ALASKA STATE MEDICAL BOARD

QUARTERLY MEETING

FRIDAY, AUGUST 9, 2024

DRAFT - AGENDA

Discussion of the following topics may require executive session. Only authorized members will be permitted to remain in the Board/Zoom room during executive session.

Location: By Zoom
Register in advance for this meeting:
https://us02web.zoom.us/meeting/register/tZMlduurqjsqHt2G2XKy2akbCXs8CqqLlzT8

Agenda

9:00 a.m. 1. Call to Order / Roll Call

9:02 a.m. 2. Review / Approval of Agenda

9:05 a.m. 3. Review / Approval of Minutes

- May 3, 2024
- May 30, 2024
- June 13, 2024
- July 18, 2024

9:10 a.m. 4. Ethics Disclosure

9:15 a.m. 5. Division Update

- Budget Update
- Proposed license fee changes

9:30 a.m. 7. Investigations – Executive Session

- Case# 2022-001182
- Case# 2023-000386
- Case# 2023-000302
- Case# 2023-000019
- Case# 2023-000016
- Case# 2019-000664
- Case# 2022-000637
- Case# 2021-000613

- Case# 2022-000725
- Case# 2023-000496

11:30 a.m. 8. Deliberative Session

- OAH Case No. 22-0897-MED
- OAH Case No. 22-0726-MED

12:00 p.m. 9. Lunch Break

1:00 p.m. 10. Public Comments

1:15 p.m. 11. Board Interviews
Brian Hinnebusch, MD

1:45 p.m. 12. Old Business:

Physician – Pharmacy Agreements - *Approvals requested for new agreements received*

2:30 p.m. 13. New Business:

Review and Discuss Priority Action Items

2:45 p.m. 14. Break

3:00 p.m. 15. Malpractice Case Reviews (Executive Session)

4:00 p.m. 16. Applicant Review

- Full Board Review (Executive Session)
- Ratification of Full Licenses

Osteopaths, Allopaths, Physician Assistants

4:30 p.m. 17. Closing Business / Adjourn

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS, AND PROFESSIONAL LICENSING

STATE MEDICAL BOARD
MINUTES OF MEETING
Friday, May 3, 2024

These are DRAFT minutes prepared by staff of the Division of Corporations, Business and Professional Licensing. They have not been reviewed or approved by the Board.

By authority of AS 08.01.070(2) and in compliance with the provisions of AS 44.62, a quarterly meeting of the Alaska State Medical Board was held Friday, May 3, 2024.

1. Call to Order/ Roll Call
The meeting was called to order by Chair Nimmo at 9:01 a.m.

Roll Call
Board members present:

David Barnes, DO
Sarah Bigelow Hood, PA-C
Matthew Heilala, DPM
Lydia Mielke, Public Member (Secretary)
Eric Nimmo, MD (Chair)
David Paulson, MD
David Wilson, Public Member

Board staff present: Natalie Norberg, Executive Administrator, Jason Kaeser, Licensing Supervisor, Jacob Olsen, Licensing Examiner, Alisa Perkins, Licensing Examiner

2. **Review / Approval of Agenda**

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote the Alaska State Medical Board amended the agenda to include a discussion regarding whether the board should issue a position statement on SB 115.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson.

The was item was added to the agenda after item #10, and before the lunch break.

3. **Review/Approval of Minutes**

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board accepted the minutes for the February 16, 2024 meeting as presented.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board accepted the minutes for the April 11, 2024, board meeting as presented.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson.

4. Ethics Disclosures

Ethics reporting by board members is done on a quarterly basis and is a standing item on the quarterly meeting agenda. The Chair requested Ms. Norberg query each board member.

There were no ethical disclosures made by board members.

5. Physician Health Committee Update

Dr. Foland was invited to address the Board. Dr. Foland acknowledged and once again thanked the Medical Board for its work to adopt a consistent and predictable referral process to the PHC for physicians with a DUI charge. The process appears to be continuing to work well. Dr. Foland further thanked the Board for its consideration to revise the professional fitness questions on licensing applications. Finally, Dr. Foland asked for clarification regarding whether being subject to a consent agreement equates to having a restricted or conditioned license reported to the NPDB. Ms. Norberg offered to seek clarification from the Dept. of Law and get back to the Physician Health Committee on this matter.

6. Old Business:

A. Regulation Project

Changes to the physician application for licensure

Chair Nimmo invited Ms. Norberg to introduce this issue:

During the November 16, 2023, board meeting, the Board approved a regulation project that would eliminate redundant requirements from the application for MD's, DO's and DPM's. This included the elimination of hospital verifications, AMA/ AOA physician profiles and the DEA clearance. These changes were incorporated into a draft document by the Dept. of Law for the board to review at the February 16, 2024, meeting. At that meeting the Board approved an edit to the draft, to clarify that applicants must disclose on their application for licensure any adverse actions taken by a hospital or health care facility, *at any time* against the applicant, not just within the last five years. This language change was incorporated into the new draft that is presented to the Board.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by a roll call vote, the Alaska State Medical Board approved the changes to 12 AAC 40.010 through 12 AAC 40. 050, as presented and drafted by the Dept. of Law, in project number 2024200012, to be submitted for public comment.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson.

7. New Business

A. Board Priorities / Annual Report

Chair Nimmo invited Ms. Norberg to introduce this topic. A draft strategic planning document containing examples of guiding principles, goals, strategies, activities, and tasks for the Board to consider for the year was presented. Board members reflected on the document and offered additional ideas for board priorities. Taking a proactive position on special interest topics, such as gender affirming care of minors, was identified by some board members as a potential priority for the board to consider. This notion was countered with the acknowledgement that the board has opted in recent history to take a neutral position on special issues such as the use of ivermectin. Mr. Wilson asserted that taking a position on special issues and using data and scientific research to support the Board's position in order to protect and safeguard the public should be considered a responsibility of the Board. Mr. Wilson also asserted that the Board should be more involved in the legislative process by taking positions on bills and nominating a spokesperson to testify on behalf the board. Other board members also supported the idea of having one or more legislative liaisons available to speak to the legislature on behalf of the board. Dr. Heilala raised concerns about board members being overextended and asked to do too much. Dr. Heilala supports exploring restructuring the board to have standing subcommittees tasked with licensing or investigation assignments and re-examining the Interstate Licensure Medical Compact. Dr. Barnes raised the concern of interference from insurance companies and physician autonomy. Other board members concurred that this is a topic for which the Board may want to issue a position statement. Ms. Norberg was asked to follow up with Board members individually after the meeting to collect and compile their top three priorities to be considered further at a later date.

8. Investigation Unit Update

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions, for the purpose of discussing Case #2022-000247 with Board and Investigative staff remaining during the session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

The board entered executive session at 9:50 a.m. The board returned on the record at 10:05 a.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the board accepted the Consent Agreement as proposed for Ben Prom in Case No. 2022-000247.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson
Abstained: Ms. Bigelow-Hood

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions, for the purpose of discussing Case # 2022-000726 with Board and Investigative staff remaining during the session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

The board entered executive session at 10:07 a.m. The board returned on the record at 10:13 a.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the board imposed a civil fine as proposed for John Mendelson in Case #2022-000726.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson
Abstained: Dr. Heilala

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions, for the purpose of discussing Case #2023-000843 with Board and Investigative staff remaining during the session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

The board entered executive session at 10:16 a.m. The board returned on the record at 10:23 a.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the board granted Dan Muschevici, MD an extension of audit until the end of the current license cycle in Case #2023-000843.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions, for the purpose of discussing Case #2023-000850 with Board and Investigative staff and Dr. Gallant remaining during the session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

The board entered executive session at 10:26 a.m. The board returned on the record at 10:51 a.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the board approved an audit exemption for Dr. Gallant upon the submission of a sworn attestation from Dr. Gallant that she completed the required number of CME's in Case #2023-000843.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

9. Break – The Board went off the record at 10:52 a.m. and returned on the record at 11:04 a.m.

10. Residency Exemption Request – Kleber Fertin, MD

Chair Nimmo requested Ms. Norberg introduce this item. As a foreign educated physician, Dr. Fertrin does not meet the residency requirements required in Statute and Regulation to be licensed in Alaska. Alaska statute allows for the medical board to grant an exemption if the applicant is deemed to hold sufficient training and professional experience. Dr. Kleber requested to address the board to request an exemption, however he no showed during the time allotted for his interview.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the board decided to table a decision on granting Dr. Fertrin a license.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Mr. Wilson

Agenda Item Added: SB 115 – Physician Assistant Scope of Practice

Chair Nimmo introduced and opened the floor for discussion regarding whether the Board should issue a statement regarding SB 115. Ms. Bigelow Hood provided some background for the bill, including the Alaska Physician Assistant Association's call to modernize the regulations and attempts in good faith over multiple years to work with the medical board on modernization, prior to the bill being introduced. The pros and cons of physician assistants having independent practice were briefly explored. Several members observed that this is an important bill, and the Board probably should have taken a position, however with two weeks left in the legislative session, it seems too late.

On a motion duly made by Ms. Mielke, seconded by Mr. Wilson, and decided by roll call vote, the board decided against issuing a statement regarding SB 115.

Roll Call: Nays, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

11. Lunch Break

The Board went off the record at 11:38 a.m. The Board returned on the record at 12:31 p.m.

Due to reconvening early from the lunch break and being ahead of schedule, the Chair decided to address agenda item #16, Applicant Review.

Applicant Review

Full Board Review

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood and approved by roll call vote, the Alaska State Medical Board enter into executive session in accordance with AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions, for the purpose of discussing license applications with board staff remaining during session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

The Board entered executive session at 12:32 p.m. The Board returned on the record at 12:47 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and decided by roll call vote, the board denied granting a license to Dr. Mahesh Karandikar. The Board cited in its decision concerns re**lated to Dr. Karandikar's ability to provide safe patient care based on his history of malpractice cases resulting in catastrophic injury or death to patients and the substantiated findings that led to a suspension of license in Wyoming in 2018 and restricted license in Washington in 2020.**

Roll Call: Nays, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Mr. Wilson

Ratification of Full Licenses

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board approved the following list of physician assistants for full licensure.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

	Lic Type	First Name	Last Name
1.	PA	Marcus	Bruno
2.	PA	Marissa	Caldarella
3.	PA	Thomas	Clopton
4.	PA	Karsen	Cullen
5.	PA	Jenna	Gilbert
6.	PA	Preston	Gorman
7.	PA	Henry	Hathaway
8.	PA	Hillary	Herr
9.	PA	Alicia	Karagianes
10.	PA	Kelsey	Kramer
11.	PA	Sonja	Kuhta
12.	PA	Matteson	McCarty
13.	PA	Michael	Molnar
14.	PA	Joseph	Montgomery

	Lic Type	First Name	Last Name
15.	PA	Heidi	Schulz
16.	PA	Todd	Plocher
17.	PA	Kurtt	Pulver
18.	PA	Grant	Robbins
19.	PA	Richard	Siersma
20.	PA	Kelsey	Thompson
21.	PA	Peter	Voss
22.	PA	Michael	Wechter

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood and approved by roll call vote, the Alaska State Medical Board approved the following list of osteopathic physicians for full licensure.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

	Lic Type	First Name	Last Name
1.	DO	Shawn	Achtman
2.	DO	Katelyn	Bailey
3.	DO	Minden	Collamore
4.	DO	Kimberly	Dimanna
5.	DO	Angelique	Ferayorni
6.	DO	Christopher	Galbick
7.	DO	Susan	Garand
8.	DO	Ryan	Gorman
9.	DO	Kyle	Hirschman
10.	DO	Alex	Jabourian
11.	DO	Paul	Kaplan
12.	DO	Alicia	Kiger
13.	DO	Nicole	Kunar
14.	DO	Steven	Leong
15.	DO	Lindsey	Migliore
16.	DO	Benjamin	Nance
17.	DO	Daniel	Nargizian
18.	DO	Jayesh	Patel
19.	DO	Dane	Pernot
20.	DO	Adam	Raymond
21.	DO	Richard	Smith
22.	DO	Terrance	Stone
23.	DO	Sarah	Tinsler
24.	DO	Bradley	Werrell
25.	DO	Casey	Willman
26.	DO	Lynda	Williamson
27.	DO		

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board approved the following list of allopathic physicians for full licensure.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

	Lic Type	First Name	Last Name
1.	MD	Bilawal	Ahmed
2.	MD	Jahangir	Ahmed
3.	MD	Rajaa	Almestady
4.	MD	Anna	Anderson
5.	MD	Betty	Anderson
6.	MD	Naomi	Arenson

	Lic Type	First Name	Last Name
36.	MD	Jason	Degani
37.	MD	Ayanna	Diarra
38.	MD	Barbara	Distad
39.	MD	Thomas	Doohan
40.	MD	Andrew	Dorizas
41.	MD	Christopher	Drummond

7.	MD	Timothy	Ballard
8.	MD	Mitali	Bapna
9.	MD	Saurabh	Basundhra
10.	MD	Stephen	Bayles
11.	MD	Scott	Beach
12.	MD	Joshua	Beck
13.	MD	Nikole	Benders-Hadi
14.	MD	Brandon	Berger
15.	MD	Erik	Berger
16.	MD	Sameer	Berry
17.	MD	Erika	Bisgaard
18.	MD	Jonathan	Bloch
19.	MD	Robert	Bowen
20.	MD	Daniel	Borbon
21.	MD	Valerie	Brooke
22.	MD	Eileen	Bulger
23.	MD	Elizabeth	Burgess
24.	MD	Daniel	Burritt
25.	MD	Rachael	Carricaburu
26.	MD	Sarah	Carlson
27.	MD	Jacob	Carlile
28.	MD	Elizabeth	Carpenter
29.	MD	Rebecca	Cisneros
30.	MD	Chi	Chan
31.	MD	Michel	Choueiri
32.	MD	Adam	Corman
33.	MD	Tait	Dalton
34.	MD	Peter	Davis-Allen
35.	MD	Khaled	Deeb
42.	MD	Sutapa	Dube
43.	MD	Sean	Dugan
44.	MD	Sean	Dwijendra
45.	MD	Bishoy	ElBebawy
46.	MD	Samuel	Emerson
47.	MD	Ramez	Ethnasios
48.	MD	Michael	Farber
49.	MD	Megan	Farnsworth
50.	MD	Sarah	Fatool
51.	MD	Andrew	Ferguson
52.	MD	Steven	Fitts
53.	MD	Zachary	Forcade
54.	MD	Karenne	Fru
55.	MD	Daniel	Funsch
56	MD	Malini	Ganesh
57.	MD	Robert	Geise
58.	MD	Anita Rae	Glasson
59.	MD	Zoe	Glick
60.	MD	Monica	Gomberg
61.	MD	Heather	Gridley
62.	MD	Andrea	Greenfeld
63.	MD	Joseph	Guarisco
64.	MD	Tyler	Haas
65.	MD	Donald	Haering
66.	MD	Gregory	Harders
67.	MD	Ryan	Hargraves
68.	MD	Arash	Hassantoufighi
69.	MD	Christopher	Hebert
70.	MD	Michael	Heinrich

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71.	MD	Nancy	Heisel
72.	MD	Julian	Horwitz
73.	MD	Natalie	Howshaw
74.	MD	Jennifer	Huckabee
75.	MD	Yumi	Ishihara
76.	MD	Michael	Jaffe
77.	MD	William	Janss
78.	MD	Jiyeon	Jeon
79.	MD	Nicholas	Johnson
80.	MD	Nathan	Jones
81.	MD	Kimia	Kani
82.	MD	Shannon	Keil
83.	MD	Stephen	Keiser
84.	MD	Meenal	Kheterpal
85.	MD	Imad	Khan
86.	MD	Louis	Kim
87.	MD	Meghana	Kinariwala
88.	MD	Robert	Klemisch
89.	MD	Diana	Kumar
90.	MD	Garson	Lee
91.	MD	Sujin	Lee
92.	MD	Gus	Leotta
93.	MD	Barbara	Levy
94.	MD	Kimberly	Liekweg
95.	MD	Fredrica	Lofquist
96.	MD	Elizabeth	Loggers
97.	MD	Quinton	Lucas
98.	MD	Elizabeth	Madva
99.	MD	Vicky	Mathwig
100.	MD	Christian	McCartney
101.	MD	Gregory	McCormick
102.	MD	Ruth	McGovern
103.	MD	Charles	Minn
104.	MD	Ambreen	Mohamed
105.	MD	Jason	Mounts
106.	MD	Patrick	Mullet
107.	MD	Wayne	Murphy
108.	MD	Julia	Nelson
109.	MD	Amy	Newhouse
110.	MD	Stephanie	Osiecki
111.	MD	Tyler	Ovella
112.	MD	Hetal	Patel
113.	MD	Jayendra	Patel
114.	MD	Brian	Park
115.	MD	Melissa	Park
116.	MD	Kathryn	Pennington
117.	MD	Mara	Phillips
118.	MD	Donald	Pierce
119.	MD	Pollyanna	Pitt
120.	MD	Naomi	Pomerantz
121.	MD	Carmen	Purl
122.	MD	Meera	Ravindranathan
123.	MD	Mark	Reimer
124.	MD	Jonathan	Richina
125.	MD	Rifat	Rifat
126.	MD	Liza	Rodriguez
127.	MD	Enrique	Rodriguez-Paz
128.	MD	Mariajose	Rojas-DeLeon
129.	MD	Joshua	Roland
130.	MD	Daniel	Roubik
131.	MD	Cynthia	Sacco
132.	MD	Gregory	Sacher
133.	MD	Jane	Sailer
134.	MD	Scott	Sanderson
135.	MD	John	Schwab
136.	MD	Garret	Schuchart
137.	MD	Jonathan	Scott
138.	MD	Jeffrey	Sellman
139.	MD	Jeremy	Semeiks
140.	MD	Joseph	Shivdler
141.	MD	Preetika	Sidhu
142	MD	Skyler	Simpson
143.	MD	Krishni	Somaratne
144.	MD	Richard	St Cyr
145.	MD	Matthew	Stampfl
146.	MD	James	Stensby
147.	MD	Barclay	Stewart
148.	MD	Carrie	Sun

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149.	MD	Katharine	Tansavatdi
150.	MD	Sarena	Teng
151.	MD	Genevieve	Viamonte
152.	MD	Kerri	Voigts
153.	MD	Tina	Walker
154.	MD	Teresa	Walsh
155.	MD	Cornell	Wells
156.	MD	Wells	Weymouth
157.	MD	Joanne	Wu

12. Public Comments / Board Correspondence

Chair Nimmo recognized three persons to address the Board:

1) Jackie Robertson, private citizen; urged the Board to consider the needs of chronic pain patients and support policies that eliminate the stigma and the barriers to access legitimate, needed pain medication.

2) Meghan Hall, physician assistant working in Alaska; thanked the Board for its time and consideration regarding the modernization of physician scope of practice; she appreciates the collaboration and looks forward to continued collaboration.

3) Pam Ventgen, Executive Director of the Alaska State Medical Association; urged the board to consider meeting monthly in order to expedite the processing of full licenses, citing concerns with the temporary permits that are issued to practitioners, including barriers to hospital privileges, insurance contracts and DEA licenses. Ms. Ventgen asserted that the Medical Board's silence to the legislature on the issue of independent practice of physician assistants is a grave mistake. Her overall impression is that the Board has missed opportunities to be an asset to the state and needs to figure out how to become a more efficient body.

13. Board Interviews

Ashley Gibbs, MD

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood and approved by roll call vote, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions, for the purpose of discussing Dr. Ashley Gibb's application for licensure, with Board staff remaining during the session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

The board entered executive session at 1:16 p.m. The board returned on the record at 1:25 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood and approved by roll call vote, the Alaska State Medical Board approved Ashley Gibbs, MD a full license.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

Taichi Imamura, MD

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions, for the purpose of discussing Dr. Taichi Imamura's application for licensure, with Board staff remaining during the session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

The board entered executive session at 1:32 p.m. The board returned on the record at 1:53 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board approved Taichi Imamura, MD a full license.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

Benjamin Huneycutt, MD

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions, for the purpose of discussing Dr. Benjamin Huneycutt's application for licensure, with Board staff remaining during the session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

The board entered executive session at 1:56 p.m. The board returned on the record at 2:10 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board approved Benjamin Huneycutt, MD a full license.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

Adam Kishman, PA

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions, for the purpose of discussing Adam Kishman's application for licensure, with Board staff remaining during the session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

The board entered executive session at 2:13 p.m. The board returned on the record at 2:27 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board approved Adam Kishman, PA a full license.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

Eric Wright, MD

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions, for the purpose of discussing Dr. Eric Wright's application for licensure, with Board staff remaining during the session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

The board entered executive session at 2:30 p.m. The board returned on the record at 2:35 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board approved Eric Wright, MD a full license.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, and Mr. Wilson

15. Malpractice Case Reviews

The Chair recommended that the Board enter executive session.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board entered into executive session, in accordance with AS 44.62.310 (c)(3), and Alaska Constitutional Right to Privacy Provisions, with board staff remaining in the session, for the purpose of discussing malpractice cases involving the following practitioners:

1. Chi Dau, MD
2. Giulia Tortora, MD
3. Gregory Norkus, MD
4. James Forage, MD
5. Jesse Kincaid, MD
6. Matthew Leonard, MD
7. Parin Cho, MD

Roll Call Vote: Yeas, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Barnes, Dr. Nimmo, and Mr. Wilson.

The Board went off the record and entered executive session at 2:7 p.m. The Board returned on the record at 3:35 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote the Alaska State Medical Board decided to take no further action with respect to malpractice cases involving the following physicians:

1. **Giulia Tortora, MD**
2. **James Forage, MD**
3. **Jesse Kincaid, MD**
4. **Matthew Leonard, MD**
5. **Parin Cho, MD**

Roll Call Vote: Yeas, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Barnes, Dr. Nimmo, and Mr. Wilson.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote the Alaska State Medical Board decided to request the Executive Administrator draft a non-disciplinary advisory letter for the following physicians pertaining to their involvement in the reviewed malpractice cases:

1. **Chi Dau, MD**
2. **Gregory Norkus, MD**

Roll Call Vote: Yeas, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Barnes, Dr. Nimmo, and Mr. Wilson.

16. Applicant Review (see pages 5-10)

20. Closing Business/Adjourn

Chair Nimmo called for any final business.

On a motion duly made by Ms. Mielke, seconded by Sarah Bigelow Hood, and approved by roll call vote the Alaska State Medical Board decided to initiate a regulation project to grant board staff, including the Executive Administrator or Licensing Supervisor, the authority to grant full licenses to applicants with no "yes" answers to professional fitness questions and no malpractice cases.

Roll Call Vote: Yeas, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Barnes, Dr. Nimmo, and Mr. Wilson.

Chair Nimmo announced a special meeting for Board Training, scheduled for May 23. Board members requested to have this meeting date changed to May 30, 4:00 to 6:00 pm.

The next quarterly meeting date is scheduled for August 9, 2024.

The meeting was adjourned by unanimous consent at 3:50 p.m.

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS, AND PROFESSIONAL LICENSING

STATE MEDICAL BOARD
MINUTES OF MEETING
Thursday May 30, 2024

These are DRAFT minutes prepared by staff of the Division of Corporations, Business and Professional Licensing. They have not been reviewed or approved by the Board.

By authority of AS 08.01.070(2) and in compliance with the provisions of AS 44.62, a special meeting of the Alaska State Medical Board was held Thursday, May 30, 2024.

1. Call to Order/ Roll Call
The meeting was called to order by Chair Nimmo at 4:01 p.m.

Roll Call
Board members present:
David Barnes, DO
Sarah Bigelow Hood, PA-C
Matt Heilala, DPM
Lydia Mielke, Public Member (Secretary)
Eric Nimmo, MD
Brent Taylor, MD (New)
David Wilson, Public Member

Newly appointed board member, Dr. Brent Taylor was introduced and welcomed.

State employees present:
Sylvan Robb, CBPL Division Director; Erika Prieksat, Chief Investigator; Harriet Milks, Assistant Attorney General; Shelley Irons, Investigator; Angel Romero, Investigator; Natalie Norberg, Executive Administrator

Board member, David Paulson, MD joined the meeting at 4:07 p.m.

2. Review / Approval of Agenda

On a motion duly made by Ms. Mielke and seconded by Ms. Bigelow-Hood, the Alaska State Medical Board approved by roll call vote the agenda as presented.

Roll Call: Yeas, Dr. David Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Taylor, and Mr. Wilson.
Absent: Dr. Paulson

3. Investigative & Legal Training

On a motion duly made by Ms. Mielke and seconded by Ms. Bigelow-Hood, the Alaska State Medical Board entered executive session for the purpose of discussing matters under AS 44.62.310(c) (3), related to attorney-client privilege.

Roll Call: Yeas, Dr. David Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Taylor, and Mr. Wilson.
Absent: Dr. Paulson

Staff remained in the session and all others were excluded.

The Board entered executive session at 4:05 p.m. The Board exited executive session at 5:47 p.m.

4. Executive Session for Investigative cases
Case: 2023-001041

On a motion duly made by Ms. Mielke and seconded by Ms. Bigelow-Hood, the Alaska State Medical Board entered executive session for the purpose of discussing matters under AS 44.62.310(c)(2) & (3) involving Division case #2023-001041 with Investigations and Board staff remaining in the session and the reviewing board member abstaining from the session.

Roll Call: Yeas, Dr. David Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

The Board entered executive session at 5:48 p.m. The Board exited executive session at 5:57 p.m.

On a motion duly made by Ms. Mielke, seconded by Dr. Barnes, and approved by roll call vote, the Alaska State Medical Board accepted the consent agreement as presented for Audrey Kelley, P.A. in case: 2023-001041

Roll Call: Yeas, Dr. David Barnes, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.
Abstained: Ms. Bigelow-Hood

Case: 2024-000353

On a motion duly made by Ms. Mielke and seconded by Ms. Bigelow-Hood, the Alaska State Medical Board entered executive session for the purpose of discussing matters under AS 44.62.310(c)(2) involving Division case #2024-000353 with Investigations and Board staff remaining in the session.

Roll Call: Yeas, Dr. David Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

The Board entered executive session at 5:59 p.m. The Board exited executive session at 6:04 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow-Hood, and approved by roll call vote, the Alaska State Medical Board accepted the Voluntary Surrender of License for Dr. Steven Powell in case #2024-000353.

Roll Call: Yeas, Dr. David Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

On a motion duly made by Ms. Mielke and seconded by Ms. Bigelow Hood, the Alaska State Medical Board entered executive session for the purpose of discussing matters under AS 44.62.310(c)(2) involving an application for licensure with board staff remaining in the session.

Roll Call: Yeas, Dr. David Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

The Board entered executive session at 6:10 p.m. The Board exited executive session at 6:25 p.m.

On a motion duly made by Ms. Mielke, seconded by Dr. Barnes, and approved by roll call vote, the Alaska State Medical Board postponed a decision on granting Dr. Arif Chowdhury until additional information is received.

Roll Call: Yeas, Dr. David Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

5. Deliberative Session

On a motion duly made by Ms. Mielke and seconded by Ms. Bigelow-Hood, the Alaska State Medical Board entered into a deliberative session under AS 44.62.310(d) solely to make a decision concerning the proposed consent agreement,

In the Matter of Barry Grey
Board Case Number 2023-000022
Office of Administrative Hearings Case Number 23-0612-MED

Roll Call: Yeas, Dr. David Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

Administrative Law Judge Max Garner, serving as the mediator in this matter, remained with the Board during the deliberative session, all others were excluded, including board and investigative staff.

The Board entered executive session at 6:30 p.m. The Board exited executive session at 6:49 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow-Hood, and approved by roll call vote, the Alaska State Medical Board accepted the consent agreement as proposed

In the Matter of Barry Grey
Board Case Number 2023-000022
Office of Administrative Hearings Case Number 23-0612-MED

Roll Call: Yeas, Dr. David Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

6. Applicant Review

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow-Hood, and approved by roll call vote, the Alaska State Medical Board approved the following list of applicants for full licenses.

Roll Call: Yeas, Dr. David Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

	Lic Type	First Name	Last Name
1.	PA	Lissette	Carrera
2.	DO	Michael	Caruso
3.	DO	McKay	Frandsen
4.	MD	Cindy	Hsieh
5.	MD	Randa	Jaber
6.	MD	Jessica	Kelley
7.	MD	Jasmina	Krstic
8.	MD	Perry	Lee
9.	MD	Elizabeth	Malik
10.	MD	Joseph	Migliuri
11.	DO	Angela	Palitto
12.	MD	Amin	Rabiei
13.	MD	Michaela	Tsai
14.	MD	Dominic	Van Nielen
15.	MD	Ian	Wisecarver
16.	PA	Marina	Zanzarini

7. Wrap up /Adjourn

Board members agreed on June 13th for a special meeting date to discuss board priorities, the annual report, and the physician assistant work group.

The Meeting was adjourned by unanimous consent at 6:56 p.m.

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS, AND PROFESSIONAL LICENSING

STATE MEDICAL BOARD
MINUTES OF MEETING
Thursday June 13, 2024

These are DRAFT minutes prepared by staff of the Division of Corporations, Business and Professional Licensing. They have not been reviewed or approved by the Board.

By authority of AS 08.01.070(2) and in compliance with the provisions of AS 44.62, a special meeting of the Alaska State Medical Board was held Thursday, June 13, 2024.

1. Call to Order/ Roll Call
The meeting was called to order by Chair Nimmo at 4:02 p.m.

Roll Call
Board members present:
Eric Nimmo, MD, Chair
David Barnes, DO
Matt Heilala, DPM
Lydia Mielke, Public Member (Secretary)
Brent Taylor, MD (New)

State employees present:
Sonia Lipker, Senior Investigator, Natalie Norberg, Executive Administrator, Jason Kaeser, Licensing Supervisor

Board members, David Wilson, joined the meeting at 4:11 p.m., David Paulson joined at 4:22 p.m. and Sarah Bigelow Hood joined at 4:25 p.m.

2. Review / Approval of Agenda

On a motion duly made by Ms. Mielke and seconded by Dr. Barnes, the Alaska State Medical Board approved by roll call vote the agenda as presented.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Dr. Nimmo, and Dr. Taylor
Absent: Ms. Bigelow Hood, Dr. Paulson and Mr. Wilson

3. Investigations Update

On a motion duly made by Ms. Mielke, seconded by Dr. Taylor, and approved by a roll call vote, the Alaska State Medical Board entered executive session under AS 44.62.310(c)(2) & (3) involving Division case #2023-000030 with Investigations and Board staff remaining in the session and the reviewing board member abstaining from the session.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Dr. Nimmo, and Dr. Taylor
Absent: Ms. Bigelow Hood, Dr. Paulson and Mr. Wilson

The Board entered executive session at 4:06 p.m. The Board exited executive session at 4:25 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board decided to table the imposition of a civil fine and request a voluntary suspension of license involving Division case #2023-000030.

Roll Call: Yeas, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.
Abstained: Dr. Barnes

4. Strategic Goals and Priorities

Chair Nimmo introduced this topic, referencing the *Goals and Priorities* document drafted by Ms. Norberg, which includes a compilation of former Board priorities and strategies and new strategies identified by board members through an online survey process.

On a motion duly made by Ms. Mielke, seconded by Dr. Barnes, and approved by roll call vote, the Alaska State Medical Board approved the 2024 board priorities, goals and strategies as presented.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

Sarah Bigelow Hood requested an additional priority be added to the list: The board's advocacy for a statutory change related to eliminating the requirement to respond to subpoena requests only by telephone and adding the ability to respond through an email.

On a motion duly made by Ms. Mielke, seconded by Dr. Barnes, and approved by roll call vote, the Alaska State Medical Board decided to revise the 2024 board priorities, goals and strategies to include advocating for statutory change related to the method for subpoena responses.

Roll Call: Yeas, Dr. David Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

Chair Nimmo recommended as a next step, the board rank the list of strategies in the order of their perceived urgency or priority in order to help the board identify a timeline for pursuing its goals and strategies.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board approved to request the Executive Administrator to poll board members for the purpose of ranking the list of board goals and strategies in priority order.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

Chair Nimmo asserted that two items should not wait to be prioritized and could be immediately addressed by the board. The first of these issues being the consideration of establishing a regular, short, monthly meeting for the purpose of addressing time-sensitive business items such as licensing applications, investigative matters, or possibly interviews. Several board members spoke in favor of adopting a regular, monthly meeting schedule, allowing for flexibility as needed.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board approved the implementation of a regular monthly meeting schedule to address business that cannot wait until the quarterly meetings.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

The second priority item raised by Dr. Nimmo was the matter related to the authorization of Board staff to approve full licenses for applicants with clean records. At the last quarterly meeting the Board approved the initiation of a regulation project aimed to address this matter. Ms. Norberg explained that after a thorough examination, it was determined that the framework for this delegated authority currently exists in statute and regulation and a new regulation project is not necessary. This goal may be achieved through a Board motion.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board granted Natalie Norberg, Executive Administrator, the authority to approve full licensure to applicants with a complete application and no "yes" answers to professional fitness questions.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

5. Annual Report

Chair Nimmo invited Ms. Norberg to introduce the draft Annual Report. Ms. Norberg explained that a report containing a summary of the Board's activities is required annually to the legislature. The report must be approved by the board before it can be transmitted to the legislature. It was suggested that the aforementioned statutory change, related to eliminating the requirement to respond to subpoena requests only by telephone, be added under the "needs" section of the report. Additionally, the final numbers of approved licenses will be updated just prior to the report's submission to reflect the most accurate statistics for the year.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board approved the FY 2024 draft annual report as presented and with the amendments as discussed.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

6. Physician Assistant Work Group

Chair Nimmo reminded board members that at the February 2024 board meeting the Physician Assistant Work Group was tabled for the duration of the legislative session. Now that the legislative session is over, the board must decide whether to 1) reconvene the work group; 2) maintain the existing

work group membership, and if so; 3) what to do about the two vacant work group positions. Ms. Bigelow Hood asserted that there is still a strong public interest in having the regulations modernized. Mr. Wilson asked for clarity regarding the key changes that need to be made for the regulations to be "modernized." Prescribing and scope of practice restrictions, remote practice rules and requirements for an alternate collaborating physician were examples of topics previously identified as needing to be updated. Several board members voiced support for reconvening the work group.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board approved the reconvening of the Physician Assistant for Work Group for the purpose of recommending changes to modernize existing regulations and directed the Executive Administrator to solicit statements of interest from physicians who may be interested in joining the work group to replace the physicians who dropped out.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Matt Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

7. Applicant Review

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood and approved by roll call vote, the Alaska State Medical Board approved the following list of applicants for full licensure.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Paulson, Dr. Taylor and Mr. Wilson

	Lic Type	First Name	Last Name
1.	MD	Kyle	Bonar
2.	PA	Jennifer	Brooks
3.	PA	Lissette	Carrera
4.	MD	Dawn	Clancy
5.	DO	Kelsey	Flynn
6.	MD	Lilian	Holloway
7.	DO	Patrick	Moran
8.	MD	Khalid	Mughal
9.	DO	Frias	Naji
10.	MD	Laura	Nason
11.	MD	Emil	Sanchez

8. Wrap up /Adjourn

Chair Nimmo opened the floor for board members to discuss the issue of the recusal of the Reviewing Board Member's participation in deliberative sessions; after noting that it appears the matter continues to remain unresolved after the special legal training and discussion on this topic during the May 30 special board meeting. Board members reflected on their experiences as reviewing board members and provided suggestions for ensuring the process is unbiased, defensible and protects the public. Some members suggested that having increased access to legal council during deliberative sessions would increase their confidence in the process and make them feel more comfortable about having the

Reviewing Board Member Excluded from sessions. In conclusion, Chair Nimmo summarized the consensus of the board as being that Reviewing Board Members will be excluded from deliberative sessions unless there are extraordinary circumstances.

The Meeting was adjourned by unanimous consent at 5:46 p.m.

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS, AND PROFESSIONAL LICENSING

STATE MEDICAL BOARD
MINUTES OF MEETING
Thursday July 18, 2024

These are DRAFT minutes prepared by staff of the Division of Corporations, Business and Professional Licensing. They have not been reviewed or approved by the Board.

By authority of AS 08.01.070(2) and in compliance with the provisions of AS 44.62, a special meeting of the Alaska State Medical Board was held Thursday, July 18, 2024.

1. Call to Order/ Roll Call
The meeting was called to order by Chair Nimmo at 3:58 p.m.

Roll Call
Board members present:
Eric Nimmo, MD, Chair
David Barnes, DO
Sarah Bigelow-Hood, Vice-Chair
Matt Heilala, DPM
Lydia Mielke, Public Member (Secretary)
Brent Taylor, MD
David Wilson, Public Member
Absent: David Paulson, MD

State employees present:
Natalie Norberg, Executive Administrator and Jason Kaeser, Licensing Supervisor

2. Review / Approval of Agenda

On a motion duly made by Ms. Mielke and seconded by Dr. Heilala, the Alaska State Medical Board approved by roll call vote the agenda as presented.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow-Hood , Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Taylor, and Mr. Wilson
Absent: Dr. Paulson

3. Applicant Review / Board Interviews

- **Arif Chowdhury, MD**

Dr. Chowdhury introduced himself and requested to go into executive session for his interview.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow-Hood, and approved by a roll call vote, the Alaska State Medical Board entered executive session under AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions for the purpose of discussing Dr. Chowdhury's application for licensure with Board staff remaining in the session

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow-Hood , Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Taylor, and Mr. Wilson
Absent: Dr. Paulson

The Board entered executive session at 4:11 p.m. The Board exited executive session at 4:18 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood and approved by roll call vote, the Alaska State Medical Board approved Arif Chowdhury, MD a full license.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Taylor and Mr. Wilson
Absent: Dr. Paulson

- **Kleber Fertrin, MD**

Dr. Fertrin was a no-show for his interview.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow-Hood and approved by roll call vote, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions, for the purpose of discussing Dr. Kleber Fertrin's application for licensure, with Board staff remaining during the session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Taylor and Mr. Wilson
Absent: Dr. Paulson

The board entered executive session at 4:40 p.m. The board returned on the record at 4:57 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood and approved by roll call vote, the Alaska State Medical Board tabled a decision to grant Kleber Fertrin, MD a license.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Taylor and Mr. Wilson
Absent: Dr. Paulson

4. Regulation Project Update

Chair Nimmo invited Ms. Norberg to introduce this topic. It was explained that the draft regulations went out for public comment. Comments received were compiled for the board's review to contemplate prior to a final vote on the changes. Chair Nimmo read the public comments outload to the board.

In considering all public comments received and costs to private persons, on a motion duly made by Ms. Mielke and seconded by Ms. Bigelow-Hood, the Alaska State Medical Board adopted the proposed regulations for file number 2024200012 pertaining to the elimination of redundant requirements for licensure for physicians to streamline and expedite the licensure process as proposed and publicly noticed.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Taylor and Mr. Wilson
Absent: Dr. Paulson

5. Ratification / Discussion of physician participants for PA Work Group

Chair Nimmo explained that prior to today's meeting the statements received from physicians interested in serving on the Physician Assistant Regulation Change Work Group were compiled and provided to board members, who were then asked to each select their top two choices to serve on the work group through an electronic survey process. The results of this survey were presented. The physicians with the most votes included doctors Daniel Reyolds and Jonathan Barnes.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood and approved by roll call vote, the Alaska State Medical Board approved physicians Daniel Reynolds and Jonathan Barnes to serve on the Physician Assistant Regulation Change Work Group.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Nimmo, Dr. Taylor and Mr. Wilson
Absent: Dr. Paulson

6. Wrap up / Adjourn

The meeting was adjourned by unanimous consent at 4:59 p.m.

Medical Board	FY 18	FY 19	Biennium	FY 20	FY 21	Biennium	FY 22	FY 23	Biennium	FY 24 1st - 3rd QTR
Revenue										
Revenue from License Fees	$ 347,304	$ 2,380,618	$ 2,727,922	$ 578,308	$ 2,597,830	$ 3,176,138	$ 945,106	$ 2,876,309	$ 3,821,415	$ 380,563
General Fund Received					$ -	-	$ 272,744	$ 173,090	445,834	$ -
Allowable Third Party Reimbursements	3,517	184	3,701	$ -	$ -	-	$ -	$ -	-	$ -
TOTAL REVENUE	$ 350,821	$ 2,380,802	$ 2,731,623	$ 578,308	$ 2,597,830	$ 3,176,138	$ 1,217,850	$ 3,049,399	$ 4,267,249	$ 380,563
Expenditures										
Non Investigation Expenditures										
1000 - Personal Services	488,823	473,122	961,945	420,810	521,976	942,786	446,216	454,584	900,800	350,907
2000 - Travel	17,577	15,801	33,378	13,357	-	13,357	8,875	1,471	10,346	822
3000 - Services	44,741	31,730	76,471	23,009	46,044	69,053	69,997	97,210	167,207	68,100
4000 - Commodities	2,016	1,525	3,541	1,252	1,290	2,542	3,278	3,045	6,323	2,099
5000 - Capital Outlay	-		-	-	-	-	-	-	-	-
Total Non-Investigation Expenditures	553,157	522,178	1,075,335	458,428	569,310	1,027,738	528,366	556,310	1,084,676	421,927
Investigation Expenditures										
1000-Personal Services	210,010	226,965	436,975	264,001	272,106	536,107	289,348	336,511	625,859	293,408
2000 - Travel		2,104	2,104	2,032	-	2,032	2,655	-	2,655	-
3023 - Expert Witness	1,700	7,577	9,277	16,050	22,775	38,825	31,350	14,000	45,350	19,635
3088 - Inter-Agency Legal	60,885	34,329	95,214	56,267	33,435	89,702	42,629	208,613	251,242	200,426
3094 - Inter-Agency Hearing/Mediation	9,299	28,803	38,102	18,640	911	19,551	11,870	61,195	73,065	36,473
3000 - Services other		3,348	3,348	1,919	625	2,544	1,257	2,126	3,383	481
4000 - Commodities		-	-	-	-	-	-	-	-	69
Total Investigation Expenditures	281,894	303,126	585,020	358,909	329,852	688,761	379,109	622,445	1,001,554	550,494
Total Direct Expenditures	835,051	825,304	1,660,355	817,337	899,162	1,716,499	907,475	1,178,755	2,086,230	972,421
Indirect Expenditures										
Internal Administrative Costs	225,669	263,046	488,715	285,614	316,771	602,385	250,301	286,502	536,803	214,877
Departmental Costs	150,736	168,176	318,912	123,361	143,500	266,861	122,427	120,114	242,541	90,086
Statewide Costs	78,101	72,595	150,696	90,219	108,989	199,208	92,456	86,033	178,489	64,525
Total Indirect Expenditures	454,506	503,817	958,323	499,194	569,260	1,068,454	465,184	492,649	957,833	369,488
			-			-				
TOTAL EXPENDITURES	**$ 1,289,557**	**$ 1,329,121**	**$ 2,618,678**	**$ 1,316,531**	**$ 1,468,422**	**$ 2,784,953**	**$ 1,372,659**	**$ 1,671,404**	**$ 3,044,063**	**$ 1,341,909**
Cumulative Surplus (Deficit)										
Beginning Cumulative Surplus (Deficit)	$ 137,265	$ (801,471)		$ 250,210	$ (488,013)		$ 641,395	$ 486,586		$ 1,864,582
Annual Increase/(Decrease)	(938,736)	1,051,681		(738,223)	1,129,408		(154,809)	1,377,996		(961,347)
Ending Cumulative Surplus (Deficit)	$ (801,471)	250,210		$ (488,013)	$ 641,395		$ 486,586	$ 1,864,582		$ 903,235
Statistical Information										
Number of Licenses for Indirect calculation	7,138	8,421		9,801	12,808		8,259	9,221		

Additional information:

- *General fund dollars were received in FY21-FY23 to offset increases in personal services and help prevent programs from going into deficit or increase fees.*
- *Most recent fee change: Fee reduction FY23*
- *Annual license fee analysis will include consideration of other factors such as board and licensee input, potential investigation load, court cases, multiple license and fee types under one program, and program changes per AS 08.01.065.*

Appropriation Name (Ex)	(Multiple Items)
Sub Unit	(All)
PL Task Code	MED1

Sum of Budgetary Expenditures	Object Type Name (Ex)				
Object Name (Ex)	1000 - Personal Services	2000 - Travel	3000 - Services	4000 - Commodities	Grand Total
1011 - Regular Compensation	333,613.91				333,613.91
1014 - Overtime	29.68				29.68
1021 - Allowances to Employees	288.00				288.00
1023 - Leave Taken	65,125.31				65,125.31
1028 - Alaska Supplemental Benefit	24,486.26				24,486.26
1029 - Public Employee's Retirement System Defined Benefits	20,455.79				20,455.79
1030 - Public Employee's Retirement System Defined Contribution	16,699.19				16,699.19
1034 - Public Employee's Retirement System Defined Cont Health Reim	10,686.66				10,686.66
1035 - Public Employee's Retiremnt Sys Defined Cont Retiree Medical	3,154.08				3,154.08
1037 - Public Employee's Retiremnt Sys Defined Benefit Unfnd Liab	47,728.28				47,728.28
1040 - Group Health Insurance	104,901.21				104,901.21
1041 - Basic Life and Travel	49.62				49.62
1042 - Worker's Compensation Insurance	2,716.10				2,716.10
1047 - Leave Cash In Employer Charge	9,212.11				9,212.11
1048 - Terminal Leave Employer Charge	6,380.38				6,380.38
1053 - Medicare Tax	5,560.38				5,560.38
1063 - GGU Business Leave Bank Usage	598.96				598.96
1069 - SU Business Leave Bank Contributions	140.94				140.94
1077 - ASEA Legal Trust	376.73				376.73
1079 - ASEA Injury Leave Usage	44.14				44.14
1080 - SU Legal Trst	123.30				123.30
1970 - Personal Services Transfer	(8,055.98)				(8,055.98)
2000 - In-State Employee Airfare		347.51			347.51
2005 - In-State Non-Employee Airfare		474.79			474.79
3002 - Memberships			3,865.00		3,865.00
3023 - Expert Witness			19,635.00		19,635.00
3035 - Long Distance			53.63		53.63
3036 - Local/Equipment Charges			14.33		14.33
3044 - Courier			65.21		65.21
3045 - Postage			433.42		433.42
3046 - Advertising			929.55		929.55
3057 - Structure, Infrastructure and Land - Rentals/Leases			119.68		119.68
3085 - Inter-Agency Mail			765.85		765.85
3088 - Inter-Agency Legal			257,000.46		257,000.46
3094 - Inter-Agency Hearing/Mediation			42,233.10		42,233.10
4002 - Business Supplies				75.53	75.53
4005 - Subscriptions				2,082.50	2,082.50
4006 - I/A Commodity Purchases				10.00	10.00
Grand Total	**644,315.05**	**822.30**	**325,115.23**	**2,168.03**	**972,420.61**

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

Re: Your Understanding and Support

June 19, 2024

Ms. Natalie Norberg, Executive Director
Alaska State Medical Board
P.O. Box 110806, Juneau, AK 99811-0806

Dear Ms. Norberg:

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

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

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

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

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

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

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

Very truly yours,

Pz

Xiulu Ruan, MD

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

Re: Your Understanding and Support

Date: June 15, 2024

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

Dear Mr. Quinn:

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

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

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

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

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

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

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

Most respectfully,

Xiulu Ruan, MD

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

Xiulu Ruan, MD; June 2, 2024

I. INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

II. LEGAL FRAMEWORK

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

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

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

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

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

III. DISCUSSION

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

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

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

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

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

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

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

1306.04(a) provides:

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

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

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

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

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

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

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

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

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

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

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

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

E. Several Major Flaws In Moore 1975

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ii. Relevant caselaw involving the fallacy of antecedent includes:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Conclusion

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

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

Xiulu Ruan, MD
66857019
F.C.I. Oakdale I, U1
P.O. Box 5000
Oakdale, LA 71463

SHREVEPORT
24 JUN 2024 PM

To: Ms. Natalie Norberg
Alaska State Medical Board
P.O. Box 110806
Juneau, Alaska 99811-0806

99811-080606

From: christine woods <christinewoods523@gmail.com>
Sent: Friday, July 5, 2024 12:57 PM
To: Board of Psychologists (CED sponsored) <boardofpsychologists@alaska.gov>; Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: request for PSYPACT Introduction in Alaska

Hello,

My name is Christine Woods, I am a Neurology Physician in Alaska.

I am reaching out regarding request for introduction of Legislation for PSYPACT, which is the Psychology Interjurisdictional Compact (PSYPACT) - it is an interstate compact designed to facilitate the practice of telepsychology and the temporary in-person, face-to-face practice of psychology across state boundaries.

Additional information is easily accessed on their website and through their staff at info@psypact.org
Website: www.psypact.org

I was advised by the group to reach out to state licensing boards to request initiation of psypact legislation & support to help facilitate increased access to mental health care for Alaskans.
As a physician in the community, I see firsthand the high demand and needs of patients receiving consistent psychological support, and request consideration of working with Psypact on legislation to benefit our state.

Sincerely,

Dr Christine Woods

From: Board, Medical (CED sponsored)
To: Jgreco@mwe.com
Subject: RE: Telehealth
Date: Tuesday, June 11, 2024 2:00:46 PM
Attachments: image001.png
image002.png
image003.png

Greetings,

Thank you for your inquiry. No, the Alaska State Medical Board has not adopted the 2022 updated version, model policy for telemedicine. The 2014 remains in effect.

Best regards,

Natalie Norberg, LMSW
Executive Administrator, State Medical Board
Corporations, Business & Professional Licensing
natalie.norberg@alaska.gov
Office: 907-465-6243 | Fax: 907-465-2974
www.commerce.alaska.gov

From: Greco, Jayda <Jgreco@mwe.com>
Sent: Monday, June 10, 2024 11:33 AM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Telehealth

Good Afternoon,

Has the board adopted the most recent version of the Model Policy for the Appropriate Use of Telemedicine in the Practice of Medicine? We note the statute mentions the 2014 version, but it has recently been updated as of 2022.

12 AAC 40.943. Standards of practice for telemedicine. (a) The guiding principles for telemedicine practice in the American Medical Association (AMA), Report 7 of the Council on Medical Service (A-14), Coverage of and Payment for Telemedicine, dated 2014, and the Federation of State Medical Boards (FSMB), Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine, dated April 2014, are adopted by reference as the standards of practice when providing treatment, rendering a diagnosis, prescribing, dispensing, or administering a prescription or controlled substance without first conducting an in-person physical examination under AS 08.64.364.

Thank you!

JAYDA GRECO (SHE/HER/HERS)
Associate
McDermott Will & Emery LLP 444 West Lake Street, Suite 4000, Chicago, IL 60606-0029
Tel +1 312 984 7709 **Email** jgreco@mwe.com
Website | **vCard** | **LinkedIn**

Chambers USA, Band 1 Healthcare | *The Legal 500 USA*, Tier 1 Healthcare: Service Providers and Healthcare: Insurers | *U.S. News - Best Lawyers* "Best Law Firms," Tier 1 Healthcare | *Law360*, "Health Team of the Year"

From: Andrea Ciccone
To: Andrea Ciccone
Subject: Re: New Board Member Training Program
Date: Friday, July 26, 2024 12:51:28 PM
Attachments: Outlook-214krjr5.png

Dear Executive Directors,

The registration is now open for the inaugural FSMB New Board Member Training program. The registration link is below. Please forward it to your board members that may be interested in participating.

State Medical Board Member Training | FSMB (pathlms.com)

We will advertise this in next week's eNews as well.

If you have any questions, please let me know.

Thanks!
Andrea

From: Andrea Ciccone <aciccone@fsmb.org>
Sent: Tuesday, July 2, 2024 5:20 PM
To: Andrea Ciccone <aciccone@fsmb.org>
Subject: New Board Member Training Program

Dear Executive Directors,

We are excited to announce the inaugural FSMB New Board Member Training program, an initiative designed to support and educate new members of state medical boards on their critical roles and responsibilities. This comprehensive training, offered virtually over three interactive webinars, will cover a wide array of topics, including foundational aspects of professional regulation, legal overviews, policymaking, accountability, licensing, and disciplinary processes, as well as ethics and professionalism, among others.

The three modules will be held on the following dates and times:

- August 20 1:00-3:00 ET
- September 25 10:00-12:00 ET
- October 11 10:00-12:00 ET

The training has been designed with the expressed needs of state medical boards in mind and

is targeted at new board members who have recently joined state medical boards and are seeking to understand the landscape of medical regulation and their part in it. Our faculty comprises experienced professionals and experts in the field of medical regulation and board governance, ensuring that participants receive the highest quality education directly from individuals who have staffed and served on state medical boards.

Registration for the FSMB New Board Member Training will open soon, and we encourage all member boards to inform their new appointees about this valuable opportunity. Stay tuned for more information on how to register and participate in this program. If you have any questions in the meantime, please feel free to reach out to me.

Thanks so much!

Andrea

Andrea L. Ciccone, JD (she/her/hers)
Vice President, Engagement and Member Services

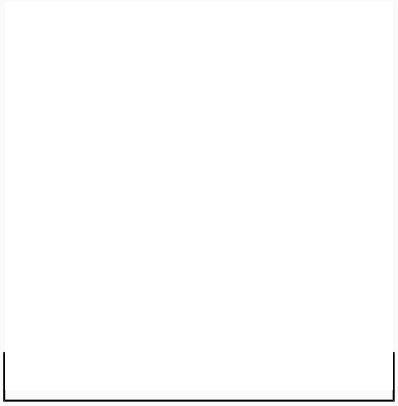
Federation of State Medical Boards
1775 Eye St NW | Suite 410 | Washington, DC 20006
o: 202-601-7801 | aciccone@fsmb.org | www.fsmb.org

From: Board, Medical (CED sponsored)
To: Norberg, Natalie M (CED)
Subject: FW: OFFICIAL NOTICE - CALL FOR COMMENT
Date: Wednesday, July 24, 2024 11:22:08 AM

Not sure if you or a board member would be interested in this.

- Jason

From: Sandy Saylor <CPMEStaff@cpme.org>
Sent: Monday, July 22, 2024 7:41 AM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: OFFICIAL NOTICE - CALL FOR COMMENT



CPME Publications 720 and 730 (Continuing Education Committee)

OFFICIAL NOTICE – CALL FOR COMMENT

In keeping with the Council on Podiatric Medical Education's obligation as an accrediting body to inform its community of interest of proposed changes to approval standards, requirements, and procedures, the council wishes to notify organizations and individuals regarding proposed revisions to CPME documents 720, *Standards and Requirements for Approval of Continuing Education in Podiatric Medicine* and 730, *Procedures for Approval of*

Continuing Education in Podiatric Medicine.

Every six (6) years, the Council conducts a comprehensive review of its standards, requirements, and procedures associated with its evaluation activities. The Continuing Education Ad Hoc Committee began meeting two years ago. Following twelve meetings (in person and virtual) the Continuing Education Ad Hoc Committee completed its revision of each standard and formally adopted both draft documents in March, agreeing that they were ready for review by the council. At its April 2024 meeting, the council reviewed and approved the draft documents and determined that the revised documents will be disseminated to the community of interest for a period of 60 days.

Click on this link, CPME 720 and 730 Revisions, to view Draft I of the documents for comment.

To submit comment, you are welcome to complete this this survey and you may also submit written comments to ssaylor@cpme.org.

Next steps: The CPME will review the survey responses and comments from the community of interest at their October 2024 meeting to determine if the documents are ready for adoption.

You are encouraged to forward this message as you see appropriate. The Council is seeking the broadest possible input. Please send your comments by ***August 20, 2024*****,** to ssaylor@cpme.org.

Thank you.

Sandra Saylor
Associate Director of the Council on Podiatric Medical Education
11400 Rockville Pike
Suite 220
Rockville, Maryland 20852
301-581-9290
ssaylor@cpme.org

Our mailing address is:
Council on Podiatric Medical Education
11400 Rocvill Pike, Suite 220
Rockville, MD 20852

From:	Richard Lawhern
To:	tseamon@albme.gov; Board, Medical (CED sponsored); mdarian@do.az.gov; support@armedicalboard.org; publicaffairs@mbc.ca.gov; dora_medicalboard@state.co.us; dph.medicalworkforce@ct.gov; customerservice.dpr@delaware.gov; doh.hpla@dc.gov; medicalboard@flhealth.gov; medbd@hawaii.gov; bom@bom.idaho.gov; dph.medicaldisciplinary@illinois.gov; plaboard@pla.in.gov; medicalboard@iowa.gov; kbha@ks.gov; kbml@ky.gov; lsbme@lsbme.la.gov; maine.medicalboard@maine.gov; mbpmail@maryland.gov; bom@mass.gov; bom@michigan.gov; medical.board@state.mn.us; msbml@msbml.ms.gov; boardofregistration@health.mo.gov; dlibsdmed@mt.gov; dhhs.medicalboard@nebraska.gov; nevada.medicalboard@medboard.nv.gov; nh.boardofmedicine@nh.gov; njconsumeraffairs@njconsumeraffairs.org; nmbme@state.nm.us; opmc@health.ny.gov; ncmedboard@ncmedboard.org; ndbom@nd.gov; med.board@ohio.gov; omb@omb.ok.gov; omb@omb.state.or.us; st-medboard@pa.gov; doh.elicense@health.ri.gov; Staci.Fischer@health.ri.gov; medboard@llr.sc.gov; sdbmoe@state.sd.us; medical.health@tn.gov; verifcic@tmb.state.tx.us; verifcic@tmb.state.tx.us; b1@utah.gov; AHS.VDHMedicalBoard@vermont.gov; medbd@dhp.virginia.gov; medical.commission@doh.wa.gov; bhp@dhp.virginia.gov; dsps@wisconsin.gov; wyomedboard@state.wy.us; secretary@alabamapublichealth.gov; dph.commissioner@alaska.gov; director@azdhs.gov; ADH.Sec@arkansas.gov; secretary@cdph.ca.gov; cdphe.executive.director@state.co.us; DPH.Commissioner@ct.gov; dhss.secretary@delaware.gov; secretary@flhealth.gov; DPH.commissioner@ga.gov; doh.director@hawaii.gov; dhw.director@dhw.idaho.gov; dph.director@illinois.gov; ISDH.commissioner@isdh.in.gov; idph.director@idph.iowa.gov; KDHE.commissioner@ks.gov; CHFS.Secretary@ky.gov; DHH.Secretary@la.gov; DHHS.commissioner@maine.gov; DHMH.Secretary@maryland.gov; DPH.commissioner@mass.gov; MDHHS.director@michigan.gov; MDH.commissioner@state.mn.us; MSDH.commissioner@msdh.state.ms.us; DHSS.director@health.mo.gov; DPHHS.director@mt.gov; DHHS.director@nebraska.gov; DHHS.director@dhhs.nv.gov; DHHS.commissioner@dhhs.nh.gov; NJDOH.commissioner@nj.gov; NMDOH.secretary@state.nm.us; NYSDOH.commissioner@health.ny.gov; NCDOH.commissioner@dhhs.nc.gov; NDDOH.director@nd.gov; ODH.director@odh.ohio.gov; OSDH.commissioner@health.ok.gov; OHA.director@state.or.us; PADOH.secretary@pa.gov; RIDOH.director@health.ri.gov; SCDHEC.director@scdhec.gov; SDDOH.secretary@state.sd.us; TNDHS.commissioner@tn.gov; DSHS.commissioner@txdshs.org; UDOH.executive.director@utah.gov; VDH.commissioner@vermont.gov; VDH.commissioner@vdh.virginia.gov; Secretary@doh.wa.gov; WVDHHR.secretary@wv.gov; DHS.secretary@wisconsin.gov; WDH.executive.director@wyo.gov; doh@dc.gov; info@fsmb.org
Cc:	Stephen Nadeau; Joseph Parker MD; Pat Irving; Mark Ibsen MD; Susan Franzheim; MONTY GODDARD; Jay Joshi; Jonelle Elgaway; Kristen Ogden; Ashley Rogers; Louis Ogden
Subject:	Online Meeting Request RE July 23 2024 FDA Listening Session on "The Real Opioid Crisis in Three Charts"
Date:	Friday, July 26, 2024 5:19:16 AM
Attachments:	FDA Listening Session Minutes - Publication Draft V1.1.docx

For Board Members of All US State Medical Boards and for staff of all US State Secretaries of Health.

This communication is to request online meetings with senior members of staff for all Medical and Pharmacy Boards and State Secretaries of Health. We offer a 15-minute briefing to discuss the implications of this material for major policy changes by your Board.

The attached information was briefed Tuesday of this week to senior officials at the FDA Center for Drug Evaluation and Research. It has also been published online and shared with organizations noted below. CC addressees of this correspondence comprise the Speakers Bureau of the National Campaign to Protect People in Pain.

Please reach out to us IMMEDIATELY. Restrictions on availability of safe and effective pain care for millions of Americans are the most important in American healthcare today.

We would appreciate the courtesy of your acknowledgement of receiving this

message. See below

Richard A "Red" Lawhern PhD
Patient Advocate
Twitter: @Lawhern1
Facebook: https://www.facebook.com/red.lawhern
My Publications: http://www.face-facts.org/Lawhern
Personal Website: http://www.lawhern.org

This communication shares compiled meeting notes from a Listening Session conducted for senior officials in the US FDA by seven members of the Speakers Bureau of the National Campaign to Protect People in Pain on July 23, 2024. To facilitate an urgently needed US Inter-Agency and public discussion, these meeting notes have been posted this morning to Linked-In.com and to multiple Facebook groups -- as well as delivered by email to the following organizations.

Intended recipients

Administrators, National Institutes of Health, HEAL Initiative RFI (expiring July 30)

Office of the Director, National Institute on Drug Abuse

Office of the Executive Secretary, US Centers for Disease Control and Prevention
attention, CDC Director and senior staff
CDC-Info online gateway
Board of Scientific Counselors, National Center for Injury Prevention and Control.

Immediate Office of the Secretary of Health and Human Services
Assistant Secretary of Health
Office of the Inspector General

Office of the US Surgeon General
National Office for Drug Control Policy, Executive Office of the President

US Drug Enforcement Agency, Division of Diversion Control
for all senior DEA Staff

AMA Substance Use and Pain Care Task Force,
and all 29 participating organizations
Offices of US Colleges of Medicine and Board Certification organizations including
American Academy of Family Physicians
American Psychiatric Association
American Academy of Pediatrics
American College of Obstetricians and Gynecologists

American College of Physicians
American Osteopathic Association

Editors of healthcare media organizations, including
Medscape
Kaiser Permanente Health
Reason Magazine
KevinMD
STAT News
Pain News Network
American Council on Science and Health
Journal of Medicine of the National Association of Medical Doctors
Medical Research Archives of the European Society of Medicine
PAINWeek
(permission to re-publish or extract at length hereby granted)

Multiple investigative reporters and editors in US National media.

Legislative Directors and Chiefs of Staff in the US House of Representatives and Senate committees and subcommittees on health and judiciary

Email distribution lists of over 1,000 knowledgeable pain management clinicians, pain patients, family caregivers and patient advocates

==========

I invite you to engage in a spirited public conversation on the issues raised by these meeting notes.

Richard A "Red" Lawhern PhD
Patient Advocate
Twitter: @Lawhern1
Facebook: https://www.facebook.com/red.lawhern
My Publications: http://www.face-facts.org/Lawhern
Personal Website: http://www.lawhern.org

The Real Opioid Crisis in Three Charts

– An FDA Listening Session--

Richard A Lawhern, PhD, Pat Irving, RN, Monty Goddard, Kristen and Louis Ogden, Steven E Nadeau, MD, L Joseph Parker MD

July 23, 2024

INTRODUCTION:

On July 23, 2024, seven members of the Speakers Bureau of the National Campaign to Protect People in Pain participated in a one-hour "listening session" to brief senior officials in the US FDA Office of Communications, Professional Affairs and Stakeholder Engagement (PASE), Center for Drug Evaluation and Research (CDER).

Presenting and Supporting Attendees comprised authors as above.

FDA Audience: A group of six to eight FDA officials was headed by Marta Sokolowska, Ph.D., Deputy Center Director for Substance Use and Behavioral Health in the FDA's Center for Drug Evaluation and Research (CDER)

Subject: "The Real Opioid Crisis in Three Charts", with four additional speaker presentations.

Session ground rules (reviewed as we began the session, by Christopher Melton, PASE staff): Listening sessions are informal venues in which neither the presenters nor the FDA are committed to take specific actions.

- From the FDA side, no information is provided that is not public domain, nor may FDA choose to later communicate decisions made on the basis of information offered.

- From the presenters' side, no restrictions are placed on public disclosure of materials or speaker notes offered during the Listening Session.

- It was understood by all that meeting notes may be communicated widely by presenters in social media, print media, and online networks.

Text offered in the present review is from speaker notes prepared before the Listening Session. Minor additions and revised emphasis during the live Session were incorporated during the session.

INITIAL PRESENTATION: Richard A Lawhern, PhD for the Speakers Bureau of the National Campaign to Protect People in Pain.

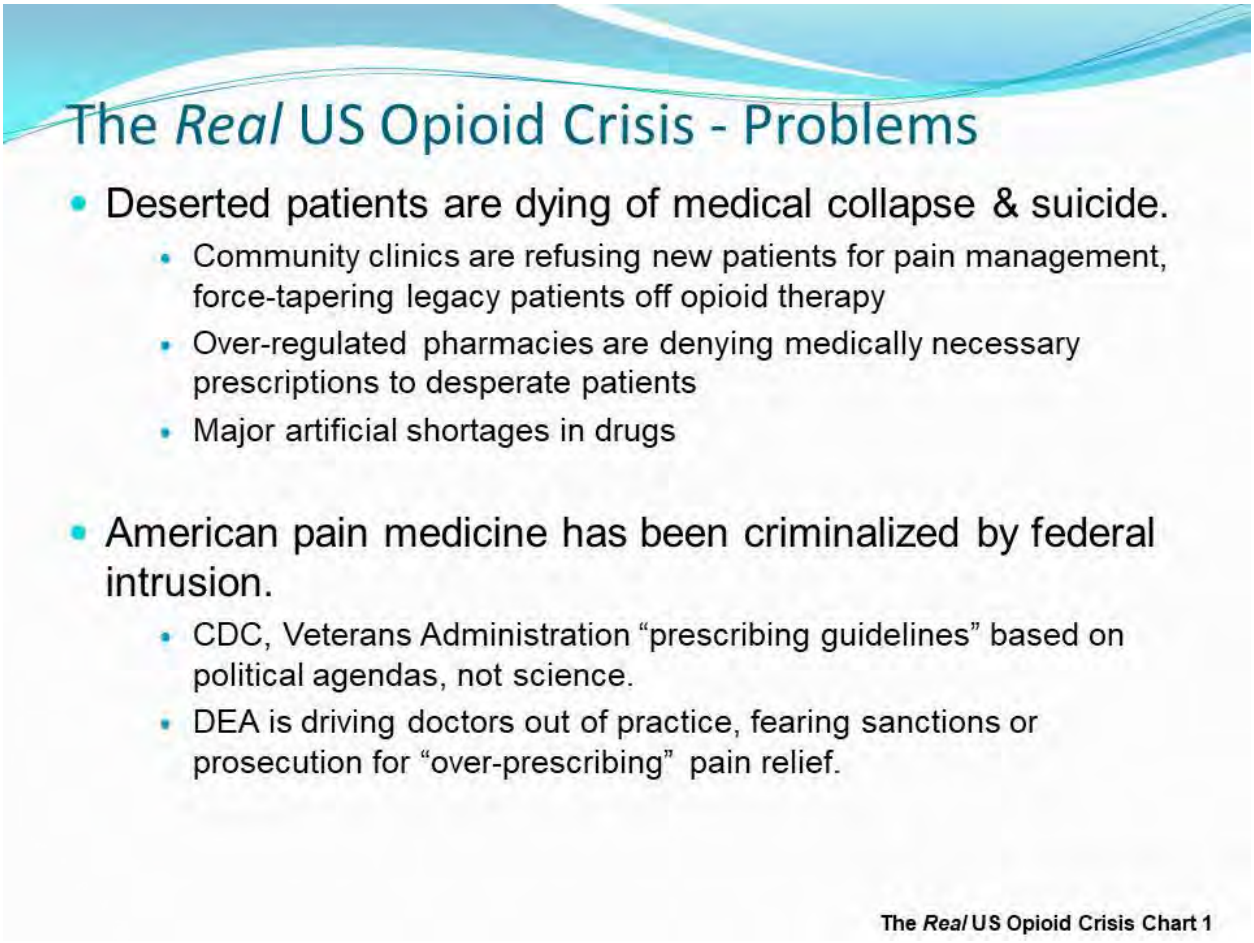
Good afternoon and thank you for convening this listening session. I speak on behalf of thousands of patients and doctors who are being deeply harmed by misdirected National public health policy for treatment of chronic and acute pain, including those assessed to be victims of opioid addiction. This is arguably the single most important issue in American healthcare today. As the premier US Agency that validates accepted prescribing practices for the treatment of pain, we believe it is essential that your Agency take action to engage with this issue and to correct public narratives that are destroying lives.

My presentation is supported by a National alliance of doctors, subject matter experts and patient advocates. This network has literally thousands of years' experience in

clinical practice, patient safety education, patient advocacy and healthcare writing. Our Speakers Bureau members have no financial conflicts of interest; all of us are unpaid volunteers. Follow-up contact data is provided later in this briefing.

Your presenter is Richard A Lawhern PhD. I am a healthcare writer, data analyst, and subject matter expert on public policy for the treatment of pain employing prescription opioid pain relievers. Over the past 27 years, I have authored or coauthored over 250 papers, articles and interviews in a mixture of peer-reviewed and editor-reviewed clinical journals and mass media. Like my colleagues in the Alliance, I am easily found in searches of Google Scholar or Perplexity.ai .

Information presented herein has a currency cutoff date of June 2024. The presentations were offered by Zoom meeting session, on July 23, 2024.



This is the first of three charts that describe the "Real" opioid crisis in terms of

- Problems
- Realities
- Needed Legislative Solutions

This presentation was originally constructed for legislative staff in the US House and Senate, and has been adapted for this listening session. Our unifying theme is that the FDA is charged with oversight and practice standards for appropriate prescribing practice. This mission is now being usurped by the US DEA, which has prosecuted and imprisoned or sanctioned hundreds of clinicians for prescribing in a manner authorized by the FDA. This misdirection has been compounded by mission creep in the US CDC and the Veterans Administration, and by the inappropriate application of CDC practice guidelines that violate both basic science and medical ethics.

It is common these days to speak of the US "opioid crisis" or sometimes the "opioid epidemic". However, I emphasize the term "real" in this briefing. In many ways almost everything the government thought it knew about this crisis has turned out to be wrong; on science; on ethics; and on public health policy.

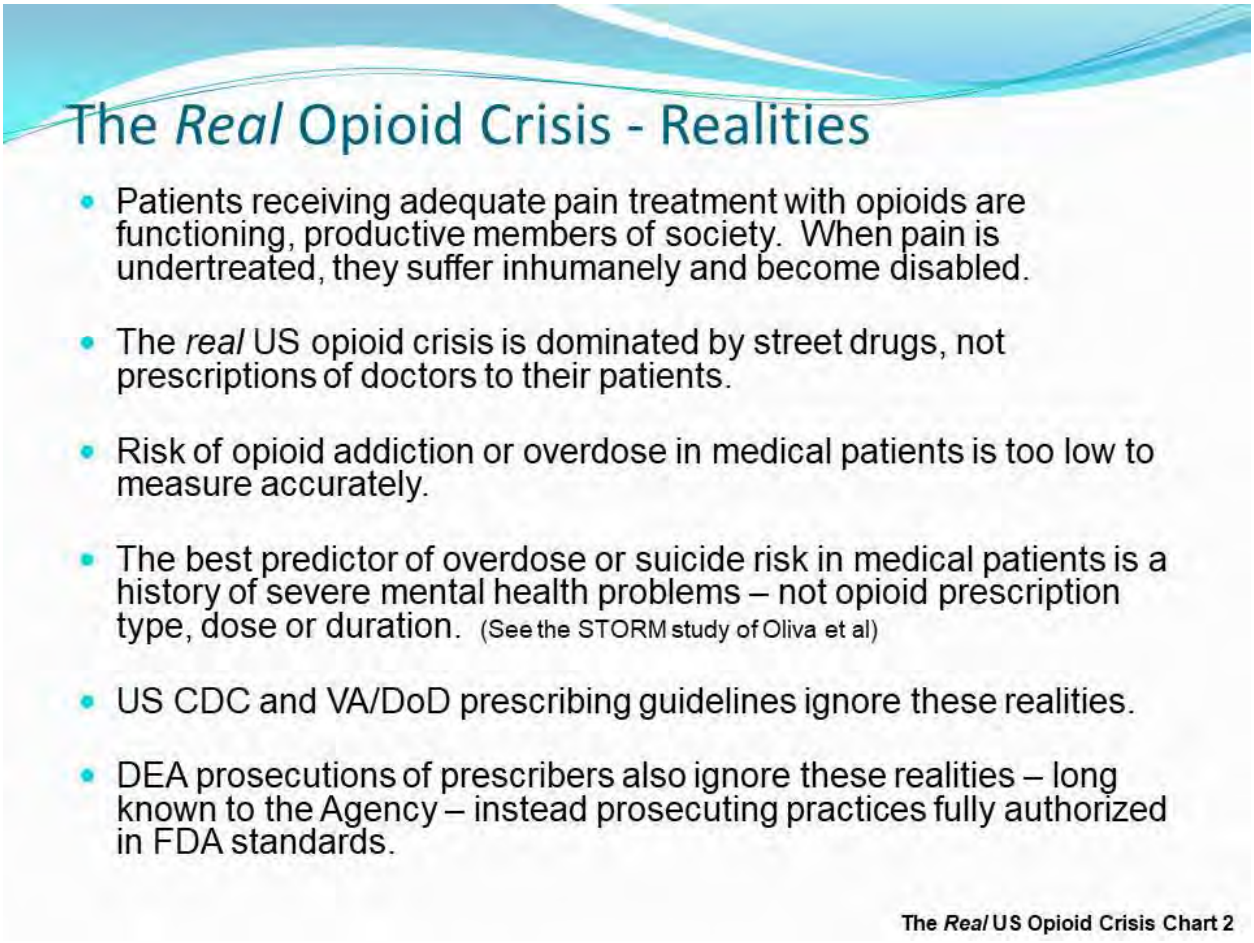
Pain is one of the most terrible afflictions known to humanity, and yet it is the most common symptom that brings patients to a doctor's office. The National Academies of Medicine estimate that over 100 million Americans experience clinically significant pain each year – possibly 40 million of whom at levels that compromise daily quality of life and shorten life expectancy. Costs in lost productivity are over $1 Trillion every year.

But these days, large numbers of new and legacy patients are being abandoned or turned away when they ask for help in managing their pain. Legacy patients in many clinical practices are being force-tapered to ineffective doses of the only safe and effective therapies we have that work to manage their pain. By this I mean prescription opioid pain relievers.

These patients are being abandoned when their doctors are shut down or become too frightened to treat pain or addiction, using FDA-approved medications and therapies. Thousands are dying from medical collapse and suicide. Millions are struggling with DEA-mandated artificial prescription drug shortages, even if they have found the rare doctor who is still willing to treat them.

It is not going too far to say that the two main culprits in this torture are the opioid prescribing guidelines published by US Centers for Disease Control, greatly magnified by an unjustifiable nationwide witch hunt conducted against pain doctors by the US Drug Enforcement Agency. In their zeal to eliminate every possibility of drug diversion, they are destroying the practice of pain medicine in America.

Let's look now at some realities related to this debacle of misdirected policy.



Many acute and chronic pain patients who receive adequate treatment continue to be productive members of society despite their ongoing medical issues. When denied pain treatment, however, they suffer needlessly and often lapse into disability and social isolation, with loss of employment and even homelessness. I have personally talked with people in pain who were ***living in their cars*** due to loss of employment and inability to pay home mortgages. Thousands commit suicide.

This situation is simply unacceptable. In the name of "saving" a tiny fraction of people in pain from addiction or overdose death, US public health policy is now condemning and criminalizing their doctors and driving millions of patients into agony and death.

I say that we're dealing with a "tiny" fraction of people. Multiple published studies estimate overdose mortality among clinically managed patients somewhere between 2% and two-tenths of 1% - two patient deaths per thousand who are treated by a doctor. Such numbers are confounded by misdiagnoses of opioid use disorder by doctors

untrained or poorly trained in the field of addiction. Another factor is the long-standing confusion between physiologic dependence on opioids versus addiction. As noted by authorities such as Dr Nora Volkow of the National Institute on Drug Abuse, these medical conditions are not the same thing. References at the end of this briefing will confirm this truth.

Arguably and as I have myself written for publication, “there is no such thing as opioid use disorder”. The term first appeared in the Diagnostic and Statistical Manual for Mental Disorders of the American Psychiatric Association (DSM-5). That document was publicly repudiated two weeks before publication by the US National Institutes of Health as a basis for organizing mental health research.

Risks of opioid addiction or overdose among patients who are treated in an on-going doctor-patient relationship are too small to accurately measure. As belatedly acknowledged by US CDC, mortality statistics are dominated by street drugs. And as not yet acknowledged by CDC and DEA, these statistics always have been! CDC guideline writers knew or should have known these realities even in 2016, and certainly knew them in 2022 before they published. DEA senior management has known since at least as far back as 2019.

When prescription drugs are found in a postmortem blood screen, they are almost always combined with several other toxic substances plus alcohol – something that almost never occurs in chronic pain patients. The great majority of people who overdose don’t have a current prescription. And a huge majority of patients will never overdose, even if they go through withdrawal symptoms when a doctor tapers them off medication too rapidly.

Based on the studies of Elizabeth M Oliva and her colleagues in the STORM model, analyzing records of more than 1.1 million US Veterans, the best predictor for patients who might have problems with opioids is a history of severe mental health problems. These include bipolar disorder, clinical depression, chronic anxiety, past hospitalization for overdose, or previous suicide attempts. These factors are four to 20 times more predictive of near-term overdose or suicide events than past treatment with opioids of any kind.

Unfortunately, these realities were utterly ignored in the prescribing guidelines issued by the US CDC and Veterans Administration. US DEA has likewise ignored the reality that prescription opioid pain relievers are only one of eight factors that contribute to accidental drug deaths in America – and that prescriptions have never been a dominant driver of deaths in the so-called “opioid crisis.” DEA-published studies addressed this reality in 2019, when the opioid crisis had become a moral panic. But DEA still -- half a decade later -- continues to target doctors who prescribe opioids; including doctors who

take on the patients of other doctors whom the DEA has forced out of practice or sent to prison.

Major and unjustifiable damage has been done to doctors and their patients by restrictions on prescription of opioid pain relievers. The National Campaign to Protect People in Pain believes that this damage can only be remedied by Federal legislation to decriminalize American pain medicine and put treatment decisions back in the hands of clinicians rather than unqualified law enforcement authorities. This legislation will likely involve:

- Repealing or amending the Controlled Substances Act of 1970
- Removing DEA authority to set production quotas on Federally controlled substances
- Eliminating abusive prosecutorial and Administrative Court Judge practices that unfairly deny clinicians resources to defend themselves or otherwise bias court proceedings against defendants, including the use of "expert" witnesses who hold extreme opinions not representative of the general medical

consensus.

  - Stop pre-trial asset seizures against doctors,
  - Stop the coercion of employees of doctors to testify against them,
  - Stop the use of plea-bargained testimony by otherwise unqualified witnesses selected to support assertions of prosecutors who lack medical training,
  - Require that “expert witnesses” are actually qualified by training and hands-on clinical practice to testify to dangerous or unprofessional behavior of defendants,
  - Direct judges and juries to entertain good-faith defenses of clinicians under the terms of the Supreme Court decision in Ruan vs. the United States.

- Restrict the mission of the Drug Enforcement Administration to interdiction of illegally imported or manufactured narcotics, and apprehension of distributors and street sellers of illegal drugs – leaving the policing of medicine to appropriate authorities, which are State medical boards, as the Supreme Court has made clear in multiple rulings.

Also vital is the immediate repeal of the (secretly crafted) Injunctive Relief clauses of the National Opioid Settlement, which we will shortly address in a further short presentation. These clauses have created a nightmarish maze of pharmacy over-regulation that is widely causing rejections of legitimate prescriptions, as well as shortages of prescription drug inventories at pharmacies.

Repeal is also needed of the Veterans Administration Act of 2019, to remedy a de facto system-wide VA policy of “no opioids to any patient for any reason.”

The 2016 and 2022 CDC guidelines on prescription of opioids are widely recognized as biased by anti-opioid misinformation compounded by very weak, inadequate and cherry-picked research. These guidelines must be publicly repudiated and withdrawn without replacement. While correction of unprofessional or dangerous clinician behavior is appropriate and needed, the appropriate authorities are at the level of State Medical Boards, not Federal Agencies or law enforcement.

As a footnote directed specifically to this audience at FDA, I must also assert that there is abundant published evidence that the entire trials literature on safety and effectiveness of prescription opioid pain relievers must be (figuratively) burned to the ground and done over. No published trial – including those reviewed for the US CDC guidelines by the US Agency for Healthcare Research and Quality -- has employed protocols that account for genetically mediated polymorphism in liver enzymes that

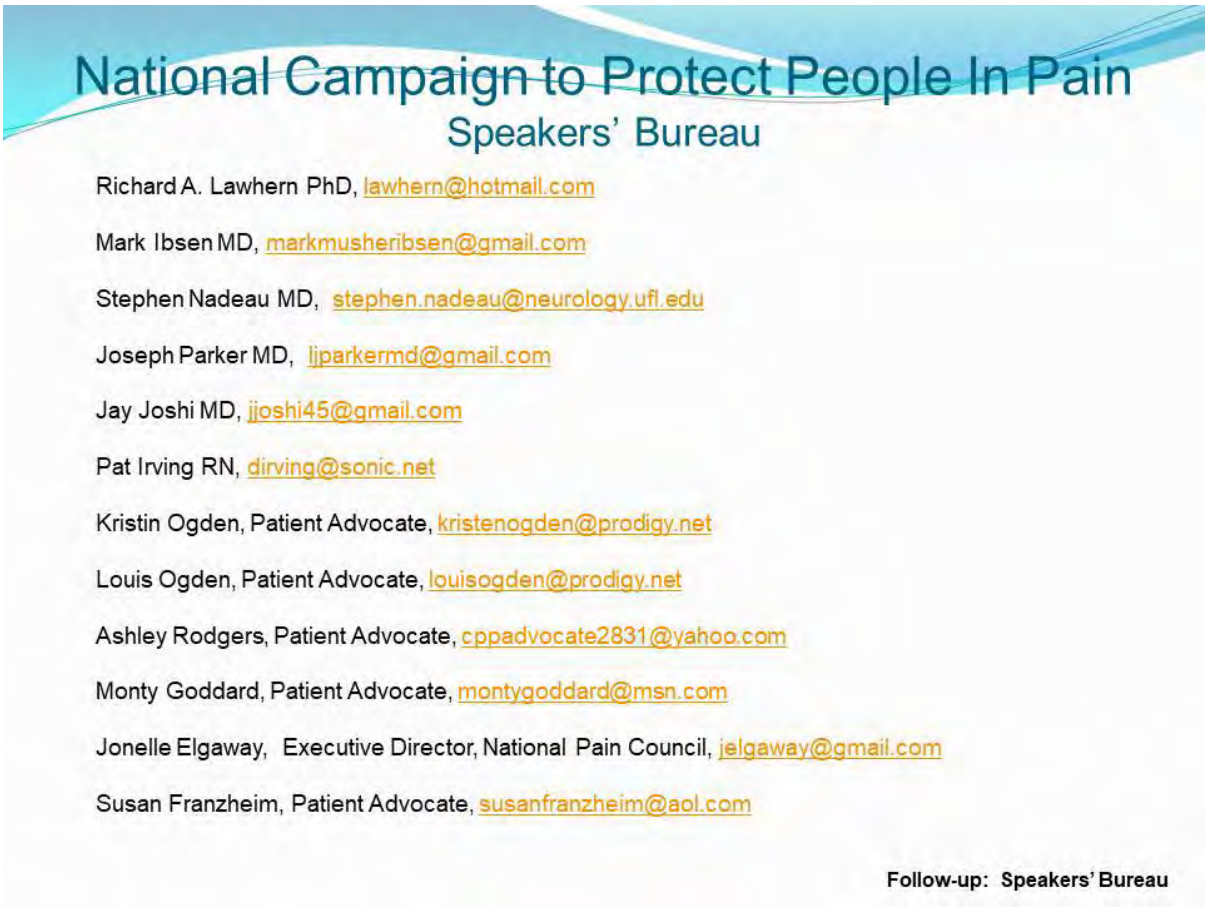
metabolize opioids in the liver. Omission of this 25-year established medical literature has rendered CDC prescribing guidelines fatally flawed and actively dangerous to patients and their clinicians. There is no such thing as an average individual patient.

The crisis among legacy pain patients has been heightened by both artificial and inappropriate DEA limits on opioid production, and horrendous bureaucratic barriers created by the Injunctive Relief provisions of the National Opioid Settlement. We urge you to take public action to address both.

We must also point out that present FDA procedures for determining the adequacy of prescription opioid supplies are seriously deficient. The FDA has no grasp on shortages that happen BETWEEN THE MANUFACTURER AND THE PHARMACY, caused by Thresholds imposed by the Injunctive Relief provisions of the National Opioid Settlement. By contrast, estimates performed by the American Society of Health-System Pharmacists (ASHP) clearly show shortages at the pharmacies of Norco and Oxycodone, although the FDA shows adequate supplies. It is crucial that the FDA amend their measurement process.

SOURCES AND FURTHER PRESENTATIONS

The following are the 12 members of the Speakers Bureau of the National Campaign to Protect People in Pain, several of whom are present today. We are available for follow-up discussions or clarifications, should FDA wish to do so – if necessary, under confidentiality agreements.



The next two pages comprise a list of 10 supporting references drawn from hundreds of papers and articles in clinical and popular literature. This material can help to prepare senior officials of the FDA for further discussions or a request for public comment in the Federal Register.

The *Real* Opioid Crisis – References 1

1. American Academy of Family Physicians, "Frontline Physicians Call on Politicians to End Political Interference in Evidence Based Medicine", May 15, 2019 https://www.aafp.org/news/media-center/more-statements/physicians-call-on-politicians-to-end-political-interference-in-the-delivery-of-evidence-based-medicine.html

2. L. Joseph Parker MD, "The Persecution of Pain Management Doctors", *Journal of Medicine,* National Association of Medical Doctors, August 23, 2023 https://www.namd.org/journal-of-medicine/3104-the-persecution-of-pain-management-doctors.html

3. Richard A. Lawhern, PhD, "Everything the Government Thinks It Knows About the Opioid Crisis is Wrong", *KevinMD*, July 1, 2023 https://www.kevinmd.com/2023/07/everything-the-government-thinks-it-knows-about-the-opioid-crisis-is-wrong.html

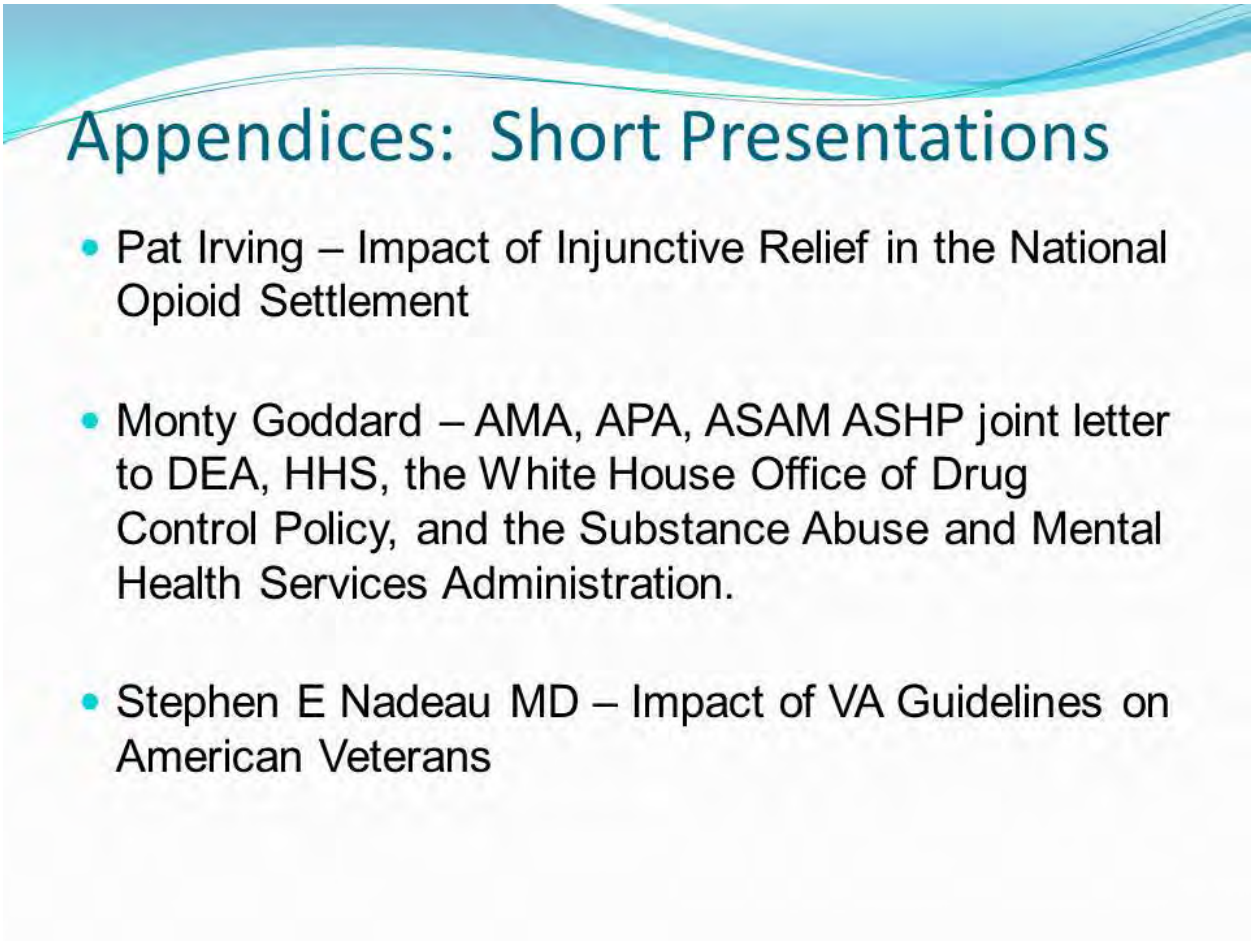
4. Steven E Nadeau MD and Richard A Lawhern, PhD, "The Two Opioid Crises – Problems, Causes, and Potential Solutions: An Analytic Review", *Medical Research Archives* of the European Society of Medical Doctors, December 31, 2023 https://esmed.org/MRA/mra/article/view/4846/99193547539

5. Richard A Lawhern, PhD, "Resources for Clinicians in Pain Medicine – Correcting Medical Mythologies on Prescription of Opioid Analgesics", *Medical Research Archives*, of the European Society of Medical Doctors, https://esmed.org/MRA/mra/article/view/4860

The *Real* Opioid Crisis – References 1

As an additional resource for FDA, we also offer our deep experience with the literature of pain medicine and addiction. I (Dr Lawhern) maintain bookmark files on over 15,000 papers, articles and presentations in this field. Members of the Speakers Bureau are networked by email and in social media with thousands of practicing clinicians and tens of thousands of suffering patients and family caregivers. We can deploy announcements to over 100,000 potential readers in 15 minutes, should you wish to do so.

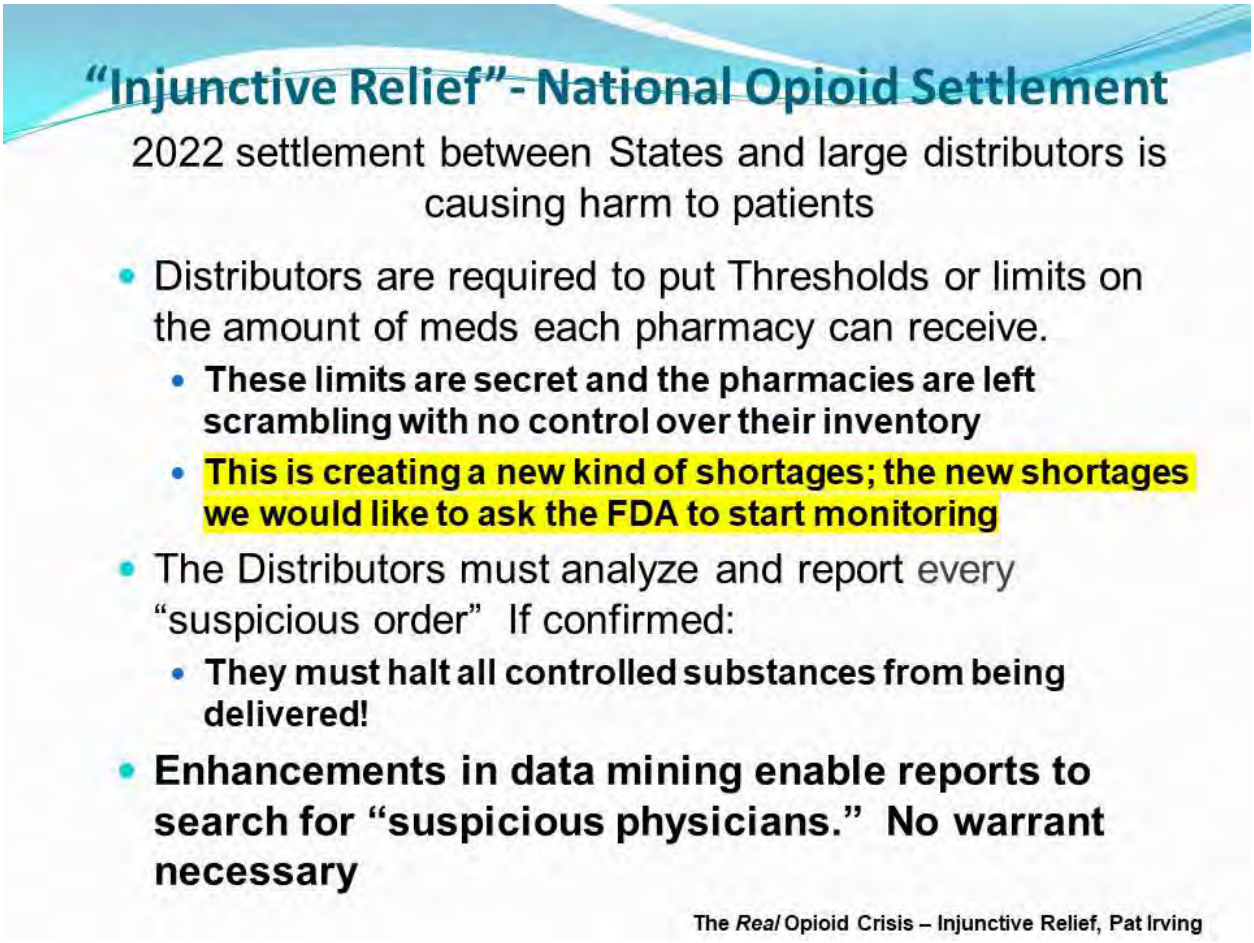
Thank you for your time and attention. We will next offer short presentations by Alliance colleagues who are also in attendance at this Listening Session. We have added one presentation by patient advocate Kristen Ogden and her husband Louis Ogden. to the agenda initially transmitted to FDA. Mrs. Ogden will speak third, followed by Doctor Steven E Nadeau.



PRESENTATION BY PAT IRVING, RN

Hello. My name is Pat Irving and I am an RN with over 40 years of healthcare risk assessment and patient safety experience. I have been an advocate for patients with chronic pain since having endured a forced taper of my own legitimate pain medication.

I am eager to speak to you today about a crisis in healthcare that may be unknown to you, or at the very least the impact of which has not been well appreciated. I am referring to the negative impacts of the National Opioid Settlement Injunction and specifically how the injunction relates directly to the work of the FDA.



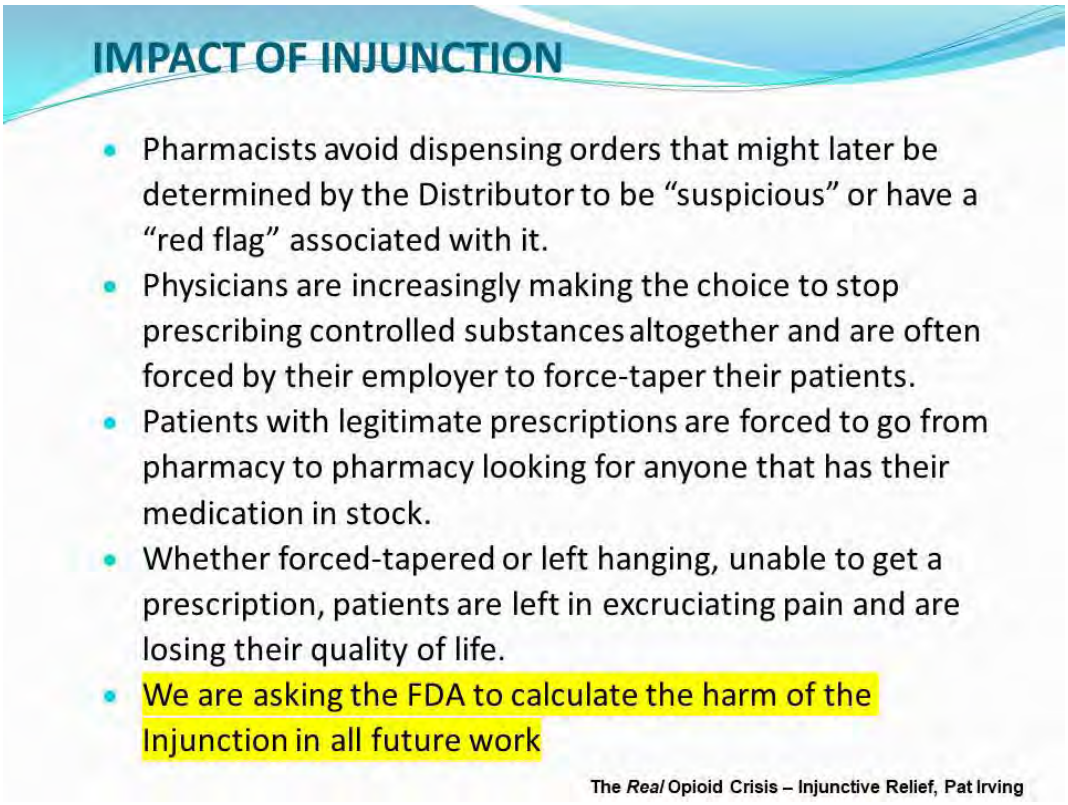
First, some background. In 2022, as part of the Opioid Settlement there is a corresponding Injunction that was designed to increase oversight by Distributors over pharmacies ordering controlled substances. These restrictions unfortunately were fueled by erroneous beliefs that prescription medications (not street medications) were the primary driver of the opioid crisis. We now have abundant evidence that this is not, nor was it ever, true.

Because prescribing guidelines were driven by an overt anti-opioid sentiment, the Injunctive Relief mandates do not follow either science or any current government guidelines. The injunction instead implemented restrictions in the pharmacy chain that were so strict that artificial shortages are occurring and patients with legitimate prescriptions are unable to pick up the medications they desperately need.

The mechanisms for this harm are as follows:

First, the Injunction forces the Distributors to implement thresholds dictating the amount of controlled substances any given pharmacy can obtain in a month. These thresholds are calculated by algorithms that are hidden from the pharmacies and the threshold amounts are mandated to be held secret. Pharmacies now have no way of knowing what their future inventory is going to be…and what is worse, if they fill more than their quotas they are reported both to the DEA as well as their state's AG.

Patients are left scrambling, trying to pick up their legitimate prescriptions. Unfortunately, the system is now driven by fear and no one can help them. The obvious next question is: Can you, the FDA, see these secret algorithms and the cuts they are making in the supply chain? Are you measuring them? My colleague Monty Goddard will explore implications of this question in his upcoming comments.



The second mechanism for harm woven into the Injunction is that Distributors are "deputized" as mini-arms of the DEA. The Distributors are now expected to pre-emptively determine whether an order is a "suspicious order" or if it has "Red Flags." If a pharmacist assesses one or both these conditions to exist, they must immediately halt the order. Before the Injunction, there would have been ample communication between Distributors, pharmacies and physicians.

But remember that the system is now run by fear. Doctors and patients can no longer call their pharmacists to resolve issues. There is just the arbitrary halting of legitimate medications. In the patient's world, they have been shorted the amount of medication they have been prescribed. And there is often no effective recovery from this action.

I hope it is evident in this short description, that the Injunction embedded in the National Opioid Settlement is something the FDA must be aware of. We plead with you to assess effects of the Injunction as you move forward into this very new landscape. I will now hand you over to Monty Goddard who will further discuss the impact of the Injunction on the FDA and the patients whom your organization is tasked to protect.

PRESENTATION BY MONTY GODDARD

My name is Monty Goddard, I have a master's degree in civil engineering and have been a licensed professional engineer in California for over 45 years. I retired as a GS-15 equivalent, NSPS-YD3 in 2010, after over 36 years of federal service. Five years ago, nine years after I retired, I was "forced" to become a pain patient advocate when my wife's quality of life and my "Golden Years" were destroyed by our own governments' mis-targeted "War on the Opioid Epidemic".

After six years of surgeries and after all other pain control protocols were tried and failed to provide adequate pain relief, 22 years ago, in 2002, my wife was placed on high dose opioid medications. For a decade and a half, these medications gave my wife her life back. She could once again physically function! Tragically, unjustly, inhumanely, my innocent wife has been force-tapered to a dosage which no longer enables enough pain control to allow her enough physical function to enjoy a reasonable quality of life.

Before I expand on Pat's comments, I have two other items I would like to share.

First, I have researched the American Society of Health-System Pharmacists (ASPH.org) drug shortages database, which for at least a year has listed significant

shortages of Hydrocodone and both variants of Oxycodone. I also viewed the FDA drug shortages database, which for this same period has listed ZERO hydrocodone and oxycodone shortages. This dichotomy is a major problem. If the FDA does not even acknowledge there is a shortage of these two essential pain medicines, then FDA can certainly take no related remedial action, as you did in concert with the DEA, in November of last year to address ADHD medication shortages with the manufacturers.

The FDA needs to modify its methodology for collecting and reporting drug shortages to better reflect the reality experienced by pain patients whose legitimate prescriptions go unfilled due to shortages on pharmacy shelves. These all-too-real shortages, which are not currently acknowledged by the FDA, are negatively impacting prescribers, pharmacists, and most importantly innocent suffering patients.

Second, the DEA's November 2023 proposed 2024 controlled substances production quota announcement in the Federal Register contained this statement: "FDA predicts that levels of medical need for schedule II opioids in the United States in calendar year 2024 will decline on average 7.9 percent from calendar year 2023 levels." At a time when the population is growing older, States are enacting laws easing the legitimate prescribing of opioids, and State Medical Boards (like California's) are publishing guidance encouraging physicians to return to the practice of pain medicine, this FDA recommendation appears illogical.

The FDA needs to reevaluate and publish the rationale for this and future related recommendations.

I'll conclude with a brief follow-on to Pat Irving's comment about the State AGs' nationwide opioid settlement's harm to the controlled substances supply chain to pharmacy shelves.

On May 10th of this year, the American Medical Association, the American Pharmacists Association, the Association of Addiction Medicine, and the American Society of Health-System Pharmacists sent a joint letter to the DEA, HHS, the White House Office of Drug Control Policy, and the Substance Abuse and Mental Health Services Administration. This letter unequivocally documented all four co-signers' agreement concerning the harms being done to patients as a direct result of the state AGs' nationwide opioid settlement with three major distributors of controlled substances. The letter requests the addressees to influence some relief of the AGs' settlement harm to the supply of medications for opioid use disorder (MOUDs) -- **but not for other similarly impacted controlled substances**.

To that end, those of us meeting with you today have initiated correspondence to the signatories of the May 10th letter suggesting they expand their "ask" to encompass all controlled substances and to include the state AG's on distribution of their all-inclusive request.

PRESENTATION BY KRISTEN OGDEN (Spoken Without Charts)

Good afternoon. My name is Kristen Ogden. I am not a medical professional or a scientist. I am an advocate and caregiver for my husband of 51 years, Louis Ogden. I have been advocating for him for the past 25 years and have been more fully engaged in advocacy since I retired from Federal service in 2014 with 36 years of service. I am a 1975 graduate of the College of William and Mary, and at the time of my retirement, I was serving as Director of Strategic Planning and Performance Management for the Defense Commissary Agency.

Louis has suffered from chronic pain since age 6. In 2010, after years of seeking help for his severe constant pain with no success, he was accepted as a patient by well-known California pain specialist, Dr. Forest Tennant, and we began quarterly trips to CA from our home in Virginia which continue to the present. Upon retiring in 2014, I decided to focus my advocacy efforts on one specific pain patient population: persons who suffer from severe, incurable pain and have failed all traditional treatments. These were the patients accepted for medical care in Dr. Tennant's pain clinic in West Covina, CA, and I had the privilege of getting to know many of them through my advocacy efforts and serving as a volunteer in Dr. Tennant's clinic.

We engaged these patients and their family members in advocacy, and I co-founded a small advocacy group called Families for Intractable Pain Relief. Our goals are 1) to raise awareness of severe, constant intractable pain and the challenges faced by those who suffer from it, and 2) to ensure access to whatever treatments are needed to properly care for these individuals. We support the appropriate prescribing of opioids at any dose by qualified physicians as a last resort treatment to relieve the severe intractable pain of any patient for whom such dose is deemed necessary to stabilize function and enable a decent qualify of life. As Louis first said publicly at our first FDA meeting in 2014, high-dose opioid therapy gave him the best quality of life he had ever experienced as an adult. He still believes that, as do I, and he is now 74 years old.

Louis' quality of life and our lives as a couple improved tremendously in late 2010 as Dr. Tennant's approach to pain care began working: pain medications, hormone management, attention to diet, and gentle exercise. Our improved quality of life continued through early 2013, but then things headed downhill, gradually at first and then drastically. In late 2017, the DEA raided Dr. Tennant's clinic, home, and office. Although they never identified any failure or wrongdoing on his part and never charged him with any infraction, they pressured him to retire and, on the advice of his attorneys, he closed his clinic June 30, 2018. Before closing, Dr. Tennant provided each patient with 3 30-day prescriptions, wrote referrals, and assisted patients to find other care as best he could.

Fast forward to November 1, 2022. The DEA delivered to Louis' then physician, Dr. David Bockoff, an Order to Show Cause and Immediate Suspension of Registration. By then, many of Dr. Tennant's former patients had found Dr. Bockoff and were receiving care from him. This time, all 240 of Dr. Bockoff's patients were immediately cut off with no prescriptions and no referrals. In effect, the DEA ordered Dr. Bockoff to abandon his patients; that is illegal in California and most other states.

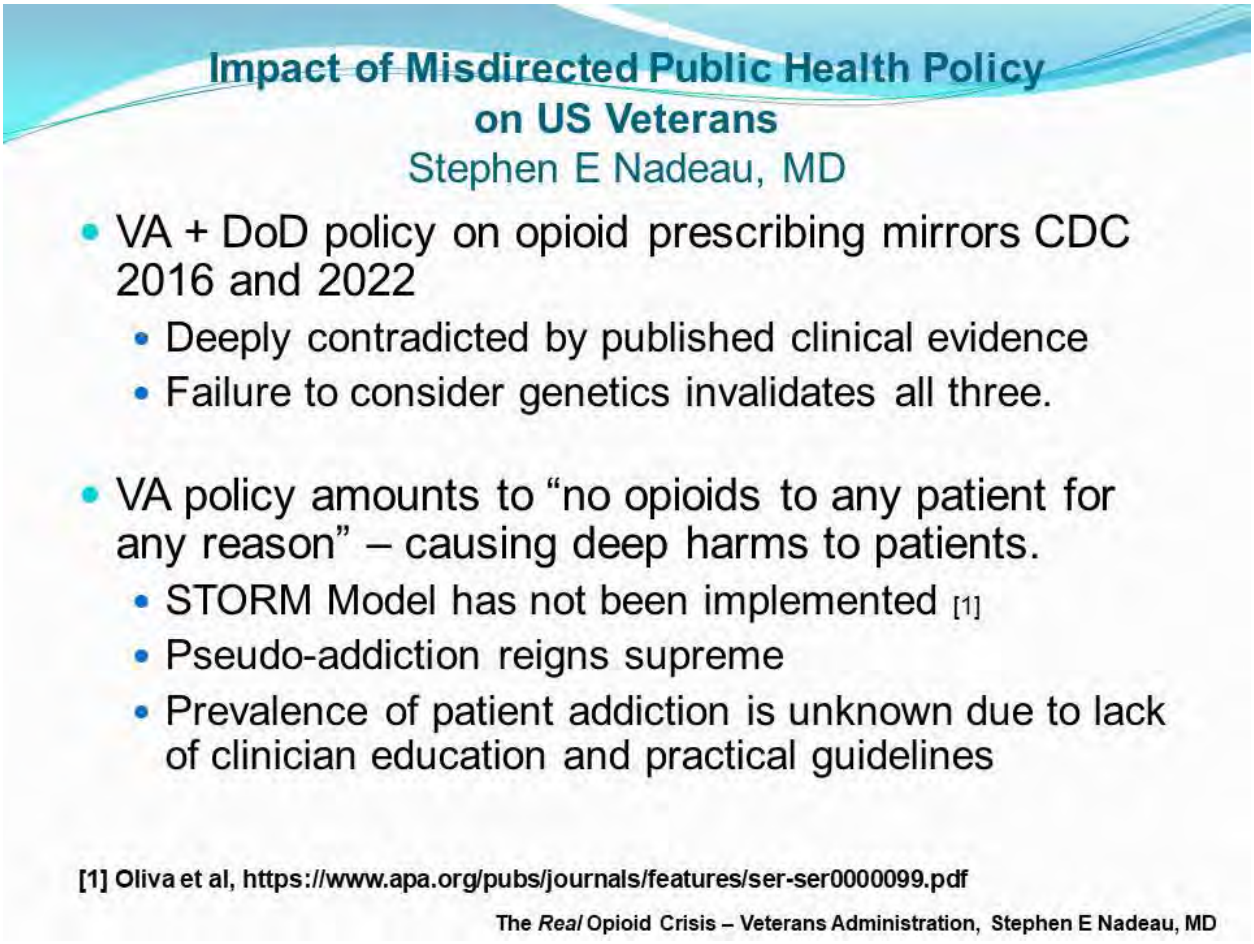
By this time, many doctors had already left the practice of pain care, and the few still practicing were reluctant to accept these patients. Within a short period of time, patient Danny Elliott and his wife committed suicide. At least two other patients died from the sudden loss of their medications. These individuals had been doing well and would probably be alive today had Dr. Bockoff not been shut down.

Despite all efforts to inform and educate CDC and DEA about the existence of severe, intractable pain patients, those agencies continue to show no regard for the needs of such patients. To the CDC and DEA, they are all addicts or drug traffickers. The stigma against persons who use opioids … "those drugs" … continues. We have not been allowed to fill Louis' prescriptions for pain medications in Virginia since late 2018. Since June 2019, I have flown from VA to CA and back every month to get his prescriptions filled.

My purpose in sharing these events is to say to you that **what you do matters**. When FDA develops policies that address opioids, **it matters**. When you put a black box warning on benzodiazepines, **it matters**. When you underestimate the magnitude and impact of drug shortages, **it matters**. If I had enough time today, I would give the presentations I gave at FDA in January 2018 and June 2019 about the value of opioids to the many patients with the kind of pain my husband endures if he has no pain medications. Instead, please just know that we face ridiculous, almost unbelievable barriers every day to obtain care and medications. We continue our fight against these barriers, "red flags, unwarranted dose ceilings and the many myths and misconceptions that underlie the stigma and hysteria caused by anti-opioid zealots. Our motto is "Never Give Up!" ***And we won't!***

I appreciate this 6th opportunity to speak to FDA representatives. Thank you for your time.

PRESENTATION BY STEPHEN E NADEAU MD



FDA Conversation: My prospective contributions: Nadeau

I am Steve Nadeau. I am a professor of neurology in the University of Florida, College of Medicine and a staff neurologist at the Malcom Randall VA Medical Center in Gainesville. My research interests have been in cognitive and computational neuroscience, neurorehabilitation, and more recently, the use of opioids and other drugs in management of chronic pain and the nature and solutions to the clinical and illicit opioid crises. I have published 8 papers in peer reviewed literature, most with Red Lawhern, since 2015. I have been in clinical practice for 42 years and much of my clinic population has been comprised of people with chronic pain.

VA policies bearing on opioid prescriptions, both in practice and expressed in its guideline documents, have mirrored the CDC guideline documents of 2016 and 2022. However, at least at my VA Medical Center, these guidelines have been pushed to what is very close to a no opioid policy. They have not incorporated the recent innovations by Oliva et al, published in 2017, and the adoption of the STORM system that she and her colleagues created — a most enlightened approach.

I constantly see patients in inadequately treated chronic pain, some in so much pain that it is difficult for them to even communicate, many with disability that could easily be remedied by treatment with a modest opioid regimen, many getting alternative, often very expensive, and generally ineffective invasive treatments, and nearly all suffering a vast reduction in quality of life, often abjectly suffering.

The concept of pseudo-addiction seems to have been originally ventured by Weisman and Haddox and by Fishbain and colleagues in 2008. It referred to a common and easily understandable phenomenon. Physicians to this day receive little training in managing chronic pain and are very conscious of the crisis of opioid addiction that has plagued this country since the aftermath of the civil war. Thus, they have always been very hesitant about prescribing opioids, particularly in higher dosage.

When patients still in pain ask for higher opioid doses to relieve their pain, this is often interpreted as incipient addiction. More recently, DSM-5 has codified this notion of incipient addiction in terms of the definition of opioid use disorder (OUD), a check list of 11 items. Unfortunately, someone in severe pain desperately seeking relief would receive a high OUD score. Scientific data on the incidence of addiction, as traditionally defined, have been severely clouded by the concept of OUD. In my 42 years of practice, I have encountered exactly two patients with actual addiction, both faculty members in existential crisis

Interface between pain and addiction. The fog created by the DSM codification of OUD has made it all but impossible to discern the prevalence of true addiction, as traditionally defined, in clinical populations. My own personal experience over 42 years of practice has been that addiction does exist in clinical patients but it is exceedingly rare and is it typically observed by clinicians in the context of a mental health crisis. Oliva et al, in their pioneering VA funded study published in 2017, identified the major predictors of overdoses and suicide attempts. These were

- severe psychiatric disease,
- multiple inpatient psychiatric admissions,
- multiple suicide attempts and
- multiple ER visits for drug overdose.

All patients were on an opioid regimen, undoubtedly because of concurrent severe physical pain. The contribution of opioid dose to outcome measures was nil. In effect, opioids were implicated in these events as innocent bystanders to a deeper existential crisis. Severe mental health problems, often accompanied by physical pain, social isolation, unemployment, and hopelessness are the major drivers of illicit drug use and overdose. For those using illicit drugs, the drugs likely provide a means of temporarily escaping suffering through achievement of oblivion.

Impact of misdirected public health and law enforcement policy on patients and clinicians. In my personal observation, the major factor driving physician behavior in the wake of CDC 2016 has been policies adopted by health care providers. These providers were informed by their legal departments that the Guidelines posed increased liability risk if certain clinicians were allowed to prescribe in excess of CDC guidelines. Practitioners are closely monitored and if they exceed the guidelines, their clinical privileges are threatened. Much has been made of DEA prosecutions of clinicians, sometimes leading to imprisonment.

Indirect effects of such prosecutions have been very consequential. Many pain management specialists have left their practices and many primary care physicians have ceased prescribing opioids. All clinicians are now guided almost entirely by CDC guidelines. Closely examined, the scientific basis for those guidelines appears to be close to nil, as we have shown in this Listening Session and in extensive published peer-reviewed papers.

FINAL REMARKS

As the Listening Session neared 2 PM, Dr Lawhern spoke again to summarize main points of the hour:

1. If the FDA audience carries away nothing else from this session, you should remember this: There is no such thing as opioid use disorder. Data published by the CDC itself completely discredits the notion that doctors prescribing to their patients are responsible for the US opioid crisis. And both CDC and DEA have known this reality for years.

2. US CDC and US DEA are usurping missions delegated to the FDA by law, in the establishment of safety standards for prescription drugs.

3. The consequence of this usurpation is the ongoing destruction of American pain medicine.

    a. CDC prescribing guidelines incorporate outright fraud:

        i. Failure to address genetically moderated opioid metabolism

ii. Misrepresentation of the effectiveness of non-opioid alternative therapies.

iii. One-size-fits all MMED dose criteria unsupported by science

iv. Misrepresentation of opioid therapy, especially high-dose opioid therapy, as ineffective for long-term use

b. DEA prosecutions are grounded on non-representative "expert witnesses" who testify to anything DEA wants, no matter how false.

c. Administrative court judges deny defendants adequate representation by pre-trial asset confiscations and by rulings biased in favor of the DEA.

4. It is now known beyond contradiction that incidence of iatrogenic addiction and overdose is too small to measure accurately within the existing confounds of diagnosis and poor clinician training. Law enforcement is particularly ill-equipped to comment on this issue.

5. It is also known to CDC and DEA that doctors overprescribing to patients were ***never*** a significant cause of the US opioid crisis -- and are not now.

6. We appeal to FDA to take public action to repudiate and demand withdrawal of injunctive relief provisions and systems imposed by the National Opioid Settlement

7. We encourage FDA to take immediate action to correct its own databases concerning shortages of prescription opioids created by the opioid settlement injunction.

8. We also ask FDA to publicly repudiate and demand withdrawal of CDC/VA/DoD prescribing guidelines without replacement.

9. We ask FDA to publish minutes of this meeting for public review, consistent with prevailing policy and public law. We intend to publish our own notes widely in social media platforms that generate hundreds of thousands of views per week.

10. In a spirit of transparency, we also disclose that stakeholder participants in this session are co-complainants in formal complaint actions filed May 21, 2024 with the US DoJ Office of Civil Rights and the Office of the Inspector General of DHHS, alleging criminal fraud and denial of US citizens' civil rights on the part of CDC authors and approving officials for the 2016 and 2022 published opioid prescribing guidelines.

11. Individually and as a group, we are available to support further FDA deliberations in this most important issue in American healthcare.

QUESTIONS FOR CLARIFICATION

The FDA audience chose not to ask clarifying questions. Marta Sokolowska, Ph.D., Deputy Center Director for Substance Use and Behavioral Health in the FDA's Center for Drug Evaluation and Research (CDER), thanked the presenters for their input, particularly with respect to patient lived experiences and FDA database issues.

A message was received from FDA/PASE on the next day, from the session administrator:

> I want to express another huge thank you to you and all of your associates from the National Campaign to Protect People in Pain (NCPPP), for sharing your perspectives related to Opioids.
>
> Your primary objective of educating US FDA senior staff on the lack of any consistent relationship between rates of opioid prescribing versus risk of iatrogenic opioid addiction, hospitalization, or overdose-related mortality was accomplished during yesterday's Listening Session.
>
> The presentation provided insights that were impactful, helpful, and important to FDA / CDER. All of us on the call are incredibly grateful to be a part of the Listening Session with you and your colleagues. Hearing your perspective is critical to ensuring that the FDA / CDER can better understand the challenges faced by the public.
>
> If you have any questions, concerns, or additional feedback, you are welcome to contact us by replying to this email. Again, thanks so much for your time.
>
> Thank you again for your efforts to execute the … Listening Session!
>
> As we continue working to provide the best service possible to our constituents, we ask that you please complete [a] brief voluntary feedback survey link.
>
> The link is omitted here to avoid swamping FDA with immediate feedback that they may not be staffed to process formally.

==========

Meeting notes herein have been shared with FDA/PASE, with our encouragement to circulate them further. FDA has made no commitment to do so as of the date of publication.

WE ARE A NATION IN PAIN AND WE WILL NOT BE SILENCED!

From: Frances Cain (FSMB)
To: Frances Cain (FSMB)
Cc: Andrea Ciccone
Subject: June 2024 USMLE Quarterly FSMB Update on USMLE
Date: Tuesday, June 25, 2024 12:56:18 PM
Attachments: Outlook-zyukwo0a.png
Quarterly FSMB Update on USMLE - June 2024.pdf

Dear State Board Executive Directors,

Attached is the June 2024 edition of the Quarterly FSMB Update on USMLE.

In this edition, we are happy to spotlight USMLE volunteer **Gerard (Gerry) Dillon, PhD, a public member of the Pennsylvania State Board of Medicine!**

Other highlights include:

- Update on the June 2024 USMLE Composite Committee meeting – and congratulations to **Dr. Cheryl Walker-McGill** on her election as Chair of the committee
- USMLE Orientation for State Board Members and Staff
- 2023 USMLE Aggregate Performance Data
- Score Reporting Timeline
- USMLE Content Outline Update

I hope you find this update informative. Please do not hesitate to contact me if you have any questions or if I can be of assistance in any way.

Take care,
Frances

Frances Cain, MPA
Director, Assessment Services

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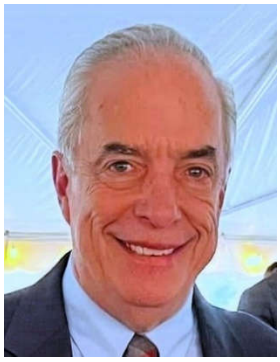
Quarterly FSMB Update on USMLE®

June 2024, Vol. 5, No. 2

USMLE Volunteer Spotlight



Gerard (Gerry) Dillon, PhD
Public Member
Pennsylvania Board of Medicine

I have been a public member of the Pennsylvania Board of Medicine for four years. Being a member of a state board has allowed me the opportunity to work with FSMB in several ways. I have represented my board as a delegate to FSMB's annual meeting, am on the Editorial Board for the Journal of Medical Regulation and am currently on the FSMB Ethics and Professionalism Committee.

Prior to joining the board of medicine, I worked at NBME for more than forty years, spending nearly all that time helping to develop examinations to be used in the medical licensing process. I was witness to the hard work and dedication of members of the national faculty of content experts (many of whom were and are members of state medical boards) who develop test materials, set testing standards and provide direction for the USMLE program. I was also witness to the excellence of the testing professionals who strove to make the examinations as reliable and valid as possible. The stated goal was always to provide the best possible assessment tool for the state medical boards to use in the licensing process.

My opportunity to be a USMLE volunteer started with my appointment to the State Board Advisory Panel to the USMLE program. The panel is made up of approximately 10 individuals who are members of state boards from around the country. The panel meets annually and has an opportunity to interact with USMLE program members (including ECFMG, FSMB and NBME staff). USMLE uses the panel as a sounding board for the direction that the program takes in terms of policies, test design, standard setting, score reporting and other issues. The USMLE staff also seeks input from the member states about the pressing issues they encounter locally and how those might impact or be impacted by the examination system. It is also a wonderful opportunity to "compare notes" with colleagues from sister boards on the issues that impact all regulators. This dialogue between and among examination developers and users is enormously important, and I consider myself fortunate to be a part of it.

Finally, one of the many things I have become aware of since becoming a member of a state medical board is how trusting we are of all the excellent partner organizations that contribute to the regulatory process in this country. The USMLE program and its parents, FSMB and NBME, are among some of the most important of these organizations. It is an honor to be a small contributor to this process, and I would encourage my state board colleagues to consider how they might become part of this program.

USMLE Orientation for State Board Members and Staff

Since 2007, FSMB and NBME have hosted an annual USMLE Orientation workshop for state board members and staff with an interest in learning about and/or participating in the program. To date, 209 individuals from 60 medical and osteopathic boards have participated in an orientation workshop. Sixty-five past participants (representing 35 boards) have served subsequently with the USMLE program. This includes participation on standard setting panels and advisory panels, as well as serving on the USMLE Management Committee, the USMLE Composite Committee and/or item writing and item review committees.

If you or any of your board members or staff are interested in attending the Orientation, please contact Frances Cain, FSMB's Director of Assessment Services, at fcain@fsmb.org.

USMLE Composite Committee Update

At the June 2024 USMLE Composite Committee meeting, the committee elected Cheryl Walker-McGill, MD, MBA, (North Carolina) as Chair for a two-year term. Congratulations, **Dr. Walker-McGill**!

The committee met over two days and discussed a revision to the committee's rules of operation, appeals stemming from decisions of the Committee for Individualized Review, appointment of new members, organizational updates, an update on USMLE Management Committee activities, discussions of form design and exam security and a review of plans for an ongoing transformation of the USMLE exam.

Other members of the committee include representatives of FSMB who serve or have served on state medical boards - FSMB Past Chair Jeffrey Carter, MD, (Missouri); FSMB Past Chair Sarvam TerKonda, MD, (Florida-Medical); Kristin Spanjian, MD, (Montana); and Danny Takanishi, Jr., MD, (Hawaii).

2023 USMLE Aggregate Performance Data

2023 performance data are now available for all USMLE Steps. These data include examinee volume and passing percentages categorized by:

- first-taker and repeater examinees
- U.S./Canadian and international students/graduates
- allopathic and osteopathic examinees

Performance data for USMLE administrations dating back to 2013, as well as Score Interpretation Guidelines, are also available on the USMLE website.

Score Reporting Timeline

The USMLE program will no longer implement dedicated score delay periods for the Step examinations. Most exam scores will continue to be reported within four weeks after an examinee completes their test. However, in rare cases, various factors may delay score reporting. Examinees are advised to allow at least eight weeks to receive their score reports.

USMLE Content Outline Updated

To help ensure the relevancy of content on the USMLE, the USMLE program has released an updated content outline. In this update, topics in the previous "General Principles of Foundational Science" category, which focused on foundational science content, have been redistributed into respective organ system categories or included in a new category titled "Human Development."
Learn more about the update with this infographic.

What's the purpose of this update?
The USMLE is created to be clinically relevant by a diverse national faculty of medicine drawn from medical schools, state licensing boards and clinical practice settings from every region of the United States. As practice guidelines evolve or are introduced, the content on the USMLE is reviewed and modified by these experts as needed. All USMLE examinations are constructed from two classification schemes: (1) an integrated content outline, which organizes content according to individual organ systems and (2) a physician tasks and competencies outline. To ensure that foundational science principles are tested in a clinically relevant manner, this latest modification to the content

outline aims to better incorporate these topics into individual organ systems without changing the proportion of foundational science covered within the exams.

What's the impact of this change?
Foundational science knowledge is a critical building block for future physicians to develop clinical skills and reasoning. The foundational science topics included in the updated content outline are not being removed, just recategorized. Additionally, the weighting or proportion of foundational science content included in the Step exams will not change.

How will this influence examinee preparation for Step exams?
Examinees preparing for Step exams should use the updated content outline available on USMLE.org. The content outline provides a common organization of content across all three Step examinations. However, no single examination includes questions on all listed topics.

Follow USMLE on social media

We encourage state board staff to follow USMLE on social media for timely USMLE news and updates!

Facebook LinkedIn X *(formerly Twitter)*

2024 USMLE Meetings Calendar

Patient Characteristics Advisory Panel - May 22
Management Committee - June 4, August 5-7
Composite Committee - June 7-9
Committee for Individualized Review - July 16-17

Contact

Frances Cain, MPA
Director, Assessment Services
Fcain@fsmb.org

Resources

USMLE.org
Bulletin of Information
FAQs

From:	Patricia McCarty (FSMB)
To:	Patricia McCarty (FSMB)
Cc:	Lauren Mitchell (FSMB)
Subject:	FSMB Board Meeting Highlights (April 17 and 21, 2024)
Date:	Thursday, May 16, 2024 11:16:28 AM
Attachments:	image001.png April 2024 Highlights.pdf

Dear Member Board Presidents/Chairs and Staff Fellows,

Attached for your information are the highlights from the April 17 and 21 meetings of the FSMB Board of Directors. Included in these highlights are the actions taken by the House of Delegates on April 20th.

With kind regards,
Pat

Patricia McCarty, M.M.
Director, Leadership Services

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FEDERATION OF STATE MEDICAL BOARDS

Meetings of the FSMB Board of Directors
April 17 and 21, 2024
Nashville, Tennessee

Highlights

The FSMB Board of Directors met on April 17 and 21, 2024, in Nashville, Tennessee. The following is a summary of those meetings.

APRIL 17, 2024

2024 House of Delegates (HOD) Meeting

The Board of Directors discussed the reports and resolutions going before the 2024 HOD for consideration. See page three for a complete list of the actions taken by the HOD.

Informational Reports

Informational reports were provided on the activities/work of the FSMB Chair, President-CEO, Chief Advocacy Officer, Chief Assessment Officer, Chief Legal Officer, and Chief Operating Officer. Additionally, an updated Financial/Investment Report was presented. The Board received a report from the Board's Planning Committee and reports on the National Academy of Medicine's (NAM's) Action Collaboratives on *Clinician Well-being and Resilience* and *Combatting Substance Use and Opioid Crises*. Updates were also provided on USMLE operations .and the work of the Advisory Commission on Alternative Licensing Models. The Board also received information about a statement on diversity, equity and inclusion (DEI) recently approved by some of the member organizations of the Coalition for Physician Accountability.

MAY 7, 2023

New Directors of the Board

Newly installed FSMB Chair Katie L. Templeton, JD welcomed the Board of Directors' newly elected Directors-at-Large Alexios G. Carayannopoulos, DO, MPH and J. Michael

Wieting, DO, MEd, as well as Staff Fellow Kenneth E. Cleveland, MD. Ms. Templeton also congratulated George M. Abraham, MD, MPH on his election as Chair-elect, Shawn P. Parker, JD, MPA on his election as Treasurer, and Andrea A. Anderson, MD, MEd, Denise Pines, MBA, and Mark B. Woodland, MS, MD on their re-election as Directors-at-Large.

Election of Directors-at-Large to the Executive Committee

The Board of Directors elected Directors-at-Large Andrea Anderson, MD, MEd, Christy L. Valentine Theard, MD, MBA, and Mark B. Woodland, MS, MD to the Board's Executive Committee for a one-year term.

FY 2025 Board of Directors Action Plan

The Board of Directors reviewed the draft FY 2025 Board Action Plan recommended by the Board's Planning Committee. The Board approved addition of the following goal to the draft presented: *Assure cybersecurity measures and practices are in place to protect the data and information maintained and used by FSMB for its operations, activities, and services.* The Board Action Plan was approved as amended.

Committee and Workgroup Appointments

The Board of Directors approved the Chair's recommendations for FSMB standing committee appointments for the coming year including appointments to the USMLE Composite Committee and FSMB representatives to the ABMS and ACGME. The Board also authorized the Chair to finalize any outstanding committee appointments that might need to be made following the Board's meeting to ensure the work of the groups can proceed in a timely manner.

Informational Report and Resources

The Board received a presentation and discussions of the legal and fiduciary responsibilities of the Board from counsel. Additionally, the Board was provided with the schedule of Board meetings for the upcoming year and the FY 2025 FSMB Bylaws as approved by the 2024 House of Delegates.

Actions by the FSMB House of Delegates
April 20, 2024

1. The Agenda for the April 20, 2024 annual meeting of the House of Delegates was **APPROVED**.

2. The Report of the Rules Committee was **ADOPTED**.

3. The Consent Agenda for the April 20, 2024 annual meeting of the House of Delegates was **APPROVED**.

4. The Minutes of the May 6, 2023 annual meeting of the House of Delegates were **APPROVED**.

5. The FY 2025 Proposed Budget was **ADOPTED.**

6. Elections

Chair-elect: **George M. Abraham, MD, MPH (2024-2025)**
(elected by acclamation)

Treasurer: **Shawn P. Parker, JD (2024-2027)**
(elected by acclamation)

Directors-at-Large: **Andrea A. Anderson, MD, MEd (2024-2027)**
Denise Pines, MBA (2024-2027)
Mark B. Woodland, MS, MD (2024-2027)
Alexios G. Carayannopoulos, DO, MPH (2024-2026)
J. Michael Wieting, DO, MEd (2024-2025)

Nominating Committee: **Scot N. Ackerman, MD (2024-2026)**
Clarence P. Chou, MD (2024-2026)
Koomarie "Shoba" Gaymes (2024-2026)

1. Proposed Amendment #1 to the Articles of Incorporation and Bylaws contained in the Report of the Bylaws Committee was **ADOPTED**:

ARTICLES OF INCORPORATION: Article V

The corporation shall have members which will be classified as follows:

SEC. A. Medical Boards
SEC. B. Fellows
SEC. C. Honorary Fellows
SEC. D. Associate Members
~~**SEC. E. Affiliate Member Boards**~~

BYLAWS: Article II. Classes of Membership, Election and Membership Rights

~~**Section E. Affiliate Member Boards**~~

~~**A board or authority that is not otherwise eligible for membership may become an Affiliate Member Board of the FSMB upon approval of its application by the Board of Directors if the board or authority licenses either:**~~

~~**1. Allopathic or osteopathic physicians or physician assistants in the United States; or**~~
~~**2. Allopathic or osteopathic physicians if the board or authority is located in another country**~~

2. Proposed Amendment #2 to the Bylaws contained in the Report of the Bylaws Committee was **ADOPTED**:

Article II. Classes of Membership, ~~Election~~ Nomination and Membership Rights

Section H. Methods of Nomination to Elected Office **or Board of Directors**

Nomination by the Nominating Committee or Nomination by Petition pursuant to Articles III, IV, V and VIII shall be the sole methods of nomination to an elected office **or the Board of Directors** of the FSMB. A candidate who runs for and is not elected to an elected office shall be ineligible to be nominated for any other elected office during the same election cycle.

3. Proposed Amendment #3 to the Bylaws contained in the Report of the Bylaws Committee was **ADOPTED**:

Article III. Officers: Election and Duties

Section D. Terms of Office and Succession

5. The term of the Secretary is co-terminus with that of the President **of the FSMB**.

Article IV. Board of Directors

Section D. Duties of the Board of Directors

7. The Board of Directors shall establish a strategic plan for the FSMB that states the FSMB mission and objectives and shall submit that plan to the House of Delegates for ratification, modification, or rejection. The Board

shall review the current strategic plan annually and propose any amendments to the Annual Meeting of the House of Delegates for ratification, modification, or rejection. The **FSMB** President shall report of the Annual Meeting of the House of Delegates on the extent to which the FSMB's stated objectives have been accomplished in the preceding year.

4. Proposed Amendment #4 to the Bylaws contained in the Report of the Bylaws Committee was **ADOPTED**:

Article VIII. Standing and Special Committees

Section H. Nominating Committee: Process for Election

1. MEMBERSHIP: The Nominating Committee shall be composed of six Fellows and the Immediate Past Chair, who shall chair the Committee and serve without vote except in the event of a tie. **Only an individual who is a Board Member Fellow at the time of the individual's election shall be eligible for election as a member of the Nominating Committee.** With the exception of the Immediate Past Chair, no two Committee members shall be from the same member board and no officer or member of the Board of Directors shall serve on the Committee. A member of the Nominating Committee may not serve consecutive terms.
2. ELECTION: At least three Fellows shall be elected at each Annual Meeting of the House of Delegates by a plurality of votes cast, each to serve for a term of two years. ~~**Only an individual who is a Board Member Fellow at the time of the individual's election shall be eligible for election as a member of the Nominating Committee.**~~ In the event of a tie vote in a runoff election, up to two additional runoff elections shall be held. Prior to the election, the presiding officer shall cast a sealed vote, ranking each candidate in a list. The presiding officer's vote is counted for the candidate in the runoff election who is highest on the list. The presiding officer's vote is counted only to resolve a tie that cannot be decided by the process set forth in this section.

5. *Strategies for Prescribing Opioids for the Management of Pain* contained in BRD RPT 24-1 was **ADOPTED**, superseding *Guidelines for the Chronic Use of Opioid Analgesics* (HoD 2017).

6. The *Position Statement on Access to Evidence-Based Treatment for Opioid Use Disorder* contained in BRD RPT 24-1 was **ADOPTED**, superseding *Model Policy on the DATA 2000 and Addiction Treatment in the Medical Office* (HoD 2013).

7. The recommendations contained in BRD RPT 24-2: *Regulation of Physicians in Training* were **ADOPTED** and the remainder of the report filed.

8. *Guidelines for the Structure and Function of a State Medical and Osteopathic Board* contained in BRD RPT 24-3 was **ADOPTED**, superseding the previous edition.

9. The principles and recommendations contained in BRD RPT 24-4: *Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice* were **ADOPTED** and the remainder of the report filed.

10. Resolution 24-1: Post-Licensure Medical Assessment of Physician Assistants was **REFERRED TO THE BOARD OF DIRECTORS FOR ACTION**.

11. Resolution 24-2: Pathways to Licensure for International Medical Graduates was **ADOPTED**.

12. Resolution 24-3: Medical Directors of Health Insurers Making Medical Necessity Determinations was **ADOPTED**.

From: Joe Knickrehm
To: Joe Knickrehm
Subject: FDA Panel Mention of State Medical Boards
Date: Wednesday, June 5, 2024 9:22:09 AM
Attachments: image001.png

Dear Executive Directors,

FSMB would like to alert you to mention of state medical boards during an FDA advisory panel meeting yesterday in which the group rejected the use of MDMA (commonly known as Ecstasy) for the treatment of PTSD. The panel expressed concerns that data from clinical trials showed the drug's benefits do not outweigh its risks to patients. During deliberations, one panel member reminded listeners that while the FDA regulates medications, it does not regulate psychotherapy, and that responsibility would fall under the purview of state medical boards. The discussion was highlighted in a piece by Politico this morning (included below). Please reach out to FSMB with any questions or concerns.

Thank you,
Joe

Joe Knickrehm
Vice President, Communications

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Rebuke of psychedelic treatment explained

By **BEN LEONARD** and **CHELSEA CIRRUZZO**

06/05/2024 10:00 AM EDT

TOUGH DAY FOR ECSTASY — An FDA advisory committee dealt a severe blow to psychedelic medicine on Tuesday, finding that MDMA, also known as ecstasy, is not an effective treatment for post-traumatic stress disorder, POLITICO's Erin Schumaker reports.

The expert committee voted 9-2 that Lykos Therapeutics' combo regimen of therapy and MDMA is not effective and 10-1 that the treatment's risks outweigh its benefits.

"Premature introduction of a treatment can actually stifle development and stifle innovation," said Dr. Paul Holtzheimer, committee member and deputy director for research in the executive division of the Department of Veterans Affairs' National Center for PTSD.

The FDA typically follows the advice of its advisers in deciding whether to approve a new treatment. The agency expects to decide on the drug therapy's use by mid-August.

The no vote could upend a

burgeoning industry that's testing numerous mind-altering drugs as treatments for mental illnesses, including depression, anxiety and addiction. It's also a blow to the VA, which is seeking better treatments for the huge number of veterans with PTSD, and to lawmakers touting psychedelics. Here are three takeaways:

1. Experts are wary of "expectation bias."

In double-blind studies, the gold standard for clinical trials, drug study participants don't know whether they've received the drug or a placebo.

But it's hard to do double-blind studies with psychedelics, whose effects are so pronounced that participants can usually figure out whether they received the drug. People who know they received the drug may have an expectation bias toward its effectiveness, the FDA advisers said.

2. The public expressed mixed views on Lykos and MDMA therapy.

During the public hearing section of the meeting, the advisory committee heard from

groups in support of psychedelic medicine — and against it.

Veterans' advocacy groups pointed to the acute need for better PTSD treatments, which have had no significant updates in more than 20 years.

Critics of MDMA therapy and Lykos, including psychedelic researchers, expressed concern about alleged misconduct in Lykos' clinical trials, including that researchers may have pressured subjects not to report negative effects.

3. The FDA shied away from regulating therapy.

The FDA said Tuesday that the psychotherapy portion of Lykos' application wouldn't fall under the agency's purview. State medical boards and, in case of misconduct, the courts, would need to play a role.

"The FDA can't regulate everything," said Dr. Tiffany Farchione, director of the FDA's psychiatry division.

Lykos responds: In a statement after the advisory committee votes, Lykos CEO Amy Emerson said the firm was disappointed but "committed to continuing to collaborate with

the FDA with their ongoing review." She added that Lykos would work with the FDA to answer questions raised at the committee meeting. Lykos, she said, was in ongoing discussions with the FDA about a risk evaluation and mitigation strategy program that would seek to reduce the chance of adverse events stemming from its treatment.

From:	Kelly Alfred
To:	Kelly Alfred
Subject:	2024 Annual Meeting Follow-up: Policy Implementation Action Plan Reminder & Resources
Date:	Tuesday, July 16, 2024 12:32:48 PM
Attachments:	image001.png Consolidated Recommendations for Workshop.docx FSMB Action Plan Template.docx Additional Resources Links .pdf

Dear FSMB Annual Meeting Attendee,

It has been more than 2 months since the FSMB Annual Meeting where we held a first-of-its-kind policy implementation workshop focused on developing board action plans for implementing new policies for addressing sexual misconduct and opioid mis-prescribing. Many of you participated in this session with Dr. Tristan McIntosh and Dr. Jim DuBois.

As part of supporting the long-term success of this effort, we are reaching out with a friendly reminder about implementing your policy implementation action plan. To support these efforts, we are including: 1) a list of policy recommendations generated and refined by members of state medical boards, 2) a policy implementation action plan template for your board to use in the future, and 3) an annotated bibliography with relevant readings and resources.

In August, a survey will be sent out to attendees to gather information about how your board has used and implemented the policy implementation action plan. We strongly encourage you to participate in this survey and work with your board this summer to make progress on action plan implementation. Should you have any questions, please feel free to reach out to Tristan McIntosh, PhD, at t.mcintosh@wustle.edu.

Thank you for your attention to this important effort to further protect the public.

Sincerely,

Kelly C. Alfred, M.S.
Director, Education Services

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List of Policy Recommendations

This document lists the policy recommendations from McIntosh et al. (2021) *Protecting patients from egregious wrongdoing by physicians: Consensus recommendations from state medical board members and staff.* The list of recommendations, informed by state medical board members and staff, can help support effective and transparent actions and processes by boards when addressing suspected egregious wrongdoing. Each table represents the 5 different clusters of consensus-based policy recommendations, several of which map to the 2020 FSMB Physician Sexual Misconduct Report. Recommendations with one asterisk (*) indicate areas of similarity between the two documents. Recommendations with two asterisks (**) are identical across the two documents.

Cluster 1: Board Composition and Characteristics

1. Board has an adequate number of investigative staff.
2. Board is required to include gender diversity.*
3. Board has an adequate number of administrative staff.
4. Board is required to be racially diverse.
5. Board has an adequate number of members with clinical expertise that is reasonably current.
6. Board has access to adequate legal counsel.
7. Sexual misconduct cases are investigated by specialized gender-diverse teams.*
8. Board utilizes a role-diverse investigative team (e.g., including clinicians, public members, and legal counsel).**
9. Board includes more than one public member with no ties to medicine or industry.*

Cluster 2: Board Website, Outreach, and Education

1. The board website provides an easy-to-find platform for patients and other whistleblowers to file complaints.*
2. Board publishes documents on hearings and disciplinary actions on its website.*
3. Board website includes information about state laws and board policy on sexual misconduct.*
4. The board website includes information about the investigation process and what the person reporting can expect.*
5. Board markets its purpose via social media, professional organizations, and liaising with hospitals and other relevant groups.*
6. Board website defines physician sexual misconduct.*
7. Board provides physicians with specific information on what disciplinary actions occur if they violate provisions of the medical practice act.*

Cluster 3: Internal Board Operations and Investigations

1. Board has the authority to open an investigation in the absence of a complaint based on factors such as criminal history reports, prosecutorial charging instruments, FSMB, NPDB, and PMP reports, other agency and jurisdictional enforcement actions, or journalistic reporting.
2. Board established qualifications for experts consulted during investigations and hearings.*
3. Board obtains relevant mental health information during investigations.*
4. Board allows patients to present complaints in strict confidentiality.**
5. Board requires all physicians to complete a criminal background check at the time of their *application*.
6. The board permits anonymous reporting.*
7. The board defines which types of alleged misconduct trigger special procedures to protect the public (e.g., consideration of emergency suspension of a license, expedited investigation).*
8. Board has a screening committee that triages incoming complaints.
9. Board routinely checks the Prescription Monitoring Program (PMP) for the top prescribers of opioids and checks for suspicious patterns of prescribing or dispensing opioids.
10. When the NPDB has a plausible category to characterize wrongdoing (e.g., sexual misconduct), then the Board would ban the use of the "other" or "N/A" categories. "Other" or "N/A" categories would be used as a last resort.*
11. Board requires all physicians to complete a criminal background check at the time of their *renewal*.

Cluster 4: Improved Coordination and Information Sharing Between Stakeholders

1. Board issues subpoenas for witnesses and medical and business records.
2. Board provides disciplinary information to the FSMB Physician Data Center, which allows for disciplinary alerts to be sent to other jurisdictions in which the physician holds a license.**
3. Hospitals are required to report to boards when employed physicians have been dismissed or resign due to concerns about egregious wrongdoing.**
4. Board requires medical schools and post-graduate training programs to report egregious wrongdoing as a condition to licensure eligibility.**
5. Board requires all physicians to report any disciplinary action during medical school at the time of their application (e.g., suspension, warning, probation, expulsion, being requested or allowed to resign in lieu of discipline).**
6. State law indemnifies those who, in good faith, provide mandated reports or assist the board with investigations. (To indemnify means to protect the individuals from legal actions brought against them for performing their duties.)**
7. Information sharing is required between the board and the VA system, including information about physicians.
8. Board informs law enforcement that they can report accusations against a physician to the board even if criminal charges are not filed.
9. Board requires medical schools and post-graduate training programs to report any disciplinary complaints about physicians during medical school as a condition for licensure eligibility.

10. Board allows unfettered investigative information sharing about physicians with other boards, including when a physician applies for licensure and when potentially actionable out-of-state conduct occurs.
11. Insurance companies are required to report to the board each time a payment is made in a malpractice case.
12. Board has a duty to report to law enforcement any time it becomes aware of sexual misconduct or other instances of egregious wrongdoing.*
13. Board coordinates investigations with community partners (e.g., local and state police, healthcare organizations, other state agencies).
14. Board reports impaired physicians to the National Practitioners Data Bank (NPDB).
15. Board conducts joint investigations with other professional boards (e.g., nursing, physician assistants, dentistry) within the state.

Cluster 5: Licensing and Disciplinary Considerations

1. Board has the authority to make decisions and take action independently in disciplinary matters.
2. Board allows an emergency suspension or restriction of a physician when physicians are credibly accused of sexual misconduct with a minor.*
3. The board is authorized to enact an emergency suspension to prevent ongoing, egregious wrongdoing when allegations are credible, or a physician has been arrested in connection with such conduct.*
4. The board monitors physicians and their continued practice following a finding of sexual wrongdoing if a license is not revoked or suspended. **
5. The board has the authority to permanently revoke the license of a physician who is convicted of sexual misconduct. **
6. When a physician agrees to a disciplinary recommendation, an order is presented to the full board for approval.
7. When a physician declines to accept a disciplinary recommendation, formal charges are filed, and a contested case is publicly held.
8. The board considers revocation when a physician repeatedly commits lesser acts of wrongdoing, especially following remedial efforts.*
9. Certain criminal acts by physicians (e.g., sexual misconduct) are raised to the felony level, subjecting them to mandatory reporting.
10. Board suspends a physicians' license when their license is suspended in another jurisdiction.
11. Board allows an emergency suspension or restriction of a physician when physicians are in possession of a controlled substance without a valid prescription.
12. Board imposes penalties on physicians for not reporting peers who engage in egregious wrongdoing.*
13. Board utilizes preponderance of the evidence as the standard of proof in all disciplinary proceedings (rather than "clear and convincing evidence" or other standards).
14. Board fines hospitals and academic medical centers for failure to report instances of egregious wrongdoing.**

FEDERATION OF STATE MEDICAL BOARDS

Additional Resources for State Medical Boards

This document includes an annotated bibliography of resources and articles that provide additional information for state medical boards to reference as they implement new policies.

Protecting Patients from Egregious Wrongdoing by Physicians

Authors: Tristan McIntosh, Elizabeth Pendo, Heidi Walsh, Kari Baldwin and James M. DuBois

Journal: *Journal of Medical Regulation*

Abstract: Purpose: There is wide variability in the frequency and severity of disciplinary actions imposed by state medical boards (SMBs) against physicians who engage in egregious wrongdoing. We sought to identify cutting-edge and particularly effective practices, resources, and statutory provisions that SMBs can adopt to better protect patients from harmful physicians. Main findings: Using a modified Delphi panel, expert consensus was reached for 51 recommendations that were rated as highly important for SMBs. Panelists included physicians, executive members, legal counsel, and public members from approximately 50% of the 71 SMBs that serve the United States and its territories. Conclusion: The expert-informed list of recommendations can help support more effective and transparent actions and processes by SMBs when addressing suspected egregious wrongdoing. While some SMBs may be limited in what policies and provisions they can adopt without approval or assistance from state government, many of these recommendations can be autonomously adopted by SMBs without external support.

Link to article:
https://www.jstor.org/stable/pdf/48685223.pdf?casa_token=a43Gdm1ADMEAAAAA:3bfsmLLQwhaGWD4mne1wr9owSSDHNMi28Y9ENqHtW6FzHcZ6k2Pox6P1amQe5UwgFc8381zVp_wpGnEgSCN75HJCxepsVd38AWuL2UKTQRW5Mx-eRg

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What Can State Medical Boards Do to Effectively Address Serious Ethical Violations?

Authors: Tristan McIntosh, Elizabeth Pendo, Heidi A. Walsh, Kari A. Baldwin, Patricia King, Emily E. Anderson, Catherine V. Caldicott, Jeffrey D. Carter, Sandra H. Johnson, Katherine Mathews, William A. Norcross, Dana C. Shaffer, and James M. DuBois

Journal: *Journal of Law, Medicine & Ethics*

Abstract: State Medical Boards (SMBs) can take severe disciplinary actions (e.g., license revocation or suspension) against physicians who commit egregious wrongdoing in order to protect the public. However, there is noteworthy variability in the extent to which SMBs impose severe disciplinary action. In this manuscript, we present and synthesize a subset of 11 recommendations based on findings from our team's larger consensus-building project that identified a list of 56 policies and legal provisions SMBs can use to better protect patients from egregious wrongdoing by physicians.

Link to article:
https://www.cambridge.org/core/services/aop-cambridge-core/content/view/B08091D9F74DA1E7E960440748B4CF08/S1073110524000068a.pdf/div-class-title-what-can-state-medical-boards-do-to-effectively-address-serious-ethical-violations-div.pdf

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Protecting Patients from Physicians Who Inflict Harm: New Legal Resources for State Medical Boards

Authors: Elizabeth Pendo, Tristan McIntosh, Heidi Walsh, Kari Baldwin, James M. Dubois

Journal: Saint Louis University School of Law, 2022

Abstract: State medical boards (SMBs) protect the public by ensuring that physicians uphold appropriate standards of care and ethical practice. Despite this clear purpose, egregious types of wrongdoing by physicians are alarmingly frequent, harmful, and under-reported. Even when egregious wrongdoing is reported to SMBs, it is unclear why SMBs sometimes fail to promptly remove seriously offending physicians from practice. Legal and policy tools that are targeted, well-informed, and actionable are urgently needed to help SMBs more effectively protect patients from egregious wrongdoing by physicians. Past reviews of SMB performance have identified features of SMBs associated with higher rates of severe disciplinary actions against physicians, including political and professional independence and adequate funding and staffing. However, there has been little attention paid to elements of the state level legal framework that governs SMB licensing and disciplinary function, or what legal or policy tools would make SMBs more effective at protecting patients in serious cases.

Link to article:
https://scholarship.law.slu.edu/cgi/viewcontent.cgi?article=1655&context=faculty

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Preventing Egregious Ethical Violations in Medical Practice; Evidence-Informed Recommendations from Multidisciplinary Working Group

Authors: James M. DuBois, DSc, PhD; Emily A. Anderson, MPH, PhD; John T. Chibnall, PhD; Leanne Diakov, JD; David J. Doukas, MD; Eric S. Holmboe, MD; Heidi M. Koenig, MD; Joan H. Krause, JD; Gianna McMillan, MA; Marc Mendelsohn, MD; Jessica Mozersky, PhD, MBE; William A. Norcross, MD; Alison J. Whelan, MD

Journal: *Journal of Medical Regulation*

Abstract: This article reports the consensus recommendations of a working group that was convened at the end of a four-year research project funded by the National Institutes of Health that examined 280 cases of egregious ethical violations in medical practice. The group reviewed data from the parent project, as well as other research on sexual abuse of patients, criminal prescribing of controlled substances, and unnecessary invasive procedures that were prosecuted as fraud. The working group embraced the goals of making such violations significantly less frequent and, when they do occur, identifying them sooner and taking necessary steps to ensure they are not repeated. Following review of data and previously published recommendations, the working group developed 10 recommendations that provide a starting point to meet these goals. Recommendations address leadership, oversight, tracking, disciplinary actions, education of patients, partnerships with law enforcement, further research and related matters. The working group recognized the need for further refinement of the recommendations to ensure feasibility and appropriate balance between protection of patients and fairness to physicians. While full implementation of appropriate measures will require time and study, we believe it is urgent to take visible actions to acknowledge and address the problem at hand

Link to article:
https://meridian.allenpress.com/jmr/article/104/4/23/12271/Preventing-Egregious-Ethical-Violations-in-Medical

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Serious Ethical Violations in Medicine: A Statistical and Ethical Analysis of 280 Cases in the United States From 2008–2016

Authors: James M DuBois, Emily E Anderson, John T. Chibnall, Jessica Mozersky, & Heidi A. Walsh

Journal: *The American Journal of Bioethics*

Abstract: Serious ethical violations in medicine, such as sexual abuse, criminal prescribing of opioids, and unnecessary surgeries, directly harm patients and undermine trust in the profession of medicine. We review the literature on violations in medicine and present an analysis of 280 cases. Nearly all cases involved repeated instances (97%) of intentional wrongdoing (99%), by males (95%) in nonacademic medical settings (95%), with oversight problems (89%) and a selfish motive such as financial gain or sex (90%). More than half of cases involved a wrongdoer with a suspected personality disorder or substance use disorder (51%). Despite clear patterns, no factors provide readily observable red flags, making prevention difficult. Early identification and intervention in cases requires significant policy shifts that prioritize the safety of patients over physician interests in privacy, fair processes, and proportionate disciplinary actions. We explore a series of 10 questions regarding policy, oversight, discipline, and education options. Satisfactory answers to these questions will require input from diverse stakeholders to help society negotiate effective and ethically balanced solutions.

Link to article:
https://www.tandfonline.com/doi/epub/10.1080/15265161.2018.1544305?needAccess=true

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Sexual Violation of Patients by Physicians: A Mixed-Methods, Exploratory Analysis of 101 Cases

Authors: James M. DuBois, Heidi A. Walsh, John T. Chibnall, Emily E. Anderson, Michelle R. Eggers, Mobolaji Fowose, and Hannah Ziobrowski

Journal: *Sage Journals*

Abstract: A mixed-method, exploratory design was used to examine 101 cases of sexual violations in medicine. The study involved content analysis of cases to characterize the physicians, patient-victims, the practice setting, kinds of sexual violations, and consequences to the perpetrator. In each case, a criminal law framework was used to examine how motives, means, and opportunity combined to generate sexual misconduct. Finally, cross-case analysis was performed to identify clusters of causal factors that explain specific kinds of sexual misconduct. Most cases involved a combination of five factors: male physicians (100%), older than the age of 39 (92%), who were not board certified (70%), practicing in nonacademic settings (94%) where they always examined patients alone (85%). Only three factors (suspected antisocial personality, physician board certification, and vulnerable patients) differed significantly across the different kinds of sexual abuse: personality disorders were suspected most frequently in cases of rape, physicians were more frequently board certified in cases of consensual sex with patients, and patients were more commonly vulnerable in cases of child molestation. Drawing on study findings and past research, we offer a series of recommendations to medical schools, medical boards, chaperones, patients, and the national practitioners database.

Link to article:
https://journals.sagepub.com/doi/pdf/10.1177/1079063217712217

Physician Sexual Misconduct Report and Recommendations of the FSMB Workgroup on Physician Sexual Misconduct

Authors: Federation of State Medical Boards

Abstract: The relationship between a physician and patient is inherently imbalanced. The knowledge, skills and training statutorily required of all physicians puts them in a position of power in relation to the patient. The patient, in turn, often enters the therapeutic relationship from a position of vulnerability due to illness, suffering, and a need to divulge deeply personal information and subject themselves to intimate physical examination. This vulnerability is further heightened in light of the patient's trust in their physician, who has been granted the power to deliver care, prescribe needed treatment and refer for appropriate specialty consultation. It is critical that physicians act in a manner that promotes mutual trust with patients to enable the delivery of quality health care. When there is a violation of that relationship through sexual misconduct, such behavior and actions can have a profound, enduring and traumatic impact on the individual being exploited, their family, the public at large, and the medical profession as a whole. Properly and effectively addressing sexual misconduct by physicians through sensible standards and expectations of professionalism, including preventive education, as well as through meaningful disciplinary action and law enforcement when required, is therefore a paradigmatic expression of self-regulation and its more modern iteration, shared regulation.

Link to article:
https://www.fsmb.org/siteassets/advocacy/policies/report-of-workgroup-on-sexual-misconduct-adopted-version.pdf

ALASKA STATE MEDICAL BOARD CHECKLIST - PHYSICIAN-PHARMACIST COOPERATIVE PLAN

Cooperative Plan (License Record) Number: 226010 - Whale's Tail Pharmacy

Physician Name(s): John Sealander, MD — License No. 165219
_____ — License No. _____
_____ — License No. _____

Pharmacist Name (s): Julie McDonald, PharmD — License No. PHAP1954
Winston Johnson, PharmD — License No. 139982
Victoria Bumgardner, PharmD — License No. 146053

Date Received: 4/22/2024

Written Proposed Agreement addresses the following elements:

1. Includes types of cooperative practice decisions the physician is granting to the pharmacist ☐ No ☐ Yes
   Check all that apply:
   ☐ Types of diseases or conditions: List _____
   ☒ Types of medications or medication categories: List Inhalers, oral contraceptives
2. Includes procedures, decision criteria or plans the pharmacist must follow when making therapeutic decisions, particularly when initiating or modifying medications. ☐ No ☒ Yes
3. Includes expectations and requirements for the pharmacist to follow with respect to documentation of decisions made, and a plan for communication and feedback to the physician regarding decisions made ☐ No ☒ Yes
4. Includes a plan for the physician to review decisions made by the pharmacist at least once every three months. ☐ No ☒ Yes
5. Includes a plan for the pharmacist to provide the physician any patient records created under the agreement. ☒ No ☐ Yes
6. Includes a provision that allows the physician to override the agreement if the physician considers it medically necessary or appropriate. ☒ No ☐ Yes
7. Includes an acknowledgement that the physician will not receive any compensation from the pharmacist or pharmacy as a result of the care or treatment of any patient under the agreement. ☐ No ☒ Yes
8. Includes a prohibition against the administration or dispensing of any schedule I, II. III or IV controlled substances. ☐ No ☒ Yes

Comments: _____

Date Application Complete/forwarded to Board Member for Review: _____ Examiner: _____

ALASKA STATE MEDICAL BOARD CHECKLIST -
PHYSICIAN-PHARMACIST COOPERATIVE PLAN

MEDICAL BOARD MEMBER REVIEW FOR APPROVAL

☐ APPROVED ☐ HOLD FOR BOARD ☐ INTERVIEW REQUIRED

Comments: _____

_____

Date Issued: _____

Signed: _____ Date _____

PHARMACY BOARD DELEGATE ENDORSEMENT

ENDORSEMENT APPROVED ◯ YES ◯ NO

Comments if "NO" to above:

_____

_____

Endorsed by: _____ Signature/Date: _____

Collaborative Practice Agreement – Continuation of Care Protocol (Inhalers)

Agreement Statement

The following practitioners hereby authorize pharmacists employed by Whale Tail pharmacy to dispense medications in accordance with the protocols described within this agreement.

Participating Practitioners and Pharmacist

Practitioners	Pharmacists
John Sealander	Julie McDonald
Kimberly Barnes	Winston Johnson
	Victoria Bumgardner

Protocol

The purpose of this protocol is to allow for one (1) additional refill on pertinent inhaled medications in the event of an emergency or if their authorizing primary care provider is unavailable to write them a new prescription.

Upon receiving a patient in the pharmacy, the pharmacist on duty will have the option of authorizing a one-time refill of a qualifying inhaler (listed below). The refill is only to be used in instances where the qualifying medication is needed to maintain the patient's current treatment. The pharmacist is to, to the best of their ability, determine that the patient is out of medication based on prior fill history and patient testimony. If the patient qualifies based on the following criteria, the pharmacist will then create a continuation of care prescription, send the authorizing provider a refill request, and document the fill in the protocol folder where corresponding records will be kept for 6 months. The prescription will be for the smallest available unit (typically 1 inhaler of the appropriate strength). It will also include instructions to follow up with the provider for any further refills.

Patient Selection Criteria

Patients will be limited to those who:

1. Have received a prescription from an authorizing provider within the past 6 months
2. Have had prior fills of the qualifying medication
3. Have not previously received a continuation of care refill on the requested medication within the past 6 months.

Medications included

1. Albuterol (and equivalent brands or generics)

2. Advair (and equivalent generics)
3. Asmanex (and equivalent generics)
4. Breo Ellipta (and equivalent generics)
5. Combivent (and equivalent generics)
6. Dulera (and equivalent generics)
7. Flovent (and equivalent generics)
8. Levealbuterol (and equivalent generics)
9. Qvar (and equivalent generics)
10. Spiriva Handihaler (and equivalent generics)
11. Spiriva Respimat (and equivalent generics)
12. Stiolto Respimat(and equivalent generics)
13. Symbicort (and equivalent generics)
14. Trelegy (and equivalent generics)

Only medications listed above are allowed to be dispensed under this protocol.

Plan for follow up and review

The authorized physicians will receive a quarterly report of the prescriptions authorized through this protocol. Attached with this report will be any statements from the pharmacist team regarding issues or concerns.

Acknowledgment

The authorizing providers listed above will not receive any financial compensation for participation in this agreement.

Signature of Involved Parties

Kimberly Barnes NP-C

Victoria Baumgardner

Julie McDonald

This Agreement will be effective for the period of one year starting on the date of approval from the Alaska Board of Pharmacy.

Collaborative Practice Agreement – Continuation of Care Protocol ORAL CONTRACEPTIVES

Agreement Statement

The following practitioners hereby authorize pharmacists employed by Whale Tail pharmacy to dispense medications in accordance with the protocols described within this agreement.

Participating Practitioners and Pharmacist

Practitioners	Pharmacists
John Sealander	Julie McDonald
Kimberly Barnes	Winston Johnson
	Victoria Bumgardner

Protocol

The purpose of this protocol is to allow for one (1) additional refill on pertinent medications that are known to require consistent medication taking behaviors. In the event of an emergency or if their authorizing primary care provider is unavailable to write them a new prescription this protocol will allow for the pharmacist on duty to authorize the additional refill.

Upon receiving a patient in the pharmacy, the pharmacist on duty will have the option of authorizing a one-time refill of a qualifying medication (listed below). The refill is only to be used in instances where the qualifying medication is needed to maintain the patient's current treatment. The pharmacist is to, to the best of their ability, determine that the patient is out of medication based on prior fill history and patient testimony.

If the patient qualifies based on the following criteria, the pharmacist will then create a continuation of care prescription, send the authorizing provider a refill request, and document the fill in the protocol folder where corresponding records will be kept for 6 months. The prescription will be for the smallest available unit (typically 1 inhaler of the appropriate strength). It will also include instructions to follow up with the provider for any further refills.

Patient Selection Criteria

Patients will be limited to those who:

1. Have received a prescription from an authorizing provider within the past 6 months.
2. Have had prior fills of the qualifying medication.

3. Have not previously received a continuation of care refill on the requested medication within the past 6 months.

Medications included:

1. Oral Contraceptives including both brand and generic substitutions for:
    a. Conjugated Estrogens
    b. Desogestrel/Ethinyl Estradiol
    c. DIETHYLSTILBESTROL
    d. Drospirenone
    e. Drospirenone/Estetrol
    f. Drospirenone/Ethinyl Estradiol
    g. Drospirenone/Ethinyl Estradiol/Levomefolate Calcium and Levomefolate Calcium
    h. ESTRADIOL
    i. Estradiol Cypionate/Medroxyprogesterone Acetate
    j. Estradiol Valerate and Estradiol Valerate/Dienogest
    k. Ethinyl Estradiol/Ethynodiol Diacetate
    l. Ethinyl Estradiol/Etonogestrel
    m. Ethinyl Estradiol/Levonorgestrel
    n. Ethinyl Estradiol/Norelgestromin
    o. Ethinyl Estradiol/Norethindrone
    p. Ethinyl Estradiol/Norethindrone Acetate
    q. Ethinyl Estradiol/Norgestimate
    r. Ethinyl Estradiol/Norgestrel
    s. Etonogestrel
    t. L-METHYLFOLATE
    u. Levonorgestrel
    v. Levonorgestrel/Ethinyl Estradiol and Ferrous Bisglycinate
    w. MEDROXYPROGESTERONE
    x. Medroxyprogesterone Acetate
    y. Nomegestrol Acetate/Estradiol
    z. NONOXYNOL
    aa. Nonoxynol 9
    bb. Norethindrone
    cc. Norethindrone acetate/ethinyl estradiol and ethinyl estradiol and ferrous fumarate
    dd. Norethindrone acetate/Ethinyl estradiol and Ferrous fumarate
    ee. Norgestrel
    ff. Norgestrel/Ethinyl Estradiol and Ferrous Fumarate
    gg. Progesterone
    hh. Segesterone Acetate/Ethinyl Estradiol

Only medications listed above are allowed to be dispensed under this protocol.

Plan for follow up and review:

The authorized physicians will receive a quarterly report of the prescriptions authorized through this protocol. Attached with this report will be any statements from the pharmacist team regarding issues or concerns.

Acknowledgment

The authorizing providers listed above will not receive any financial compensation for participation in this agreement.

Signature of Involved Parties

John Sealander

Julie McDonald

Kimberly Barnes

Victoria Bumgardner

Winston Johnson

This Agreement will be effective for the period of one year starting on the date of approval from the Alaska Board of Pharmacy.

Whale Tail PHARMACY

333 Cold Storage Road
PO Box 709
Craig, AK 99921
907-826-5750

Subject: Submission of Collaborate Practice Agreement for Review

4/19/2024
State of Alaska, CBPL
Attn: MED
PO Box 110806
Juneau, AK 99811-0806

Dear Alaska State Medical Board,

On behalf of Whale Tail Pharmacy in Craig, Alaska, I am writing to submit a Collaborative Practice Agreement (CPA) for the board's review and approval. Attached, please find the CPA and its specifics outlining the relationship between pharmacists at Whale Tail Pharmacy and providers John Sealander and Kimberly Barnes of Peace Health in Craig, AK in accordance with Alaska State Board of Medicine regulations.

Our goal with this CPA is to foster a collaborative relationship that promotes interprofessional communication and improves patient care. We kindly request that the Alaska State Medical Board review the attached CPA and provide your approval if you see fit. Please do not hesitate to contact us if you need any additional information.

Thank you for your attention to this matter, and we look forward to hearing back from you.

Sincerely,

Julie McDonald

Julie McDonald, Pharm.D.

CERTIFIED MAIL

Retail

U.S. POSTAGE PAID
FCM LETTER
CRAIG, AK 99921
APR 26, 2024

$5.08

R2304Y122727-05

Whale Tail Pharmacy
P.O. 709
Craig, AK 9992

7022 1670 0002 3258 8421

99811

RDC 99

FIRST CLASS

State of Alaska, CBPL
Attn: Med
P.O. Box 110806
Juneau, AK 99811-0806

99811C0806 B900

ALASKA STATE MEDICAL BOARD CHECKLIST - PHYSICIAN-PHARMACIST COOPERATIVE PLAN

Cooperative Plan (License Record) Number: 225302

Physician Name(s): Jayson Weir, MD License No. 158691
License No. _____
License No. _____

Pharmacist Name (s): Ronald Wagoner, PharmD License No. 196394
License No. _____
License No. _____

Date Received: 4/22/2024

Written Proposed Agreement addresses the following elements:

1. Includes types of cooperative practice decisions the physician is granting to the pharmacist ☐ No ■ Yes
   Check all that apply:
   ☐ Types of diseases or conditions: List _____
   ■ Types of medications or medication categories: List Hormonal contraceptive therapies
2. Includes procedures, decision criteria or plans the pharmacist must follow when making therapeutic decisions, particularly when initiating or modifying medications. ☐ No ☐ Yes
3. Includes expectations and requirements for the pharmacist to follow with respect to documentation of decisions made, and a plan for communication and feedback to the physician regarding decisions made ☐ No ☐ Yes
4. Includes a plan for the physician to review decisions made by the pharmacist at least once every three months. ☐ No ☐ Yes
   Plan for quarterly random review of files described.
5. Includes a plan for the pharmacist to provide the physician any patient records created under the agreement. ☐ No ☐ Yes
6. Includes a provision that allows the physician to override the agreement if the physician considers it medically necessary or appropriate. ☐ No ☐ Yes
7. Includes an acknowledgement that the physician will not receive any compensation from the pharmacist or pharmacy as a result of the care or treatment of any patient under the agreement. ☐ No ☐ Yes
8. Includes a prohibition against the administration or dispensing of any schedule I, II. III or IV controlled substances. ☐ No ☐ Yes

Comments: _____

Date Application Complete/forwarded to Board Member for Review: _____ Examiner: _____

ALASKA STATE MEDICAL BOARD CHECKLIST -
PHYSICIAN-PHARMACIST COOPERATIVE PLAN

MEDICAL BOARD MEMBER REVIEW FOR APPROVAL

☐ APPROVED ☐ HOLD FOR BOARD ☐ INTERVIEW REQUIRED

Comments: _____

_____

Date Issued: _____

Signed: _____ Date _____

PHARMACY BOARD DELEGATE ENDORSEMENT

ENDORSEMENT APPROVED ◯ YES ◯ NO

Comments if "NO" to above:

_____

_____

Endorsed by: _____ Signature/Date: _____

THE STATE of ALASKA
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing

Alaska State Medical Board
PO Box 110806, Juneau, AK 99811
Phone: (907) 465-2550
Email: *MedicalBoard@Alaska.Gov*
Website: *ProfessionalLicense.Alaska.Gov/StateMedicalBoard*

Physician-Pharmacist Cooperative Practice Agreement Application

Under 12 AAC 40.983, a physician may participate in a cooperative agreement with a pharmacist by submitting this application and copy of the protocol to the State Medical Board for approval. A "cooperative practice agreement" is an agreement by which a physician authorizes a pharmacist to manage a patient's medication therapy.

The Board of Pharmacy must also endorse the approval before a physician and pharmacist can engage in the agreement. This is a joint application; there is no need to submit separate applications to each board.

PART I Application Type

Application Type:	☒ New Agreement ☐ Renewal ☐ Modification of Existing Agreement ☐ Termination of Agreement

PART II Cooperative Practice History

1. Agreement number for renewal, modification, and termination application types only:				
2. If a modification, describe what protocols have changed since the cooperative practice was initially issued or last renewed (e.g., new designation types added or removed):				
3. If a renewal, please confirm the protocols and services provided under the existing cooperative practice agreement have not changed since initially issued or last renewed, whichever is most recent. (If there have been changes, apply by modification.)				
Original Agreement Date:				
Requested Effective Dates for Agreement:*	**Start Date:**	03/31/2024	**End Date:**	03/31/2026

**May not exceed two years.*

PART III Designation Types

Protocol Type:	☐ Ropivacaine Nerve Block	☐ Travel Medication	☐ Immunizations	☐ Hypertension
	☐ Emergency Contraception	☐ Anticoagulation	☒ Other Emergency Medication	

PART IV Physician Information

Physician Name:	Jayson Weir	**License Number:**	158691
Email Address:	weirhere@gmail.com	**Phone Number:**	916-865-7373
Employer Name:	St Elias Specialty Hospital	**Physician Type:**	Internal Medicine

PART V Additional Physicians

Please list additional participating physicians involved in the cooperative practice agreement, if known. *Attach additional pages, if needed.*

Physician Name	Alaska License Number	Expiration Date

PART VI Pharmacy Information

Pharmacy Name:	Walmart Pharmacy 10-4474	**Alaska Pharmacy License Number:**	139621
Pharmacy Email Address:	rx-manager.s04474@stores.us.wal-mart.com		
Pharmacy Physical Address:	10096 Kenai Spur Hwy (Street) Kenai (City) AK (State) 99611-7807 (Zip)		

PART VII Pharmacist Information

Cooperating Pharmacist Name:	Ronald Wagoner	**License Number:**	196394
Email Address:	rx-manager.s04474@stores.us.wal-mart.com	**Phone Number:**	9073950871
Are you the Pharmacist-in-Charge?	☑ Yes ☐ No		

PART VIII Cooperative Practice Protocol Details (12 AAC 40.983)

1.	Does the protocol contain an agreement in which physicians authorized to prescribe legend drugs in this state authorize pharmacists licensed in this state to administer or dispense in accordance with that written protocol?	☑ **Yes**	☐ **No**
2.	Does the protocol contain a statement identifying the physicians authorized to prescribe and the pharmacists who are party to the agreement?	☑ **Yes**	☐ **No**
3.	Is a time period for the protocol specified? (May not exceed two years.)	☑ **Yes**	☐ **No**
4.	Does the protocol include the types of collaborative authority decisions that the pharmacists are authorized to make, including: **A.** Types of diseases, drugs, or drug categories involved and the type of collaborative authority authorized in each case? **B.** Procedures, decision criteria, or plans the pharmacists are to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved?	☑ **Yes**	☐ **No**
5.	Does the protocol include activities the pharmacists are to follow in the course of exercising collaborative authority, including documentation of decisions made, and a plan for communication and feedback to the authorizing practitioners concerning the specific decisions made?	☑ **Yes**	☐ **No**
6.	Does the protocol contain a list of the specific types of patients eligible to receive services under the written protocol?	☑ **Yes**	☐ **No**
7.	Does the protocol include a plan for the authorizing practitioners to review the decisions made by the pharmacist at least once every three months?	☑ **Yes**	☐ **No**
8.	Does the protocol include a plan for providing the authorizing physicians with each patient record created under the written protocol?	☑ **Yes**	☐ **No**
9.	Are the authorizing physicians in active practice, and is the prescriptive authority within the scope of the practitioners' practice?	☑ **Yes**	☐ **No**
10.	Does the protocol specify and require completion of additional training, if required for the procedures authorized under the protocol?	☑ **Yes**	☐ **No**

PART IX Agreement

For Physicians: By providing my signature below, I acknowledge that I will also comply with all provisions required by the State Medical Board's Cooperative Practice Agreement regulations.

For Pharmacists: By providing my signature below, I acknowledge that a signed copy of the approved collaborative practice application and protocols must remain at the pharmacy location at all times as required by 12 AAC 52.240(i).

☑ Attach a copy of your written protocol.

Cooperating Physician Signature:		**Date Signed:**	04/17/24
Cooperating Pharmacist Signature:	DocuSigned by: Ronald Wagner E0362FB24148437...	**Date Signed:**	April 6, 2024 | 1:46 PM PD

Purpose: This Collaborative Practice Agreement is the agreement between the appropriately state licensed PROVIDER whose name and signature appears below and the Qualified Pharmacist(s), as defined below in Section D. This PROVIDER hereby delegates authority to the Pharmacist(s) identified in Section D, credentials in accordance with the requirements of Section C, to screen patients and initiate, manage and modify treatment including the dispensing of clinically appropriate prescription and/or over-the-counter therapies for the purpose of contraception, as may be clinically indicated (collectively the "Services") and subject to the clinical protocols attached, referenced as Section A ("Clinical Protocols"). All Services pursuant to this Agreement shall be in compliance with all laws, regulations, rules and medication guidelines as well as Walmart's corporate policy.

Term and Termination. This Agreement shall remain in effect for all Eligible Patients of Walmart Inc. Pharmacies located within the State of Alaska for a period of two (2) years from the date of signature listed below unless otherwise terminated by either party. This Collaborative Practice Agreement may be terminated by the PROVIDER or Walmart Inc. at any time upon written notice.

Age Restrictions: Age eligibility varies by Clinical Service according to i) applicable federal and/or state law(s) and regulation(s), ii) Walmart Inc. Corporate Policy iii) FDA approved age limitations for drug therapies. Walmart Inc. corporate policy prohibits Pharmacists from providing Services under this protocol to any individual not of child-bearing potential.

Record Keeping: All records shall be kept in accordance with Walmart's records policy of a minimum of ten years.

Pharmacist/Provider Process and Schedule:

- Qualified Pharmacists shall include documentation of decisions made by utilizing the Self-Screening Risk Assessment Questionnaire (SSRAQ) and documenting in the electronic medical record. Patient consent forms, physical assessment/vitals, and prescriptions dispensed will be faxed to the patient's Primary Care Physician (PCP) or Women's Healthcare Provider (WHP) within 24 hours of completion of the encounter.
- Pharmacists will notify the Collaborating Physician of each patient encounter created under the protocol.
- Provider will perform Quarterly Quality Assurance Reviews with Walmart Quality Assurance to review pharmacists' actions under the protocol. Walmart Quality Assurance will provide the collaborating provider a peer-reviewed accounting of Qualified Pharmacists' actions under the protocol that shall include, but not limited to:
    - Number of patients assessed
    - Number of contraceptive therapies provided
    - Breakdown of which hormonal contraception therapies were selected
    - Step-by-step patient case review (minimum of 5 randomized patient cases)

Section A: Clinical Protocols

Pharmacist Hormonal Contraceptive Prescribing

Purpose:

To safely and effectively provide hormonal contraceptives to eligible patients. The protocol aims to increase access to contraception, improve patient convenience, and enhance reproductive healthcare services. We aim to empower pharmacists to play a crucial role in expanding contraceptive options and ensuring the well-being and reproductive autonomy of individuals in need of contraception.

Screening and Assessment:

When a patient requests hormonal contraception, the patient will be assessed for possibility of pregnancy and eligibility for contraceptive therapies. Patients will have blood pressure measured at the time of assessment by a qualified Pharmacist. Pharmacists will utilize the Standardized Contraceptive Treatment Care Pathway and the most current CDC Medical Eligibility Criteria for Contraceptive Use (MEC) to determine patient eligibility and product selection.

Collaborative Practice Provider's Dispensing Guidelines:

Pharmacists will collect relevant medical history using a Self-Screening Risk Assessment Questionnaire (SSRAQ). Patient eligibility will be determined by MEC values associated with answers reported on the SSRAQ and evaluation of the Standardized Contraceptive Treatment Care Pathway. Pharmacists may initiate therapy appropriate for patients as indicated by the MEC and Treatment Care Pathway.

- **Categories of Patients Disqualified from Treatment - Exclusion:**
  - Pregnancy or possibility of pregnancy
  - Patient has been told by a healthcare provider not to use hormones
  - Requesting therapy for an indication other than contraception
  - Known hypersensitivity to hormonal contraceptives
  - Patient has contraindicating condition(s) or medication(s) that result in MEC category 3 or 4

- **Collaborative Practice Provider's Instructions for Treatment:**
  - Any FDA-approved hormonal contraceptive within the following categories may be dispensed based upon patient preference and pharmacist consultation:
    - Combined Oral Contraceptive
    - Progestin-Only Oral Contraceptive
    - Transdermal Patch
    - Vaginal Ring
    - Self-administered subcutaneous depot medroxyprogesterone acetate (DMPA)
  - A pharmacist may initiate hormonal contraception to patients when:
    - Contraceptive choice falls within MEC category 1 or 2

- A pharmacist will NOT provide treatment and must refer any patient to a PCP/WHP in the following situations:
  - Patients for which pregnancy cannot be ruled out
  - Requests contraception type that may be unsafe for the patient based on a corresponding MEC category of 3 or 4
  - Requests contraception type pharmacist is not authorized to provide (e.g., IUD)

Documentation/Reporting:

- Pharmacists must document the patient responses to the SSRAQ, any details of the encounter, and any therapy provided in the pharmacy Electronic Health Record (EHR).
- Pharmacists will provide the patient with a patient visit summary including any contraceptive therapies provided for the patient to review with their PCP/WHP. Visit summary and any prescriptions issued will also be faxed to the patient's PCP/WHP, within 24 hours of the encounter's completion.
- If the patient was unable to be provided contraceptive therapy, a summary of the visit including the reason(s) treatment could not be provided will be provided to the patient for the patient to review with their PCP/WHP. Summary will also be faxed to the patient's PCP/WHP.

Required Counseling:

Pharmacists will counsel the patient over the course of the encounter regarding:

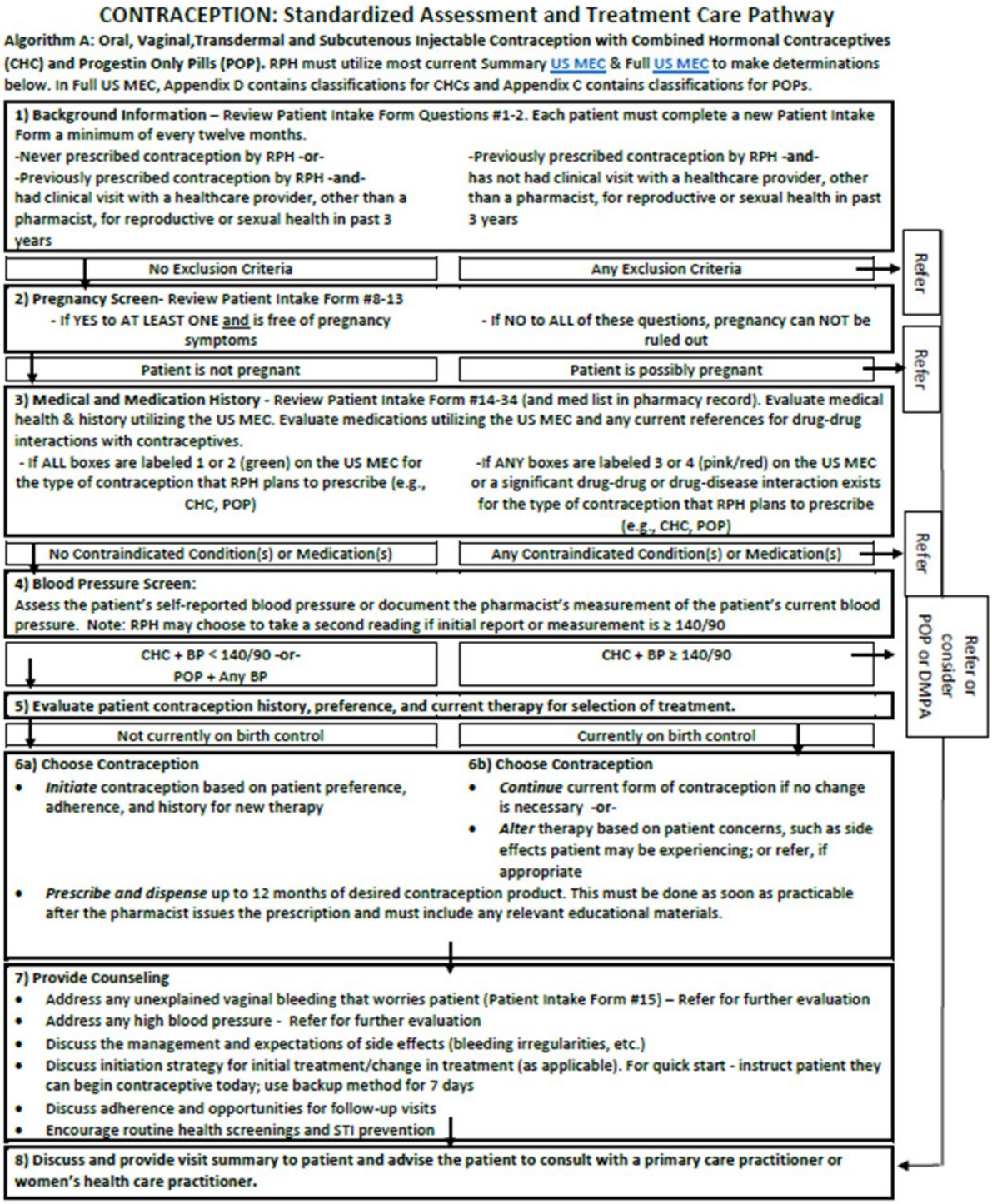
- All contraceptive dosage forms available and their proper use and effectiveness
- Importance of use of barrier methods to prevent sexually transmitted infections
- Importance of preventative care, health screenings, and well woman healthcare visit

If hormonal contraceptive was provided:

- Patients will be provided an information sheet for the type of therapy that was provided
- Pharmacists will counsel on:
  - When and how to start taking medication
  - Importance of timing of doses
  - How to manage missed doses
  - How to manage refills
- Pharmacists will counsel on common side effects in the first 3 months (e.g., headache, breast tenderness, nausea, vaginal spotting)
  - Patients will be instructed to contact pharmacist, primary care provider, or other medical provider. If symptoms have not resolved in 3 months, patient will be instructed to contact primary care provider or other medical provider.
- If an estrogen-containing product was provided: patient should be counseled on the ACHES acronym for serious side effects (e.g., abdominal pain, chest pain, severe headache, eye pain, severe leg pain)
  - Patient to contact primary care or other medical provider immediately

Section B: Standardized Assessment and Treatment Care Pathway

Pharmacists will require the patient to fill out SSRAQ and perform blood pressure assessment to determine eligibility for treatment. SSRAQ answers will be evaluated based on most current CDC MEC guidelines which will place the patient into an MEC category corresponding with their eligibility for treatment and type of therapy. Pharmacist will use the Standardized Assessment and Treatment Care Pathway listed in this section to evaluate if the patient is eligible for treatment and which treatment type the patient may be prescribed based on MEC category of assessment.



Prescription Elements:

- If a patient qualifies for a prescription, the following requirements will be followed by the pharmacist when issuing a prescription:

- Pharmacist will document the prescription using a pharmacy prescription pad
- Pharmacist will use own name and NPI as the prescriber of record, unless state regulation requires Provider to be listed as prescriber of record.
- Prescription may be written for up to a total of 12 (twelve) months, including refills
- Pharmacist must follow all state laws for elements that must appear on prescription

Section C – Pharmacist Credentialing and Training Requirements:

Pharmacists shall meet and maintain the following minimum standards to perform the Services under this Agreement.

1. Pharmacists shall maintain an active license to practice pharmacy issued by the Board of Pharmacy in the state of this Agreement.
2. Pharmacists shall successfully complete a 4-hour ACPE accredited, didactic course of education, that is specialized in the prescribing of contraceptives by a pharmacist and includes, but is not limited to:
    a. the current guidelines and recommendations of the federal Department of Health and Human Services, the American Congress of Obstetricians and Gynecologists and the Centers for Disease Control and Prevention's most recent edition of the United States Medical Eligibility Criteria (USMEC) for Contraceptive Use
    b. Is accredited by the American Council on Pharmaceutical Education;
    c. indications for use of hormonal contraceptives;
    d. assessment of risks to the patient and contraindications;
    e. emergency response to adverse events;
    f. related topics relevant to the provision of hormonal contraceptive therapy.
3. Pharmacists shall maintain in an easily retrievable location a written or electronic record of his or her completion of the course outlined above.

Pharmacists that do not meet and maintain the minimum standards listed herein will not qualify to use this Agreement and may not perform Services under this Agreement. Any pharmacist that performs Services in violation of these standards may be subject to disciplinary action up to and including termination of employment.

Section D – Pharmacists Approved to Provide Services Based on Screening under this Agreement

Upon signing below, you acknowledge that you have agreed to participate in the administration of Hormonal Contraceptive Prescribing and subsequent Services. By agreeing to participate in the provision of Hormonal Contraceptive Prescribing, you expressly acknowledge that you received and reviewed the policies and procedures that must be followed by all pharmacists conducting Hormonal Contraceptive Prescribing prior to receiving this acknowledgement. By signing below, you expressly agree to follow the policies and procedures that must be followed by all pharmacists conducting Hormonal Contraceptive Prescribing. The procedures outlined in this Agreement, along with the current program documents included on the program toolkit, must be reviewed annually by all Pharmacists and followed whenever Hormonal Contraceptive Prescribing or Services are administered to patients. To be eligible, Pharmacists must read and understand the entire Agreement and sign below. Failure to successfully complete this form prior to engaging in Hormonal Contraceptive Prescribing or Services may result in disciplinary action up to and including termination of employment.

Pharmacist Location (Club / Store # and Address):

_____

All pharmacists must sign this document below. Additional sheets may be added if necessary.

NOTE: A pharmacist choosing to administer in multiple stores listed in this Agreement must sign this section in every location in which they wish to administer.

Pharmacist (print name)	Pharmacist Signature	License Number	Date

Section E – Cooperating Physician and Pharmacist acknowledgements:

1) This Collaborative Practice Agreement may be terminated by either party. This Collaborative Practice Agreement may be terminated by the PROVIDER or Walmart Inc. at any time upon written notice to include the ability for the PROVIDER to override the agreement if medically necessary or appropriate.

2) PROVIDER will not receive any compensation from the pharmacist or pharmacy as a result of the care or treatment of any patient under the Agreement.

3) Only those treatments authorized in PROVIDER's Instructions For Treatment may be dispensed. For the avoidance of doubt, this prohibits the administration or dispensing of any schedule I, II, III, or IV controlled substances.

Cooperating Physician Signature:		**Date Signed**	04/17/24
Cooperating Pharmacist Signature:	DocuSigned by: Ronald Wagner E0362FB24148437...	**Date Signed**	April 6, 2024 | 1:46 PM PDT

12 AAC 40.983. Cooperative practice agreements with pharmacists.

(a) A physician may enter into a cooperative practice agreement with a pharmacist licensed under AS 08.80 as provided in this section. The initial agreement may not exceed two years and is subject to renewal under (j) of this section.

(b) A physician planning to enter into a cooperative practice agreement with a pharmacist must submit to the board a written proposed agreement that meets the requirements of this section. The proposed agreement must be approved by the board before cooperative practice under the agreement, if approved, begins. A proposed modification to an agreement must be submitted to the board for approval, before the modification, if approved, is implemented. The board will approve a proposed agreement or modification if it is medically appropriate and provides for the safety of the patient. If the board disapproves a proposed agreement or modification, the board shall state the reasons for its action.

(c) A cooperative practice agreement between a physician and a pharmacist must include

(1) the physician's authorization to a pharmacist or group of pharmacists to manage a patient's medication therapy;

(2) the full name, medical license number, date of issuance of license, and specialty, if any, of each physician who is a party to the agreement;

(3) the full name, place of employment, mailing address, pharmacist license number, and date of issuance of license, of each pharmacist who is a party to the agreement;

(4) a statement of the duration of the agreement, which may not exceed two years;

(5) the types of cooperative practice decisions that the physician is authorizing the pharmacist to make under the agreement, including

(A) types of diseases, medications, or medication categories involved and the type of cooperative authority to be exercised in each case; and

(B) procedures, decision criteria, or plans the pharmacist must follow when making therapeutic decisions, particularly when initiating or modifying medication;

(6) requirements that a pharmacist must follow when exercising cooperative authority, including documentation of decisions made, and a plan for communication and feedback to the physician concerning specific decisions made;

(7) a plan for the physician to review the decisions made by the pharmacist at least once every three months;

(8) a plan for providing to the physician patient records created under the agreement;

(9) a provision that allows the physician to override the agreement if the physician considers it medically necessary or appropriate;

(10) an acknowledgement that the physician will not receive any compensation from a pharmacist or pharmacy as a result of the care or treatment of any patient under the agreement;

(11) a prohibition on the administration or dispensing of any schedule I, II, III, or IV controlled substances.

(d) The physician, or a physician assistant under the supervision of the physician, must physically examine and evaluate a patient before that patient may be included under a cooperative practice agreement to which that physician is a party. The physician must issue a prescription or medication order for each patient valid for up to one year. The physician, or a physician assistant under the supervision of the physician, must conduct a physical examination of a patient at least once a year while that patient is included under a cooperative practice agreement to which that physician is a party. The requirements of this subsection do not apply to a cooperative practice agreement allowing the administration of emergency contraception, immunizations of persons 18 years of age or older, and those immunizations recommended to be given on a

yearly basis by the United States Department of Health and Human Services Centers for Disease Control and Prevention.

(e) Only a physician in active practice in this state may enter into a cooperative practice agreement under this section. An authority authorized by a physician must be within the physician's current scope of practice.

(f) A physician who enters into a cooperative practice agreement shall keep a copy of the written agreement and the records of all patients treated under it during the period of the agreement. The physician shall retain the agreement and records required by this subsection for at least seven years after the termination of the agreement.

(g) A cooperative practice agreement is terminated upon written notice by either the physician or the pharmacist. The physician shall notify the board in writing within 30 days after an agreement is terminated.

(h) The board may periodically review cooperative practice agreements approved under this section.

(i) The requirements of this section do not apply to cooperative practice agreements adopted by the physicians on medical staff of a hospital or nursing facility licensed under AS 47.32 for treatment of patients of that facility.

(j) The physician may seek renewal of a cooperative practice agreement for additional two-year periods.

(k) Notwithstanding the requirements of (b) of this section, a physician who, before June 1, 2006, has entered into a collaborative practice agreement with a pharmacist that has been approved under 12 AAC 52.240 and is still current, must obtain the board's approval of that agreement under this section not later than December 1, 2006. After that time, a physician may not participate in a cooperative practice agreement with a pharmacist except as allowed under this section.

(l) In this section, "cooperative practice agreement" means an agreement between a physician and a pharmacist by which a physician authorizes the pharmacist to manage a patient's medication therapy as specified in the agreement.

State Medical Board
Prioritized list of Action Items
Based on July 1, 2024, Board Survey Results

#1. Establish new guidelines for malpractice reviews

#2. Explore statute changes to increase board membership to decrease workload on individual members and / or advocate to allow board members to be notified of subpoenas, summary suspension or cease and desist orders by email (or telephone.)

#3. Issue position statements / practice guidance on special topics. Topics identified to date include:

a) Gender-affirming treatment for minors.
b) Insurance restrictions on physician care.

#4. Explore updating CME requirements

 # 5. Partner with the Board of Pharmacy to address opioid shortages.

#6. Explore updating regulations related to Physician-Pharmacy agreements to either eliminate or streamline the existing process

#7. Explore creating a telemedicine license apart from full medical license.

#8. Explore and adopt a definition of "physician-patient relationship" relationship

15. Applicant Review / License Approvals – Doctors of Osteopathic Medicine

	Lic Type	First Name	Last Name
1.	DO	Lien	Nguyen
2.	DO	Todd	Paxton
3.	DO	Genova	Stearns

15. Applicant Review / License Approvals – Doctors of Allopathic Medicine

	Lic Type	First Name	Last Name
1.	MD	Muna	Beeai
2.	MD	Ericka	Berger
3.	MD	Richard	Bruckner
4.	MD	Jessica	Clarke
5.	MD	Arvind	Durvasan
6.	MD	Christopher	Findley
7.	MD	Amy	Flick
8.	MD	Murray	Hamilton
9.	MD	Jeffrey	Hebert
10.	MD	Fatimah	Jah
11.	MD	Vishal	Jani
12.	MD	Peter	Kim
13.	MD	Sunil	Kurup
14.	MD	Kyle	Lapidus
15.	MD	Kerry	Latham
16.	MD	Yolanda	Lau
17.	MD	Howard	Leftin
18.	MD	Paul	Llobet
19.	MD	Michael	Mai
20.	MD	Murat	Mardirossian
21.	MD	Joseph	Martinez
22.	MD	Stephen	McElroy
23.	MD	Jennifer	McQuade
24.	MD	Daniel	Miner
25.	MD	Seema	Misra
26.	MD	Yosuke	Miyashita
27.	MD	Rushabh	Modi
28.	MD	Justin	Morgan
29.	MD	Andrea	Nelsen
30.	MD	Oleg	Odin
31.	MD	Miguel	Palos
32.	MD	Prabhjot	Pannu
33.	MD	Todd	Paxton
34.	MD	Mary	Peterson
35.	MD	Anthony	Rowe

	Lic Type	First Name	Last Name
36.	MD	Gerald	Rowland
37.	MD	David	Sanford
38.	MD	Michael	Sarkees
39.	MD	Laligam	Sekhar
40.	MD	Scott	Stoughton
41.	MD	Atilla	Uner
42.	MD	Cheryl	Villareal
43.	MD	David	Walker
44.	MD	Brad	Watkins
45.	MD	Barbara	Zimmerman
46.	MD		
47.	MD		
48.	MD		
49.	MD		
50.	MD		
51.	MD		
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65.	MD		
66.	MD		
67.	MD		
68.	MD		
69.	MD		
70.	MD		

15. Applicant Review / License Approvals – Physician Assistants

	Lic Type	First Name	Last Name
	PA	Margaret	Holbrook
	PA	Paul	Jachimek
	PA	Jeremy	Krider
	PA	Marlina	Robinson
	PA		