Programs

The length, activities and cost of reentry programs vary. Reentry programs should be comprehensive but practical and flexible enough to address a variety of situations and specialties. Reentry programs should be evidence-based and consistent with lifelong learning expectations for all practitioners. At the very least, reentry programs should include reflective self-assessment, as well as assessment of medical knowledge and skills and performance in practice by qualified preceptors.

The University of Washington School of Medicine has developed a reentry program that meets these criteria. For a current list of reentry programs outside the state of Washington, the Commission directs physicians to a list of reentry programs maintained by <u>The Physician Reentry into the Workforce</u>. <u>Project</u>.

<u>A list of reentry programs and resources can be found at the end of this guidance document.</u>

Practice Mentors

If the reentry program calls for a practitioner to use a practice mentor upon a return to practice, the practitioner should ensure that the mentor is appropriately qualified and practices in the same clinical area as the practitioner seeking reentry. The practice mentor should have the capacity to serve as a practice mentor, including sufficient time for mentoring, and an active and unrestricted medical license under no active discipline. The practice mentor may require financial compensation or incentives for work associated with practice mentoring.

Substance Use Disorders and Mental or Physical Impairment

A practitioner who has a mental or physical condition or a substance abuse disorder that currently affects or could affect the ability to practice with reasonable skill and safety should meet with the Washington Physicians Health Program and follow all recommendations before reentering the practice of medicine.

Funding

The Commission recognizes that reentry programs may be expensive and that funding will likely be borne by the practitioner, presenting a barrier for some practitioners. The Commission encourages academic medical centers to look for ways to cover some of the cost of reentry programs through research opportunities and generation of revenue through professional fee billing. Federal, state and local funding driven by physician shortages may become a funding source. Potential employers, including community hospitals and large group practices, may be willing to offset individual physician reentry costs in exchange for later service. Practitioners with disabilities may consider applying to the State of Washington Department of Social and Health Services, Division of Vocational Rehabilitation, as another potential source of funding.

Resources

American Medical Association Resources for Physicians Returning to Clinical Practice Drexel University College of Medicine Physician Refresher/Re-Entry Program Physician Retraining & Reentry at UC San Diego School of Medicine The Center for Personalized Education for Physicians (CPEP) Reentry to Clinical Practice Program CPEP Reentry to Clinical Practice KSTAR/Texas A&M Rural and Community Health Institute

Lifeguard Re-Entry/Reinstatement at Foundation of the Pennsylvania Medical Society

Number:	GUI2019-01
Date of Adoption:	May 17, 2019
Reaffirmed / Updated:	N/A
Supersedes:	Reentry to Practice, MD2015-10, November 6, 2015

Policy Statement



Title:			POL0000
References:			
Contact:	Washington Medical Commission		
Phone:	(360) 236-2750	E-mail:	medical.commission@wmc.wa.gov
Effective Date:	March 4, 2022		
Approved By:			

In 2020, the Washington State Legislature chose to extend the responsibilities of the International Medical Graduate Assistance (IMG) Work Group with the passage of Senate Bill 6551; thus creating the IMG Implementation Workgroup (Workgroup). The bill also required that the Washington Medical Commission (WMC) to "adopt a clinical assessment to determine the readiness of international medical graduates to apply and serve in residency programs and adopt a grant award process for distributing funds" pursuant to appropriation by the legislature and donations 10 received from public and private entities.

After meeting monthly throughout 2022, the workgroup has voted to propose the following Clinical Experience Assessment (CEA) meets the requirement set forth by the legislature and should adopted by the WMC.

The CEA is intended for physician assessors working with IMGs to help further prepare them for residency and determine their readiness. It is not an element of application for residency nor is it a qualification for residency. The workgroup recommends the CEA be used to exhibit what level of "entrustment" might be appropriate for a graduating student entering residency and aid IMGs success in gaining a residency position.

The CEA is to be used as a quarterly assessment or until a passing score on all competencies signifies readiness. The workgroup has also proposed that the WMC track progress over time for those licensees who made use of the CEA to see where additional education or targeted training be needed. And, they recommend the WMC create accountability standards for tracking outcomes from the use of the CEA as funding allows.



CLINICAL EXPERIENCE ASSESSMENT

Name: _____

Date:

Guidelines for ranking. Place checks the boxes below.

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

EPA 1: Gather a History and Perform a Physical Examination

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Obtain a complete and accurate history in an organized fashion.

Demonstrate patient-centered interview skills.

Demonstrate clinical reasoning in gathering focused information relevant to a patient's care.

Perform a clinically relevant, appropriately thorough physical exam pertinent to the setting and purpose of the patient visit.
EPA 2: Prioritize a Differential Diagnosis Following a Clinical Encounter



Synthesize essential information from previous records, history, physical exam, and initial diagnostic evaluations to propose a scientifically supported differential diagnosis.

Prioritize and continue to integrate information as it emerges to update differential diagnosis, while managing ambiguity.

Engage and communicate with team members for endorsement and verification of the working diagnosis that will inform management plans.

EPA 3: Recommend and Interpret Common Diagnostic and Screening Tests



Recommend first-line cost-effective screening and diagnostic tests for routine health maintenance and common disorders.

Recommend first-line cost-effective screening and diagnostic tests for routine health maintenance and common disorders.

Interpret results of basic studies and understand the implication and urgency of the results.

EPA 4: Enter and Discuss Orders and Prescriptions



Compose orders efficiently and effectively verbally, on paper, and electronically.

Demonstrate an understanding of the patient's condition that underpins the provided orders.

Recognize and avoid errors by attending to patient-specific factors, using resources, and appropriately responding to safety alerts.



Discuss planned orders and prescriptions with team, patients, and families.

EPA 5: Document a Clinical Encounter in the Patient Record



Prioritize and synthesize information into a cogent narrative for a variety of clinical encounters (admission, progress, pre- and post-op, and procedure notes; informed consent; discharge summary).

Follow documentation requirements to meet regulations and professional expectations.

Document a problem list, differential diagnosis, and plan supported through clinical reasoning that reflects patient's preferences.

EPA 6: Provide an Oral Presentation of a Clinical Encounter



Present personally gathered and verified information, acknowledging areas of uncertainty

Provide an accurate, concise, well-organized oral presentation.

Adjust the oral presentation to meet the needs of the receiver.

Demonstrate respect for patient's privacy and autonomy.

EPA 7: Form Clinical Questions and Retrieve Evidence to Advance Patient Care (*only level 3 required)



Combine curiosity, objectivity, and scientific reasoning to develop a well-formed, focused, pertinent clinical question (ASK).

Demonstrate awareness and skill in using information technology to access accurate and reliable medical information (ACQUIRE).

*Demonstrate skill in appraising sources, content, and applicability of evidence (APPRAISE).

*Apply findings to individuals and/or patient panels; communicate findings to the patient and team, reflecting on process and outcomes (ADVISE).

EPA 8: Give or Receive a Patient Handover to Transition Care Responsibility



Document and update an electronic handover tool and apply this to deliver a structured verbal handover, using communication strategies known to minimize threats to transition of care.

Provide succinct verbal communication conveying illness severity, situational awareness, action planning, and contingency planning.

1. 2. 3. 5. 4.

Demonstrate respect for patient's privacy and confidentiality.

EPA 9: Collaborate as a Member of an Interprofessional Team

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Identify team members' roles and responsibilities and seek help from other members of the team to optimize health care delivery.

Include team members, listen attentively, and adjust communication content and style to align with team-member needs.

Establish and maintain a climate of mutual respect, dignity, integrity, and trust; prioritize team needs over personal needs to optimize delivery of care; and help team members in need.

EPA 10: Recognize a Patient Requiring Urgent or Emergent Care and Initiate Evaluation and Management (*only level 3 required)



Recognize normal and abnormal vital signs as they relate to patientand disease-specific factors as potential etiologies of a patient's decompensation.

Recognize severity of a patient's illness and indications for escalating care.

*Initiate and participate in a code response and apply basic and advanced life support.

Upon recognition of a patient's deterioration, communicates situation to attending physician.

EPA 11: Obtain Informed Consent for Tests and/or Procedures



Describe the key elements of informed consent: indications, contraindications, risks, benefits, alternatives, and potential complications of the intervention.



Communicate with the patient and family to ensure that they understand the intervention including pre/post procedure activities.

EPA 12: Perform General Procedures of a Physician (*only level 3 required)



*Demonstrate technical skills required for the procedure.



Understand and explain the anatomy, physiology, indications, contraindications, risks, benefits, alternatives, and potential complications of the procedure.



Completes expected procedures and keeps log book signed by mentor

EPA 13: Identify System Failures and Contribute to a Culture of Safety and Improvement (*only level 3 required)



Identify and report actual and potential ("near miss") errors in care using system reporting structure (event reporting systems, chain of command policies).



*Participate in system improvement activities in the context of learning experiences (rapid- cycle change using plan–do–study– act cycles, root cause analyses, morbidity and mortality conference, failure modes and effects analyses, improvement projects).



Engage in daily safety habits (accurate and complete documentation, including allergies and adverse reactions, medicine reconciliation, patient education, universal precautions, hand washing, isolation protocols, falls and other risk assessments, standard prophylaxis, time-outs).



Admit one's own errors, reflect on one's contribution, and develop an individual improvement plan.



Staff Reports: November 18, 2022

Melanie de Leon, Executive Director

Travelling out of country? If you are travelling out of the United States and plan to take your DOH-issued laptop with you or check email while you are gone, we need you to take several steps prior to your departure to make sure your VPN will connect while away. Four to six weeks prior to your departure (giving us more time is better), please contact Ken Imes <u>ken.imes@wmc.wa.gov</u> and tell him where you are travelling and your travel dates – this includes travel to Canada. Ken then must submit a ticket through our system to our IT shop. About a week prior to your departure, DOH IT is supposed to contact you to set up a time to remote into your laptop so they can add you to the appropriate security group to allow you VPN access while you are out of the country. If you have any questions on this process, please contact Ken.

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 Agency policy, requests submitted after the cutoff cannot be paid out.

New Staff Member

Please welcome Taylor Bacharach-Nixon to our staff. She joins us fresh from The Evergreen State College in an Administrative Assistant 3 role. She will split her time supporting Licensing and my role, especially with the legislative session coming in January. With this addition, my shop is fully staffed and hopefully stays that way.

Recurring: Joint Operating Agreement (JOA)

We submitted a proposed JOA to the Department to begin negotiations as of June 2, 2022. We have not received a formal counter proposal at this time, but our conceptual proposals have been largely accepted. We have held several meetings with DOH representatives, mostly relating to IT services and taking back public disclosure functions. The IT sections have largely been resolved. We will be meeting with the new leadership of Public Disclosure soon to go over specifics and answer outstanding questions on both sides. Based on several DOH policy changes on which we were not consulted, we submitted two amendments the week of November 1 clarifying WMC autonomy in finances and HR training.

Audits

WMC

The WMC audit continues. All information requests have been satisfied by WMC staff and we are now waiting on analysis by the audit contractor. We hope to have preliminary results shared with us shortly after Thanksgiving.

PMP

The presentation to the J-LARC hearing was well attended by Governor's office representatives ranging from DOH to the Office of the Chief Information Officer, WSMA, WSHA, and pain patient advocates. All uniformly opposed and condemned the SAO recommendation to gain access to PMP data for auditing purposes. The arguments ranged from out of scope of the PMP to SAO's lack of expertise in medicine and pharmacology to the significant informational risk opening that database to non-essential individuals represents. The SAO representative seemed visibly surprised by the uniformity and force of the opposition. It remains to be seen what the legislators and the SAO will choose to do in 2023.

Budget Update

Our overall budget outlook can be described as on track and positive. We continue our spending at appropriated levels and our collections are within estimates. Projections for the budget at this time show us four percent underspent from our allotment.

Budget Requests/Legislative Session

The spending authority increase budget request approved by the WMC in July continues to move through the process. I presented last month to House, Senate, and OFM staff on our request and the response was positive. The package is currently under consideration with OFM and the Governor's office. The next step is inclusion in the Governor's budget. We should receive a notification in late December if that is the case.

Per the presentation from the Legislative Team that you will receive, we are looking for Commissioners to participate in legislative work. Please see Dr. Chung, Micah, or Stephanie if you are interested. Some commitments are a weekly phone/zoom meeting and others are infrequent/ad-hoc. Participation can vary by the bills and topics are under consideration by the Legislature.

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 <u>amelia.boyd@wmc.wa.gov</u>.

Amelia Boyd, Program Manager continued

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 is March 24, 2023. The <u>recruitment</u> <u>notice</u> is available on our website.

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

Rules

Two rules were recently completed:

- New Section, WAC 246-919-345, Limited Physician and Surgeon Clinical Experience License for International Medical Graduates. For more information, including the rule language, click <u>here</u>.
- Opioid Prescribing Patient Exemptions. Exemptions section revised for both Physicians (WAC 246-919-851) and Physician Assistants (WAC 246-918-801). For more information, including the rule language, click <u>here</u>.

Both rules will be effective November 25, 2022.

Mike Hively, Director of Operations and Informatics

Operations & Informatics processed four compulsory requests for records reviewing and redacting approximately 18,057 pages. Currently, there are two active requests the team is processing with a total page count of approximately 11,849. We anticipate completing the active requests before December 1, 2022.

The Litigation Hold program is now 95% complete as we work to finalize our Excel tracking tool. The official procedure, process map, and notification letters have been reviewed by

Mike Hively, Director of Operations and Informatics

WMC staff and the AAG. The program will enter its testing phase upon receipt of a new Litigation Hold Notification.

Unit Accomplishments Include:

Digital Archiving

- 274 Complaints closed BT folder is current
- 830 Active MD licensing applications
- 1,657 Active PA licensing applications
- Approximately 3,420 demographic census forms

<u>Data Requests/Changes</u>

- Approximately 1,346 open/closed inquiries (individual requests may contain requests)
- Approximately 996 address changes

<u>Demographics</u>

- Entered approximately 3,420 census forms into the IRLS database and conducted quality checks
- Conducts 1,277 secondary census contacts via email
- Created MD & PA quarterly reports October 3rd and uploaded them to the WMC website
- o Updated Secondary Contact letter with new Commissioner signatures.
- Provided MD & PA demographic data to WSMA as outlined in our Data Sharing Agreement
- Assembled a list of neurosurgeons in Pierce County

Ops & Info staff continue to convert paper-based records to digital format, submit destruction of paper-based records tickets via the Dept. of Health's Service Central system and update ILRS to reflect the records' current locations. Additionally, the Information Liaison Ken Imes assisted with facilitation and distribution of replacement I.T. equipment for staff, researched additional functionality within the Adobe-Sign platform and provide appropriate staff with instructions for the web-based information capture tool Snagit, audio editing software Goldwave, and Language Link Interpreter services. Lastly, the team continues to cross train one another in relation to digital archiving and processing compulsory records requests.

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

Legal Staff Updates:

Congratulations to newlyweds Ryan & Olivia Furbush! Ryan finished out a whirlwind summer by marrying Olivia on August 27, and then jetting off to an adventurous honeymoon in Mexico. Wishing Ryan and Olivia a full life of love and happiness!

A warm welcome to our newest team member, Stormie Redden! Stormie joined us on September 16 as our Reconsiderations Program Coordinator. She joins us from HSQA/OILS where she was the Legal Assistant supervisor and has extensive experience working with professions, boards, and commissions. Welcome, Stormie!

The Legal Unit is currently recruiting for a Staff Attorney (Hearings Examiner 3). The recruitment closes November 17. Please share this link with your network and contacts: <u>Washington State Department of Health | Job Opportunities (governmentjobs.com)</u>

Summary Actions:

In re Kristine S. 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 <u>RCW 18.130.180</u> 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. A hearing on the merits of the SOC has not yet been scheduled.

In re John C. Lucke, MD, Case No. M2021-908. On September 2, 2022, the Commission served a SOC and Ex Parte Order of Summary Suspension which suspended Dr. Lucke's medical license based on allegations that Dr. Lucke entered into an Order with the Board of Registration in Medicine for the Commonwealth of Massachusetts in which Dr. Lucke voluntarily surrendered his medical license. The conduct underlying the Massachusetts Order was a restriction of Dr. Lucke's Oregon medical license prohibiting him from performing cardiac procedures in the state of Oregon based on a finding that he performed below the standard of care. A hearing on the merits of the SOC has not yet been scheduled.

Orders Resulting from SOCs:

In re Bhanoo Sharma, MD, Case No. M2021-756. Agreed Order. On February 10, 2022, a Health Lawa Judge (HLJ), by delegation of the Commission, ordered that Dr. Sharma's medical license be suspended pending further disciplinary proceedings. The SOC alleged that in January 2021 the Oregon Medical Board entered a Stipulated Order through which Dr.

Rick Glein, Director of Legal Services continued

Sharma surrendered his Oregon license while under investigation. The underlying conduct in the Stipulated Order included negligence in Dr. Sharma's medical care to four patients and inadequate and dangerous responses to adverse events. On August 25, 2022, the Commission approved an Agreed Order in which Dr. Sharma agreed to permanently surrender his Washington medical license.

In re Richard Heitsch, MD, Case No. M2021-545. Final Order.* On August 11, 2021, the Commission filed a SOC alleging Dr. Heitsch and the Oregon Medical Board entered into a Stipulated Order ordering Dr. Heitsch to complete a course on medical documentation and prohibiting Dr. Heitsch, or any person employed by him, from treating any patient with hyperbaric oxygen therapy or performing hyperbaric oxygen therapy for any patient. In March 2022, the HLJ granted the Commission's Motion for Partial Summary Judgment, finding that there is no genuine dispute as to any material fact and limited the issue at hearing to sanctions only. A Final Order was issued on September 9, 2022, which prohibits Dr. Heitsch from treating any patient with hyperbaric oxygen therapy or performing hyperbaric oxygen therapy for any patient. Additionally, Dr. Heitsch shall obtain continuing education in the area of recordkeeping, remain in full compliance with the Oregon Order, pay a fine of \$5,000, and personally appear before the Commission.

In re Thomas J. Osten, MD, Case No. M2021-652. Final Order (Failure to Appear).* In January 2022, the Commission issued a SOC alleging Dr. Osten did not obtain a patient's permission to perform an exam or inform her what he was doing before lifting her shirt. Additionally, the SOC alleged Dr. Osten told the patient an inappropriate joke and made a comment which made the patient uncomfortable. Under a different case number, M2018-68, a Final Order was issued to Dr. Osten on August 4, 2021, which was based on similar allegations with three different female patients. In his Answer to the SOC and at an initial scheduling call, Dr. Osten indicated he wanted an in-person hearing. The HLJ advised that hearings were being conducted virtually due to the COVID-19 pandemic. At a prehearing conference on July 11, the HLJ confirmed the hearing scheduled on July 22 would be held virtually. Dr. Osten objected to the virtual hearing, and the HLJ advised that a default could be issued if Dr. Osten did not participate. Dr. Osten hung up his phone after being told multiple time that the hearing would be conducted virtually. The Commission requested an Order of Default. On July 15, the HLJ entered an Order of Default finding sufficient grounds exist to take disciplinary action against Dr. Osten's medical license and ordered that his license be indefinitely suspended.** Dr. Osten filed a Motion for Reconsideration which the HLJ denied on October 4, 2022.

In re Robert Norton, MD, Case No. M2020-708. Final Order (Failure to Respond).* In June 2021, the Commission served a Findings of Fact, Conclusions of Law, and Order for Investigative Mental and Physical Examination (Order) on Dr. Norton which required Dr. Norton to make an appointment for an evaluation within seven days of receiving the Order. Dr. Norton did not make an appointment for the required evaluation. In June 2022, the Commission filed a SOC alleging Dr. Norton failed to respond to an order issued by the Commission. Dr. Norton did not file a response to the SOC within the time allowed. The matter came before a HLJ in September 2022. The HLJ concluded sufficient grounds existed

Rick Glein, Director of Legal Services continued

to take disciplinary action against Dr. Norton's license and ordered that his medical license be indefinitely suspended.**

In re James B. Grierson, MD, Case No. M2022-238. Agreed Order. This matter was referred by the Commission to the Secretary of Health as a sexual misconduct case that did not involve clinical expertise or standard of care issues. (*See* RCW 18.130.062.) In June 2022, a SOC was issued against Dr. Grierson which alleged he became sexually intimate with a patient, including an instance of sexual intercourse in the exam room after the patient's scheduled appointment. Additionally, the SOC alleged that Dr. Grierson asked the patient to consider recanting the allegation of sexual intercourse in the exam room or on clinic property. Dr. Grierson waived the opportunity for a hearing on the merits of the SOC. On September 15, 2022, a HLJ accepted an Agreed Order which suspended Dr. Grierson's medical license for at least three years. Prior to reinstatement, Dr. Grierson shall pay a fine of \$2,000 and undergo a mental health evaluation with a focus on sexual misconduct. If and when Dr. Grierson petitions for reinstatement, the Commission may impose such additional requirements as may be necessary to protect the public.

In re Scott C. Miller, PA, Case No. M2021-272. Final Order.* On October 6, 2022, the Medical Commission issued a final order in matter of Scott C. Miller. The final order indefinitely suspends Mr. Miller's credential to practice as a physician assistant. The final order was the result of a SOC issued in October 2021 and a five-day hearing in August 2022. Mr. Miller was found to have committed unprofessional conduct in violation of RCW 18.130.180(1), (2), (4), (6), (13), and (22). A separate allegation that Mr. Miller violated RCW 18.130.180(16) was dismissed by the Commission. The terms of the final order indefinitely suspend Mr. Miller's credential to practice. Mr. Miller may petition the Commission for reinstatement of his credential after successfully completing an ethics course and undergoing a multidisciplinary assessment for fitness to practice. Mr. Miller may file a petition for judicial review of the Commission's decision with a superior court within thirty days.

In re Christopher Greenman, MD, Case No. M2021-909. Agreed Order. In February 2022, the Commission issued a SOC which alleged unprofessional conduct surrounding percutaneous coronary intervention procedures Dr. Greenman performed on five patients. On October 6, 2022, the Commission approved an Agreed Order which requires Dr. Greenman to undergo a competency assessment of his interventional cardiology clinical skills and documentation, pay a fine of \$10,000, and appear before the Commission. Upon completion of the competency assessment, the Agreed Order will be modified to incorporate the recommendations, including any practice restrictions, conditions on practice, or rehabilitative training.

*Either party may file a petition for reconsideration within ten days of service of the order. RCW 34.05.461(3); 34.05.470. A petition for judicial review must be filed and served within 30 days after service of the order. If a petition for reconsideration is filed, the 30-day period does not start until the petition is resolved. RCW 34.05.542; 34.05.470(3).

Rick Glein, Director of Legal Services continued

**A person whose license has been suspended under chapter 18.130 RCW may petition the disciplining authority for reinstatement. RCW 18.130.150.

Virtual Hearing:

In re Dara Parvin, MD, Case No. 2021-376. In March 2022, the Commission filed a SOC alleging Dr. Parvin entered into a Settlement Agreement with the Iowa Board of Medicine which placed her license to practice in the state of Iowa on probation for a period of two years upon her return to practice in that state. The underlying conduct alleged in the Iowa Settlement Agreement included making inappropriate advances on and sending suggestive messages to subordinate co-workers and a colleague. In September 2022, the HLJ granted the Commission's Motion for Partial Summary Judgment, finding that there is no genuine dispute as to any material fact and limited the issue at hearing to sanctions only. The Commission held a virtual hearing on October 21, 2022. A Final Order is expected to be issued by the end of January 2023.***

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

Item of Interest:

The Federation of State Medical Boards (FSMB) held its Attorney Board Workshop November 3-4. Our Legal Unit was well-represented, with most of our staff attorneys attending this event which is designed specifically for attorneys and legal staff of state medical and osteopathic medical boards and brings together experts in the field of medical licensure and discipline to discuss the current legal issues and trends facing state medical boards. This year Mike Farrell and Trisha were invited to moderate and present, respectively, on Prosecuting COVID-19 Related Cases. Rick was able to share information about the Commission's SMART procedure and trauma-informed training for sexual misconduct cases.

Mike Farrell, Policy Development Manager

Nothing to report that hasn't been reported elsewhere.

Freda Pace, Director of Investigations

- Recurring: Reviewing Commissioner Member Notification (RCM Notification) process: As a reminder, the RCM Notification process allows you (the RCM) and the assigned investigator an opportunity to collaborate in building the foundation for a thorough investigation. Please make sure to monitor your WMC email inbox regularly and respond timely to request for specific feedback which will help with a speedy and thorough investigation.
- Case Manager Stats: Last quarter (July, August, September), CMT reviewed 394 new cases. CMT authorized 30.46% of cases for investigation and closed 69.54%. CMT reviewed 22 RFRs and authorized 22.73% for investigation.

Freda Pace, Director of Investigations

CMT Sign-up for 2022

Our CMT sign up slots are full for the year 2022! However, 2023 is right around the corner and there are vacancies waiting for your name. We appreciate your continued participation in this very important process. We could not be able to do this work without you and your support!

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 (<u>chris.waterman@wmc.wa.gov</u>). This courtesy cancellation notice will allow Chris the opportunity to fill any last-minute vacancy needs.

Jimi Bush, Director of Quality and Engagement

Outreach

If you have a topic suggestion for our informal series "coffee with the commission" - please <u>let Jimi</u> know. We are looking to put together a coffee with the commission that discusses the discrimination policy. This CwC will be led by Mahi Zeru. If you are interested in participating, please <u>let Jimi know</u> and she will reach out to coordinate a time.

We are also working on having our Lunch and Learns on a monthly basis – not just during commission meetings and having them accredited for Category 1 CME.

Performance

The FY2022 Performance report is <u>available online</u>. Please let Jimi know if you have any questions or concerns.

Marisa Courtney, Licensing Manager

Total licenses issued from 08/17/2022-11/08/2022= 909

Credential Type	Total Workflow Count
Physician And Surgeon Clinical Experience License	1
Physician And Surgeon Fellowship License	7
Physician And Surgeon Institution License	2
Credential Type	Total Workflow Count
Physician And Surgeon License	387

Marisa Courtney, Licensing Manager continued		
Credential Type	Total Workflow Count	
Physician and Surgeon License Interstate Medical Licensure Compact	242	
Physician And Surgeon Residency License	17	
Physician And Surgeon Teaching Research License	6	
Physician And Surgeon Temporary Permit	26	
Physician Assistant Interim Permit	32	
Physician Assistant License	198	
Physician Assistant Temporary Permit	8	
Totals:	909	

Information on Renewals: August Renewals- 72.21% online renewals

Credential Type	# of Online Renewals	# of Manual Renewals	Total # of Renewals
IMLC	0	45	45
MD	1017	372	1389
MDFE	0	1	1
MDIN	1	0	1
MDRE	20	6	26
MDTR	1	4	5
PA	198	48	246
	72.21%	27.79%	100.00%

Information on Renewals: September Renewals- 73.42% online renewals

Credential Type	# of Online Renewals	# of Manual Renewals	Total # of Renewals
IMLC	0	52	52
MD	930	304	1234
MDTR	4	2	6
PA	160	38	198
	73.42%	26.58%	100.00%

Information on Renewals: October Renewals- 75.82% online renewals

Credential Type	# of Online Renewals	# of Manual Renewals	Total # of Renewals
IMLC	0	59	59
MD	991	269	1260
MDRE	1	0	1
MDTR	1	2	3
PA	142	32	174
	75.82%	24.18%	100.00%



Panel A

Personal Appearance Agenda

Friday, November 18th, 2022

	Sarah Lyle, MD, Panel Chair	Mabel Bongmba, MD	Jimmy Chung, MD	Arlene Dorrough, PA-C
	Anjali D'Souza, MD	Harlan Gallinger, MD	Elisha Mvundura, MD	Robert Pullen, Public Member
Panel Members:	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
	Robert Golden, MD	Charlotte Lewis, MD, Pro-Tem		

Compliance Officer: Anthony Elders

9:45 a.m.	Mark A. Maiocco, MD Attorney: Pro Se	M2016-575 (2016-2565) RCM: Scott Rodgers, Public Member SA: Kyle Karinen	
10:30 a.m.	Dennis J. Kim, MD Attorney: Pro Se	M2019-707 (2019-4455) RCM: Anjali D'Souza, MD SA: Kyle Karinen	
11:15 a.m.	11:15 a.m.William M. Hall, MD Attorney: Jessica CreagerM2020-686 (2020-5577 et al.) RCMS: Charlotte Lewis, MD, Scott Rodgers SA: Colleen Balatbat		
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Panel B

Personal Appearance Agenda

Friday, November 18th, 2022

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

Compliance Officer:	Mike Kramer		
9:45 a.m.	Robert J. Stewart, MD Attorney: James B. King	M2021-284 (2020-13440) RCM: Daniel Flugstad, MD SA: Trisha Wolf	
10:30 a.m.	Brenda Roberts, MD Attorney: Pro Se	M2019-73 (2017-8553) RCM: John Maldon, Public Member SA: Rick Glein	
11:15 a.m.	Celestia S. Higano, MD Attorney: John H. Rosen	M2021-48 (2020-13527 et al.) RCM: April Jaeger, MD SA: Kyle Karinen	
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