Legislative Committee Meeting

Virginia Board of Medicine

May 21, 2021 8:30 a.m.

AMENDED AGENDA

VIRTUAL MEETING OF THE Legislative Committee

Virginia Board of Medicine Friday, May 21, 2021, 8:30 a.m.

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| Roll Call Egress Instructions Approval of Minutes of January 15, 20211 Adoption of Agenda Public Comment on Agenda Items - 5 minutes per speaker DHP Director's Report |
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| Approval of Minutes of January 15, 20211 Adoption of Agenda Public Comment on Agenda Items - 5 minutes per speaker DHP Director's Report |
| Adoption of Agenda Public Comment on Agenda Items - 5 minutes per speaker DHP Director's Report Executive Director's Report |
| Public Comment on Agenda Items - 5 minutes per speaker DHP Director's Report Executive Director's Report |
| DHP Director's Report |
| Executive Director's Report |
| - |
| |
| New Business |
| Chart of Regulatory Actions |

Supplemental Information

Following page 102 is supplemental information provided to the members after the initial posting of this agenda.

Announcements

Next Meeting: September 3, 2021

Adjournment



| Agenda Item: | Approval of the minutes from January 15, 2021 |
|--------------|---|
| Staff Note: | Draft minutes that have been posted on Regulatory Townhall and the Board's website are presented. Review and revise if necessary. |

Action: Motion to approve minutes.

2 ---DRAFT UNAPPROVED----

VIRGINIA BOARD OF MEDICINE

LEGISLATIVE COMMITTEE MINUTES – Virtual Meeting

| Friday, January 15, 2021 | Department of Health Professions | Henrico, VA |
|--------------------------|---|---|
| Thady, bandary 10, 2021 | | , |
| CALL TO ORDER: | Mr. Marchese called the meeting of the Le Committee to order at 8:38 a.m. | gislative |
| ROLL CALL: | Ms. Opher called the roll; a quorum was es | stablished. |
| MEMBERS PRESENT: | Blanton Marchese, Vice-President, Chair Lori Conklin, MD, President James Arnold, DPM Amanda Barner, MD Joel Silverman, MD Ryan Williams, MD | |
| MEMBERS ABSENT: | Ray Tuck, DC | |
| STAFF PRESENT: | William L. Harp, MD, Executive Director Jennifer Deschenes, JD, Deputy Director f Colanthia Morton Opher, Deputy Director f Michael Sobowale, LLM, Deputy Director f Barbara Matusiak, MD, Medical Review Co Elaine Yeatts, DHP Senior Policy Analyst Erin Barrett, JD, Assistant Attorney Genera | or Administration or Licensing pordinator |
| OTHERS PRESENT: | Scott Castro - MSV Jerry Canaan, JD Ben Traynham, JD-MSV | |

EMERGENCY EGRESS INSTRUCTIONS

Mr. Marchese provided the emergency egress instructions.

APPROVAL OF MINUTES OF JANUARY 31, 2020

Dr. Conklin moved to approve the meeting minutes of January 31, 2020 as presented. The motion was seconded and carried unanimously.

ADOPTION OF AGENDA

Dr. Arnold moved to accept the agenda as presented. The motion was seconded and carried unanimously.

PUBLIC COMMENT

Scott Castro, Director of Health Policy for the Medical Society of Virginia (MSV), addressed the Committee members and voiced support for the current Code that allows the Board to deny licenses by endorsement based on regulatory or statutory grounds. Mr. Castro also stated that if Virginia were to join the ILMC, MSV urges that 1) the Board be able to reject applicants with disciplinary issues, and 2) the Board explore options as to how providers would avoid double jeopardy issues as it relates to past discipline in other states. Additionally, Mr. Castro voiced MSV's concern over the increased costs for licensure renewals under the ILMC. It is their belief that the license by endorsement pathway and license renewal process as they exist in the current Code is effective. In closing, Mr. Castro advised that MSV has reached out to the patron, Delegate Dan Helmer, stating its willingness to be a resource in regards to HJ 531.

EXECUTIVE DIRECTOR'S REPORT

Dr. Harp reminded the Committee of the expectation that Board of Medicine members are to continue serving until their successor has been named. The law governing the Board states that if a member moves from the Congressional District of appointment to another, the seat in the District of appointment becomes vacant. Dr. Walker has moved from the 9th to the 5th, so the 9th District seat is now considered vacant. He will be missed.

NEW BUSINESS

1. Chart of Regulatory Actions

Ms. Yeatts reviewed the Board's regulatory activity as of January 14, 2021. This report was for informational purposes only and did not require any action.

2. Report of the 2021 General Assembly

Ms. Yeatts reviewed the proposed legislation in the 2021 Session and highlighted those below (active links)

- HB 1737 Nurse practitioners; practice without a practice agreement.
- HB 1747 Clinical nurse specialist; licensure of nurse practitioners as specialists, etc.
- HB 1769 Health care providers, certain; licensure or certification by endorsement.
- <u>HB 1795</u> Counseling, Board of; licensure of professional counselors without examination.
- HB 1817 Certified nurse midwives; practice.
- <u>HB 1913</u> Career fatigue and wellness in certain health care providers; programs to address, civil immunity.
- HB 1953 Licensed certified midwives; definition of practice, licensure, report.
- HB 1959 Medication abandonment and increasing patient medication adherence; options for reducing rates.
- <u>HB 1987</u> Telemedicine.
- <u>HB 1988</u> Board of Pharmacy; pharmaceutical processors; processing and dispensing cannabis oil.
- <u>HB 2005</u> Disposition of the remains of a decedent; persons to make arrangements for funeral and disposition.

----DRAFT UNAPPROVED----

- <u>HB 2039</u> Practice as a physician assistant.
- HB 2044 Naturopathic doctors; license required.
- <u>HB 2061</u> Virginia Immunization Information System; health care entities; required participation.
- HB 2079 Pharmacists; initiation of treatment; certain drugs and devices.
- HB 2220 Surgical technologist; certification; use of title.
- HB 2259 Professions and occupations; licensure by Governor.
- HB 2272 Department of Health Professions; naturopathic doctors.
- HJ 531 Study; Joint Commission on Health Care.
- <u>SB 1107</u> Medical malpractice; limitation on recovery.
- SB 1178 Genetic counseling; conscience clause.
- <u>SB 1187</u> Department of Health Professions; practice of physical therapy.
- <u>SB 1189</u> Licensure of occupational therapists; Occupational Therapy Interjurisdictional Licensure Compact.
- <u>SB 1192</u> Department of Health Professions; naturopathic doctors.

After the presentation, Ms. Yeatts responded to a Committee member who asked the rationale behind the bill to allow the Governor to overrule the Board. Ms. Yeatts stated she is unable to accurately reflect the reason behind this bill.

3. Reconsideration of Interstate Medical Licensure Compact

Mr. Marchese noted that the DHP Telemedicine Workgroup that met August 5, 2019 suggested that the Board take a fresh look at the Interstate Medical Licensure Compact (Compact). Mr. Marchese provided some history about the Compact and said there are currently 29 member states plus the District of Columbia and Guam. The Compact originated in response to calls for license portability as well as some issues at the national level. The purpose of the Compact is to facilitate physicians practicing across state lines. The way the Compact is written, licensure is left up to the state. The structure of the Compact is dissimilar to the Nursing Compact which allows nurses to cross state lines to work. The Board of Medicine decided in 2016 to try a licensure by endorsement pathway instead of joining the Compact at that time. There are some components of the Compact that are in conflict with the Code of Virginia, including reporting complaints to the Compact before they have been thoroughly investigated.

Dr. Harp pointed the Committee to page 34 of the agenda packet and stated that the average number of licenses obtained per applicant for 2018 and 2019 was 3%, but in 2020 it dropped to 1.6%. Given the pandemic and the wish to practice telemedicine across state lines, one would think that the average number of licenses per physician would have increased in 2020. He stated that the Compact was designed for the cream of the crop – many years of practice, no disciplinary history, board certified, etc. He noted that the licensure by endorsement pathway has similar requirements and has done what the Board expected it to do, to provide an expeditious pathway and save money for applicants applying to Virginia.

Additionally, Dr. Harp referred to HJ 531 that asks the Joint Commission on Health Care to study the advantages and disadvantages of Virginia participating in the Compact.

Dr. Conklin said that she would support sending a recommendation to the Full Board to again vote "no" on Virginia joining the Compact, since the Board already has a pathway that is expeditious, more economically feasible, and maintains Board oversight.

Dr. Harp asked Ms. Yeatts if, in light of the study to be conducted by the Joint Commission on Health Care this year, would it be necessary to send a letter to the Commission stating that the Board will cooperate and provide information as needed.

Ms. Yeatts advised that she can see both sides of this issue. Communicating to the Commission in 2021, that the Board again affirms its position might be beneficial to the work of the Commission. She also mentioned that there are members of the General Assembly who think that the Board is acting for its own self-preservation by not affirming the Compact.

After discussion about what could serve as a rationale for its decision, Dr. Harp advised that he would draft a document to include history and statistics for review by counsel, appropriate Board members, and staff for presentation to the Full Board.

4. Continuing Education on Human Trafficking.

Dr. Conklin advised that, in order to renew her Texas license, she was required to complete 1 hour of continuing education in human trafficking. She said that human trafficking encompasses not only the sex trade but other occupational endeavors as well. People who come across the border are at higher risk for being exploited. She stated that prior to this training, as a physician who interviews patients prior to surgery, she would not have known how to recognize a victim of human trafficking. She then noted that, according to the Institute for Human Trafficking in Fairfax, over 25 million Americans are victims of human trafficking. Virginia ranks 6th in the nation in open cases of trafficking. More incredibly, she said that the human trade business makes more profit each year than Apple, Microsoft, Samsung and Exxon combined.

Dr. Conklin said if the Board is unable to make this training a requirement, can the Board make this information available to the licensees by posting the course information on the website? She added that it would be preferable to require an hour every biennium, but even a one-time requirement would suffice since it is a well-known problem in the Commonwealth.

After discussion, the Committee agreed that it would be acceptable to add it as a one-time requirement, understanding that it would require an action by the General Assembly with an amendment to the regulations.

Ms. Yeatts advised that this Board does not have the authority in the Code to set an annual requirement for continuing education. She agreed that this is a worthy endeavor, but thinks the best alternative is to add educational resources to the Board Briefs and the Board's webpage. Dr. Harp agreed that placing these in the Board Briefs and on the website with a link to the appropriate courses is the best avenue to take.

Ms. Deschenes stated the Board was asked to mandate continuing education (CE) on this topic previously, and it respectfully declined. Many organizations, agencies and entities have important information to disseminate and occasionally ask the Board to create a CE requirement for Board licensees. Mandatory CE on multiple topics can overwhelm licensees. The Board's stance on continuing education has been that licensees know best which CE will

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benefit them in their practice, thereby ensuring that their practice will be safer for the citizens of the Commonwealth. She also agreed that the Board Briefs, which are going directly to practitioners' mailboxes, will make it easier them to access the educational resources.

Mr. Marchese confirmed the consensus of the members that placing an article in the Board Briefs is the action to take with the hope that it gains some attention and that practitioners will take the initiative to read it.

ANNOUNCEMENTS

No Announcements.

NEXT MEETING

May 21, 2021

ADJOURNEMENT

With no other business to conduct, the meeting adjourned at 9:56 a.m.

Blanton Marchese Vice-President, Chair William L. Harp, MD Executive Director

Colanthia Morton Opher Recording Secretary Agenda Item: Regulatory Actions in Progress

Staff Note: Ms. Yeatts will cover the current regulatory activity for the Board of Medicine and the Joint Boards.

Action: None

Regulatory Actions in Process

Board of Medicine

| Board | Board of Medicine | |
|-------------------|---|---|
| Chapter | | Action / Stage Information |
| [18 VAC 85 - 20] | Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic | Conversion therapy [Action 5412] Proposed - Register Date: 2/15/21 Comment period ended: 4/16/21 No comment was received Board to adopt final regulations in June |
| [18 VAC 85 - 21] | Regulations Governing Prescribing of Opioids and Buprenorphine | Waiver for e-prescribing of an opioid [Action 5355] Final - Register Date: 5/10/21 Effective: 6/9/21 |
| [18 VAC 85 - 160] | Regulations Governing the Licensure of Surgical Assistants and Registration of Surgical Technologists | Amendments for surgical assistants consistent with a licensed profession [Action 5639] NOIRA - Register Date: 3/1/21 Comment period ended: 3/31/21 No comment was received Board to adopt proposed regulations in June |
| Board | Boards of Medicine & Nursing | |
| 18 VAC 90 - 30] | Regulations Governing the Licensure of Nurse Practitioners | Unprofessional conduct/conversion therapy [Action 5441] Proposed - Register Date: 2/15/21 Comment period ended: 4/17/21 No comment was received Nursing to adopt final regs in May Medicine to adopt final regs in June |
| [18 VAC 90 - 40] | Regulations for Prescriptive Authority for Nurse Practitioners | Waiver for electronic prescribing [Action5413]Proposed - Register Date: 5/10/21Comment period ends: 7/9/21Medicine to adopt final regs in AugustNursing to adopt final regs in September |

Agenda Item: Regulatory/Policy Actions from the 2021 General Assembly

Staff Note: Ms. Yeatts will cover the actions necessary for the Board of Medicine to take subsequent to legislation from the General Assembly.

Action: None at this time.

10 Department of Health Professions Regulatory/Policy Actions – 2021 General Assembly Board on Medicine

EMERGENCY REGULATIONS:

| Legislative source | Mandate | Promulgating agency | Board adoption date | Effective date Within 280 days of enactment |
|--------------------|---------------------------------|---------------------|---------------------|---|
| SB1189 | Occupational therapy compact | Medicine | 8/6/21 | By 12/23/21 |

EXEMPT REGULATORY ACTIONS

| Legislative | Mandate | Promulgating | Adoption | Effective date |
|-------------------|---|-----------------------|---------------------------|----------------|
| source | | agency | date | |
| HB1737 | Revise autonomous practice reg consistent with 2 years | Nursing & Medicine | N - 7/20/21 M - 8/6/21 | |
| HB1747 | Licensure of CNS as nurse practitioners – Amend Chapters 30 and 40 Delete sections of Chapter 20 with reference to registration of CNS | Nursing & Medicine | N – 7/20/21 M – 8/6/21 | |
| HB1817 | Autonomous practice for CNMs with 1,000 hours | Nursing & Medicine | N - 7/20/21 M - 8/6/21 | |
| HB1988 | Changes to pharmaceutical processors | Pharmacy | 7/6/21 | By Sept. 1st |
| HB2218/SB133 3 | Sale of cannabis botanical products | Pharmacy | 7/6/21 | By Sept. 1st |
| HB2039 | Conform PA regs to Code | Medicine | 10/14/21 | |
| HB2220 | Change registration of surgical technologists to certification | Medicine | 10/14/21 | |
| SB1178 | Delete reference to conscience clause in regs for genetic counselors | Medicine | 10/14/21 | |

APA REGULATORY ACTIONS

| Legislative | Mandate | Promulgating | Adoption date | Effective date |
|-------------|------------------------|--------------|-------------------|----------------|
| source | | agency | | |
| HB1953 | Licensure of certified | Nursing & | NOIRA | Unknown |
| | midwives | Medicine | Nursing – 7/20/21 | |
| | | | Medicine - 8/6/21 | <i>N</i> |

NON-REGULATORY ACTIONS

| Legislative | Affected | Action needed | Due date |
|--------------|--------------------|---|-------------------------|
| source | agency | | |
| HB1747 | Nursing | Notification to registered certified nurse specialists that they must have a practice agreement with a physician before licensure as a nurse practitioner as of July 1, 2021 | After March 31, 2021 |
| HB793 (2018) | Medicine & Nursing | To report data on the number of nurse practitioners who have been authorized to practice without a practice agreement, the | November 1, 2021 |

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| federal Clinical Laboratory Improvement |
| Amendments of 1988, including influenza |
| virus, urinary tract infection, and group A |
| Streptococcus bacteria, and (ii) drugs |
| approved by the U.S. Food and Drug |
| Administration for tobacco cessation |
| therapy, including nicotine replacement |
| therapy. The work group shall focus its |
| work on developing protocols that can |
| improve access to these treatments while |
| maintaining patient safety. |

Future Policy Actions:

HB2559 (2019) - requires the Secretary of Health and Human Resources to convene a work group to identify successes and challenges of the electronic prescription requirement and offer possible recommendations for increasing the electronic prescribing of controlled substances that contain an opioid and to report to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2022.

Agenda Item: Request from Virginia Society of Eye Physicians and Surgeons & Virginia Ambulatory Surgery Association

Staff Note: In the following pages, you will find email communications from representatives of VSEPS and VASA requesting the Board to be involved in the setting of a single standard of care for eye surgeries that occur in ambulatory surgery centers and physicians' offices. Public comment is anticipated.

Action: Recommend that the Board establish an ad hoc committee to study this issue, or not.

Colanthia Opher

| From: Sent: | Harp, William <william.harp@dhp.virginia.gov> on behalf of Harp, William Monday, May 3, 2021 8:51 AM</william.harp@dhp.virginia.gov> |
|----------------|--|
| To: | Colanthia D. Morton |
| Subject: | Fwd: |
| Attachments: | VASA VSEPS letter to Dr. Harp final.docx |

Hi Co-Co:

For the Legislative Committee:

----- Forwarded message ------From: Addison, Karin <<u>Karin.Addison@troutman.com</u>> Date: Fri, Apr 30, 2021 at 4:25 PM Subject: RE: To: Harp, William <<u>william.harp@dhp.virginia.gov</u>>, Cal Whitehead <<u>cal@commonwealthstrategy.net</u>>, Mark Hickman <<u>mark@commonwealthstrategy.net</u>>, Yeatts, Elaine <<u>elaine.yeatts@dhp.virginia.gov</u>> Cc: Clark Barrineau <<u>cbarrineau@msy.org</u>>

Good afternoon Dr. Harp,

Thank you for your time discussing this issue with us. Attached is a joint letter from the Virginia Ambulatory Surgery Association and the Virginia Society of Eye Physicians and Surgeons asking the Board of Medicine to convene a workgroup to discuss current standard of care, review existing patient safety requirements for outpatient and office-based procedures, and identify any deficiencies in patient protections.

Please let me know if you have any questions and we look forward to working together on this!

Karin

Karin T. Addison

Director - State Affairs

Direct: 804.697.2236 | Mobile: 804.306.7421 karin.addison@troutman.com

troutman pepper strategies 1001 Haxall Point, PO Box 1122 Virginia Ambulatory Surgery Association



April 30, 2021

Dear Dr. Harp:

According to the Ambulatory Surgery Center Association, more than half of all surgeries performed in the United States are done in an outpatient setting. In recognition of the growing trend toward lowering the cost of health care as well as ongoing concerns about COVID infections acquired in the hospital setting, it is reasonable to expect even more procedures in the future will be performed in Ambulatory Surgical Centers (ASCs) or the physician office-based environment.

As you well know, the practice of medicine and surgery is governed by rigorous patient safety criteria at both the state and federal levels. Surgeons are also influenced by professional ethical standards, accreditation requirements, payor policy, and even legal pressures. The purpose of these and additional factors is to promote safe and effective outcomes for Virginians. However, as medical science and technology advance, the laws and regulations may not consistently apply to surgical care provided in different settings. Professionals and facilities have different combinations and layers of rules.

Our organizations have begun a dialogue about these issues with the common interest in patient safety. We agree that Virginians deserve the proper standard of care and expectations wherever they receive surgical care. Patient safety must not be compromised by changing the location of the surgery.

We believe it is appropriate and timely to have a discussion between regulators and the regulated community about the growth of outpatient/ambulatory care and the settings in which the care is provided. Using an example familiar to us, cataract surgery has been one of the top two most common codes performed at ASCs on Medicare beneficiaries since at least 2008. There is a growing shift of this and other procedures from hospitals and ASC's to office procedure rooms. The Board of Medicine has a role to ensure patient safety standards reflect a Virginia standard of care by licensed physicians regardless of the location of care, in the same way the Board reviewed and provided guidance and regulation of office-based anesthesia.

The following areas deserve discussion:

- Infection control
- Life Safety and emergency management
- Nursing and anesthesia standards and personnel
- Power backup

We respectfully petition the Board of Medicine to discuss current standard of care, review existing patient safety requirements for outpatient and office-based procedures, and identify any deficiencies in patient protections. We urge you to convene an ad-hoc work group of interested specialty societies, other relevant stakeholders, and the Medical Society of Virginia. Thank you for your consideration and we look forward to assisting the Board in reviewing ambulatory surgery safety standards in Virginia.

Sincerely,

Meth C

Michael Keverline MD President Virginia Society of Eye Physicians & Surgeons

Frank Cotter Frank Cotter MD Chairman Virginia Ambulatory Surgery Association Subcommittee on Office Based Surgery

Cc: Medical Society of Virginia

From: Harp, William <<u>william.harp@dhp.virginia.gov</u>> Sent: Thursday, March 25, 2021 4:10 PM To: Addison, Karin <<u>Karin.Addison@troutman.com</u>>; Cal Whitehead <<u>cal@commonwealthstrategy.net</u>>; Mark Hickman <<u>mark@commonwealthstrategy.net</u>>; Yeatts, Elaine <<u>elaine.yeatts@dhp.virginia.gov</u>> Subject:

EXTERNAL SENDER

Dear All:

I hope everyone is doing well.

Subsequent to our conversation several weeks ago, I communicated with Elaine Yeatts and Lori Conklin, MD, current President of the Board. We noted that the 2003 Office-Based Anesthesia regulations addressed many of the issues that put patients at risk when undergoing procedures outside hospitals and ambulatory surgery centers. The regulations establish standards for all practitioners providing and/or supervising anesthesia in their offices. In a broad sense, the regulations are helpful in defining the standard of care for anesthesia in the office setting. At the Board of Medicine, we believe that a single standard of care exists for surgery as well, indeed for all patient care.

The reason that I say the anesthesia regulations help "in a broad sense" is that the Board of Medicine is authorized to determine the standard of care in any case that comes before it. Based on the facts in each case, the Board determines how the law and regulations are to be applied in a fair and equitable way, using the principles of evidence-based medicine.

During our conversation several weeks ago, we noted that there are countless procedures done in office settings and that regulations or a guidance document for office-based surgery would most likely be a statement of general surgical/operative/procedural safety principles. Such principles are taken into account now during the probable cause review of any complaint/investigation at the Board. If the expertise to do a thorough standard of care review does not exist on Board staff or the Board itself, an outside expert medical reviewer can be engaged to review the evidence in the case and offer opinion on whether the expected standard was met or not, and how much deviation from the standard occurred.

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The Board hopes that any differences between your two organizations can be resolved through negotiations. For the Board to become involved, there would need to be a request for regulations or a guidance document to address office-based surgery. All this said, the Board stands ready to address a request for rule-making or guidance on this issue.

I hope this is helpful to you.

With kindest regards,

William L. Harp, MD

Executive Director

Virginia Board of Medicine

On Thu, Mar 25, 2021 at 10:33 AM Addison, Karin < Karin.Addison@troutman.com > wrote:

Hi Dr. Harp, we are preparing our follow up information and formal letter. Are there any updates from your end? Please feel free to call me at (804) 306-7421.

Thanks!

Karin

Karin T. Addison

Director - State Affairs

Direct: <u>804.697.2236</u> | Mobile: <u>804.306.7421</u> <u>karin.addison@troutman.com</u>

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Agenda Item: Request for a guidance document on benzodiazepines

Staff Note: In the following pages, you will find email communications with Abbot Granoff, MD, an article written by Dr. Granoff, and articles from the National Institute on Drug Abuse and the National Institutes of Health. Public comment is anticipated.

Action: To recommend to the Board that it pursue the development of a guidance document on benzodiazepines, or not.

Colanthia Opher

| From: | abbot <agranoff@cox.net> on behalf of abbot</agranoff@cox.net> |
|--------------|--|
| Sent: | Tuesday, May 11, 2021 8:19 AM |
| То: | Harp, William |
| Cc: | Colanthia D. Morton |
| Subject: | Re: 9:40 AM Email |
| Flag Status: | Flagged |

Dr Harp How do I log in? I can't imagine 5 minutes to be enough time to present my issue and answer any questions he Board may have.

Abbot Granoff, MD agranoff@cox.net

On May 11, 2021, at 7:50 AM, Harp, William <<u>william.harp@dhp.virginia.gov</u>> wrote:

Dear Dr. Granoff:

Thank you for your message.

The Legislative Committee will meet virtually at 8:30 AM on Friday, May 21st. The Board will include the email string and your article in its agenda packet.

Public comment will be received at the top of the meeting. There are a number of other issues that the Committee will be discussing that day. It is customary to allow each person that wishes to offer public comment to speak for 5 minutes. You will be afforded that opportunity.

I hope this is helpful to you.

With kindest regards,

William L. Harp, MD Executive Director Virginia Board of Medicine

On Sat, May 8, 2021 at 4:05 PM abbot <<u>agranoff@cox.net</u>> wrote: Dr Harp:

It appears to me that you are putting obstacles in my path to try to get this information to the Board. You asked for supporting data. Then told me it is too much and can't be used because of copyright infringement.

The main points that I want the Board to deal with are:

I have found refusal of many Virginia practitioners to prescribe the benzodiazepines because of false and misleading information. The bottom line to the Board for my request is this. I would appreciate the Board making a statement that there are many myths and misconceptions regarding the bezodiazepines.

1. They are not addictive.

2. They can cause physiological dependence as do many other medications including antidepressants, antihypertensives, anticonvulsants.

3. They do not cause dementia.

4. Withdrawal from them is usually mild lasting no longer than 2-3 weeks. Seizures from withdrawal are rare.

5. They are very safe and effective for anxiety disorders especially panic disorder.

6. They are abused by 0.5% of people usually in association to street drugs and alcohol.

7. They can be used long term when appropriate.

8. They are being underutilized.

9. The Board has no rules against their use when properly prescribed.

You can use the DSM-5 pages 48-484, 550-556. the "APA Task Force Report on Benzodiazepines," or use my article with 45 citations "Benzodiazepines as a First Line Treatment for Anxiety Disorders" which summarizes them all. A copy is attached.

I would like to address the Board. Please let me know the time, date and place. How much time ould I get to do this?

Sincerely,

Abbot Granoff, MD

On May 7, 2021, at 4:56 PM, Harp, William <<u>william.harp@dhp.virginia.gov</u>> wrote:

Dear Dr. Granoff:

Your email had 4 attachments.

The first is the cover of an issue of "Advances in Psychiatric Treatment"

The second is a GIF that cannot be opened.

The third and fourth are copies of the preceding email string, which will be copied and placed in the agenda packet.

I ask if you have received permission to copy and distribute the first and second attachments. If you have not, the Board of Medicine cannot publish those in an agenda packet. And even if you have, the Board, in an abundance of caution

about protecting the intellectual property of others, would have to get permission to use copies in its meeting packets. And that is not the role of the Board.

You may wish to summarize whatever is in the GIF during your public comment time.

I hope this is helpful to you.

Kindest regards, WLH

Colanthia Opher

From:Harp, William <william.harp@dhp.virginia.gov> on behalf of Harp, WilliamSent:Tuesday, May 11, 2021 7:51 AMTo:Colanthia D. MortonSubject:Fwd: 9:40 AM EmailAttachments:Benzo Article complete pdf.pdf

In case I did not send this previously.

This has his article attached.

----- Forwarded message ------From: **abbot** <<u>agranoff@cox.net</u>> Date: Sat, May 8, 2021 at 4:05 PM Subject: Re: 9:40 AM Email To: Harp, William <<u>william.harp@dhp.virginia.gov</u>>

Dr Harp:

It appears to me that you are putting obstacles in my path to try to get this information to the Board. You asked for supporting data. Then told me it is too much and can't be used because of copyright infringement.

The main points that I want the Board to deal with are:

I have found refusal of many Virginia practitioners to prescribe the benzodiazepines because of false and misleading information. The bottom line to the Board for my request is this. I would appreciate the Board making a statement that there are many myths and misconceptions regarding the bezodiazepines.

1. They are not addictive.

2. They can cause physiological dependence as do many other medications including antidepressants,

antihypertensives, anticonvulsants.

3. They do not cause dementia.

4. Withdrawal from them is usually mild lasting no longer than 2-3 weeks. Seizures from withdrawal are rare. 5. They are very safe and effective for anxiety disorders especially panic disorder.

6. They are abused by 0.5% of people usually in association to street drugs and alcohol.

7. They can be used long term when appropriate.

8. They are being underutilized.

9. The Board has no rules against their use when properly prescribed.

You can use the DSM-5 pages 48-484, 550-556. the "APA Task Force Report on Benzodiazepines," or use my article with 45 citations "Benzodiazepines as a First Line Treatment for Anxiety Disorders" which summarizes them all. A copy is attached.

I would like to address the Board. Please let me know the time, date and place. How much time ould I get to do this?

Sincerely,

On May 7, 2021, at 4:56 PM, Harp, William <<u>william.harp@dhp.virginia.gov</u>> wrote:

Dear Dr. Granoff:

Your email had 4 attachments.

The first is the cover of an issue of "Advances in Psychiatric Treatment"

The second is a GIF that cannot be opened.

The third and fourth are copies of the preceding email string, which will be copied and placed in the agenda packet.

I ask if you have received permission to copy and distribute the first and second attachments. If you have not, the Board of Medicine cannot publish those in an agenda packet. And even if you have, the Board, in an abundance of caution about protecting the intellectual property of others, would have to get permission to use copies in its meeting packets. And that is not the role of the Board.

You may wish to summarize whatever is in the GIF during your public comment time.

I hope this is helpful to you.

Kindest regards, WLH

April 20. 2020

Dear Dr. Harp:

Thank you for your reply to my concerns regarding the prescribing of benzodiazepines by physicians licensed in Virginia.

However there are a number of areas that are vague and might lead to confusion, concern and fear to prescribe them. I would appreciate your clarification of these issues.

Dear Dr. Granoff:

Thank you for your message.

You indicate that you and patients that contact your office have had difficulty in finding practitioners that will prescribe benzodiazepines. You ask for the Board's policies on the prescribing of benzodiazepines.

The prescribers licensed by the Board of Medicine, including doctors of medicine, osteopathic medicine and podiatry, physician assistants and nurse practitioners are authorized by their Virginia license to prescribe Schedule VI drugs. To prescribe Schedule II through V drugs, a practitioner must be currently registered with the Drug Enforcement Administration (DEA). Benzodiazepines are Schedule IV, so to prescribe them requires current registration with the DEA.

The Board of Medicine has no laws that specifically speak to benzodiazepines.

In the Board of Medicine Regulations "Governing Prescribing of Opioids and Buprenorphine", benzodiazepines are mentioned in the following subsections - 18VAC85-21-40(C) Treatment of Acute Pain with Opioids and 18VAC85-21-70(D) Treatment of Chronic Pain with Opioids. Here is the text of these subsections.

C. Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol (an atypical opioid), the prescriber shall only coprescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

From my research there are no definitive articles that conclusively show that there is "a higher risk of fatal overdose when opioids are prescribed with benzodiazepines." It appears that this is theoretical since both substances can produce respiratory depression with benzodiazepines at the low end of the scale and Fentanyl at the high end.

I have spoken to the CDC section that puts out these statistics. They use death certificates only. These come from physicians and others of varying backgrounds and training. This can skew their conclusions to a negative slant toward the benzodiazepines. They don't look at blood to see all substance ingested nor blood levels of them at OD. Some patients in drug programs who are prescribed Suboxone or Methadone also get opiates on the street which often contain Fentanyl. They know when not to use them because of an upcoming "random" blood check. Sometimes they are caught but can cheat the system.

For example I am attaching an article from the NIH. It is a bit misleading since it doesn't detail the amount of benzo in a patient's blood at OD or the prescribed amount per day. Other NIH and CDC articles combine benzos, sedatives and hypnotics and assume their use at OD. They even add the information if the person <u>filled</u> an RX within 30 days of OD, again not taking a blood level or listing the prescribed dosage.

Look at the chart, which was produced by the CDC, at the bottom of the article from NIH. The graph shows the total opioid deaths, the opioid deaths without benzodiazepines and the opioid deaths with benzodiazepines. The amount of total opioid deaths above the deaths without benzodiazepines and deaths with benzodiazepines appear to be similar amounts. They don't list other medications or abused street drugs or alcohol. This begs the question. Are benzos in combination with opioids really responsible for the deaths? Are there other factors or chemicals involved?

I have treated patients on Suboxone prescribed by drug clinics with benzodiazepines, some at relatively high levels without any problems with respiratory depression. Some have been on them for years having them prescribed prior to my accepting them as patients. I have recently stopped accepting new patients on Suboxone or Methadone because I find some of them unreliable and I don't find it worth the risk to them or me, especially with the new proposed Board/PMP guidelines.

I believe more studies with reliable information including blood levels of all medications and street drugs including alcohol at OD necessary to discern the adverse effect of benzodiazepines in combination with opioids. Assigning the blame of OD on benzodiazepines is similar to the common myths and misconceptions of adverse effects of the benzodiazepines. See my attached article, "Benzodiazepines as a Fist Line Treatment for Anxiety Disorders."

The other concern in the C paragraph is the statement to *"document in the medical records a tapering plan..."*. Is this for tapering the opioid or the benzo? Patients with Panic Disorder and Generalized Anxiety Disorder usually require their medication for a lifetime. Requiring tapering by the Board of the benzo is an inappropriate requirement by the Board which will scare the physician from prescribing them in the first place.



Home » Drugs of Abuse » Opioids » Benzodiazepines and Opioids

Revised March 2018

More than 30 percent of overdoses involving opioids also involve benzodiazepines, a type of prescription sedative commonly prescribed for anxiety or to help with insomnia. Benzodiazepines (sometimes called "benzos") work to calm or sedate a person, by raising the level of the inhibitory neurotransmitter GABA in the brain. Common benzodiazepines include diazepam (Valium), alprazolam (Xanax), and clonazepam (Klonopin), among others.

Every day, more than 115 Americans die after overdosing on opioids.¹ However, between 1996 and 2013, the number of adults who filled a benzodiazepine prescription increased by 67%, from 8.1 million to 13.5

million.² The quantity obtained also increased from 1.1 kg to 3.6 kg lorazepam-equivalents per 100,000 adults. Combining opioids and benzodiazepines can be unsafe because both types of drug sedate users and suppress breathing—the cause of overdose fatality—in addition to impairing cognitive functions. In 2015, 23 percent of people who died of an opioid

overdose also tested positive for benzodiazepines (see graph).³ Unfortunately, many people are prescribed both drugs simultaneously. In a study of over 300,000 continuously insured patients receiving opioid prescriptions between 2001 and 2013, the percentage of persons also prescribed benzodiazepines rose to 17 percent in 2013 from nine percent in

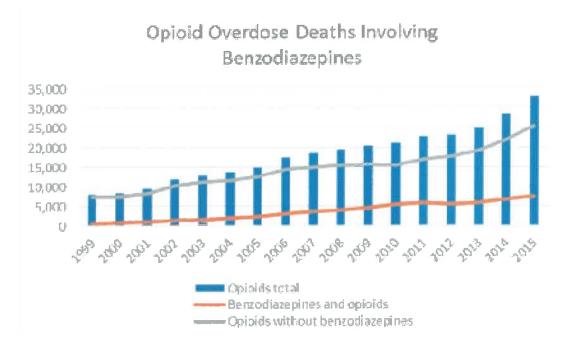
2001.⁴ The study showed that people concurrently using both drugs are at higher risk of visiting the emergency department or being admitted to a hospital for a drug- related emergency.

Previous studies have also highlighted the dangers of co-prescribing opioids and benzodiazepines. A cohort study in North Carolina found that the overdose death rate among patients receiving both types of medications was 10 times higher than among those only receiving opioids.⁵ In a study of overdose deaths in people prescribed opioids for noncancer pain in

Canada, 60 percent also tested positive for benzodiazepines.⁶ A study among U.S. veterans with an opioid prescription found that receiving a

benzodiazepine prescription was associated with increased risk of drug overdose death in a dose-response fashion. 7

In 2016, the Centers for Disease Control and Prevention (CDC) issued new guidelines for the prescribing of opioids.⁸ They recommend that clinicians avoid prescribing benzodiazepines concurrently with opioids whenever possible. Both prescription opioids and benzodiazepines now carry FDA "black box" warnings on the label highlighting the dangers of using these drugs together. People being prescribed any medications should inform their doctors about all of the other drugs and medications they use, and patients should consult with their doctors about the potential dangers of using various medications and substances together, including the use of alcohol.



Source: Centers for Disease Control and Prevention (CDC). Multiple Cause of Death, 1999-2015.

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This page was last updated March 2018

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D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol (an atypical opioid), the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medications if prescribed.

The Board has no guidance document on benzodiazepines.

This is not accurate as per Board C and D paragraphs above and the PMP regulations below. The Board is requiring a tapering dose of benzodiazepines. The Board needs a guidance document for the use of benzodiazepines. This can be the APA PRACTICE GUIDELINE FOR THE TREATMENT OF PATIENTS WITH PANIC DISORDER or the DSM-V section on Substance Use Disorders; Sedative, Hypnotic, or Anxiolytic Use Disorder. DSM-V. 2013, P:481-484,550-556. I find this section of the DSM-V very enlightening.

The Virginia Prescription Monitoring Program receives dispensing reports from pharmacies on all "covered substances." At this time, covered substances include Schedules II, III and IV; those in Schedule V for which a prescription is required; naloxone, all drugs of concern, and cannabidiol oil or THC-A oil dispensed by a pharmaceutical processor in Virginia

Effective July 1, 2022, the following check of the PMP for benzodiazepines will be required by Section 54.1-2522.1 of the Code of Virginia. Here is the relevant text.

"B. Prescribers registered with the Prescription Monitoring Program shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of benzodiazepine or an opiate anticipated at the onset of treatment to last more than 90 consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient.

Why are benzodiazepines being lumped with opiates here? According to the DSM-V only 0.5% of people taking benzodiazepines abuse them. All patients taking a benzodiazepine are being

lumped with those taking an opiate in combination. This requirement puts fear into the prescriber who will be hesitant or refuse to prescribe them.

What about patients taking a benzo, sedative or hypnotic that aren't taking an opiate?

The Director of the Department of Health Professions, who has responsibility for the Prescription Monitoring Program, was granted the following authority by the General Assembly in 2016.

54.1-2523.1. Criteria for indicators of misuse; Director's authority to disclose information; intervention.

A. The Director shall develop, in consultation with an advisory panel which shall include representatives of the Boards of Medicine and Pharmacy, the Department of Health, the Department of Medical Assistance Services, and the Department of Behavioral Health and Developmental Services, criteria for indicators of unusual patterns of prescribing or dispensing of covered substances by prescribers or dispensers and misuse of covered substances by recipients and a method for analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse to identify unusual patterns of prescribing or dispensing of covered substances by individual prescribers or dispensers or potential misuse of a covered substance by a recipient. The Director, in consultation with the panel, shall annually review controlled substance prescribing and dispensing patterns and shall (i) make any necessary changes to the criteria for unusual patterns of prescribing and dispensing required by this subsection and (ii) report any findings and recommendations for best practices to the Joint Commission on Health Care by November 1 of each year.

B. In cases in which analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse indicates an unusual pattern of prescribing or dispensing of a covered substance by an individual prescriber or dispenser or potential misuse of a covered substance by a recipient, the Director may, in addition to the discretionary disclosure of information pursuant to § 54.1-2523:

1. Disclose information about the unusual prescribing or dispensing of a covered substance by an individual prescriber or dispenser to the Enforcement Division of the Department of Health Professions; or

2. Disclose information about the specific recipient to (i) the prescriber or prescribers who have prescribed a covered substance to the recipient for the purpose of intervention to prevent misuse of such covered substance or (ii) an agent who has completed the Virginia State Police Drug Diversion School designated by the Superintendent of State Police or designated by the chief law-enforcement officer of any county, city, or town or campus police department for the purpose of an investigation into possible drug diversion.

The Board of Medicine expects its licensees to meet the standard of care in all specialties of medicine with all diagnoses and treatments. The Board has the authority to decide whether the standard of care was met in any case that comes before it, depending on the facts in the case and an evidence-based assessment of the practitioner's decision-making and skill. As you can

see from the above, the Board does not have a monolithic statement about benzodiazepines. Each case that alleges problematic prescribing of benzodiazepines will be reviewed for whether the care met, exceeded, or fell below the standard expected.

I hope this message helps to clarify the Board's policies for you.

With kindest regards,

William L. Harp, MD Executive Director Virginia Board of Medicine

The last several paragraphs of your letter regarding the Virginia Prescription Monitoring Program are so negatively vague that I believe this has and will scare all physicians from prescribing benzodiazepines.

The Board does not describe the standards of care in which benzodiazepines can be properly prescribed without getting into trouble with the Board. This is probably why I found it very difficult to get a benzodiazepine prescribed to me and for patients that call my office with the same complaint.

I am attaching a copy of my article "Benzodiazepines as a First Line Treatment for Anxiety Disorders." In it I cite the NIH, DEA, and APA. They all say that benzodiazepines are **not** addictive and no tolerance is built to them causing the dose to be continually increased. Patients can become dependent on them. Patients become dependent on any medication for any chronic medical illness. Panic Disorder, Generalized Anxiety Disorder and OCD are chronic medical illnesses. The Board is making it difficult for patients suffering from these illnesses from getting proper treatment. Benzodiazepines are safer and better tolerated than the antidepressants and have fewer side effects.

I'm also snail mailing you a copy of my book, "Panic Attacks and Phobias - A Consumer's Guide" and a copy of my DVD "Panic Attacks and Phobias Conquered - Patients Share Their Victories." There are very few and poorly designed studies comparing the benzodiazepines to antidepressants in the treatment of the Anxiety Disorders. These are lifetime illnesses that require lifetime treatment. Putting a limit on how long a benzodiazepine can be prescribed is the same as putting a limit on how long a patient can be put on insulin, antihypertensives, antiinflammatories, bronchodilators, etc. That is clearly unreasonable and would never be tolerated by the medical community. Don't patients with Anxiety Disorders or Affective Disorders remain on an antidepressant for a lifetime?

Instead of prescribing a benzodiazepine physicians are now using a myriad of medications off label to augment the antidepressants when they don't work such as Abilify, Seroquel, Geodon, Topamax, Neurontin and others. These are some of the ones I have found patients on when they come to me for treatment. The Board's actions and proposed actions are creating unexpected and dangerous problems when a safe and effective medication class is available benzodiazepines.

I hope these concerns have caused you to consider the negative effects that the Board and the PMP have put on physicians prescribing benzodiazepines and correct the reluctance of those who would properly prescribe them if the rules weren't so confusing and alarming.

Sincerely,

Abbot Granoff, MD

Plain Language Summary Benzodiazepines as a First Line Treatment for Anxiety Disorders By Abbot Lee Granoff, MD Board Certified Psychiatrist

Benzodiazepine tranquilizers have been around since 1960. These include: Xanax (alprazolam), Klonopin (clonazepam), Valium (diazepam), Ativan (lorazepam) and Librium (chlordiazepoxide).

These are the most effective medications with the least amount of side effects for the treatment of Anxiety Disorders: Generalized Anxiety Disorder, Panic Disorder, Agoraphobia, Social Phobia, School Phobia and brief periods of stress.

There are many myths and misconceptions about these very safe and useful medications from doctors, non-physician mental health workers and the media. The American Psychiatric Association, Nation Institute of Health and DEA have produced documents showing their safety. They are not addictive, do not produce tolerance (the need to continually increase the dose) and are rarely abused. Most of the abuse comes from mixing them with alcohol and street drugs. They have much fewer side effects compared to the SSRI, tricyclic and other antidepressants. When they are dosed properly there are often no side effects. They can be safely used long term and even a lifetime.

Because of misinformation, doctors are reluctant to and even fear prescribing them. As a result, this useful class of medications, benzodiazepines, are currently underutilized.

This article helps to correct that misinformation and is a guide for properly prescribing them.

Abstract

Benzodiazepines have become a pariah in the treatment of Anxiety Disorders. There are many myths and misconceptions about them. Increasingly it is dogma rather than research or clinical experience that benzodiazepines are addicting, abused and dangerous. The APA, NIH and DEA have produced documents that contradict these misunderstandings. This information along with juried medical reports and physician experience seems to be continually overlooked despite the scientific validity of the evidence.

This article attempts to provide both the scientific evidence and the over 44 years of experience of a private practice psychiatrist that benzodiazepines are a safe and effective class of medications. The lack of physician, media and public understanding along with marketing by benzodiazepine competitors has relegated these medications to a scorned second-class status. Many doctors that have seldom or ever prescribed benzodiazepines have strongly held, rigid and negative beliefs about them.

This article also attempts to explain how to prescribe the benzodiazepines safely and effectively.

The benzodiazepines are safe for short and long-term use, even a lifetime. They are the most effective medications with the least amount of side effects for the treatment of most Anxiety Disorders. Fear of the benzodiazepines has led them to be markedly underutilized.

Benzodiazepines as a First-Line Treatment for Anxiety Disorders

Many articles, medical presenters and the media perpetuate the myth about "addiction," dependence meaning addiction, building tolerance, inappropriate use of and abuse of benzodiazepines.^{1,2,3,4} Physiologic adaptation and discontinuance syndrome can occur.^{5,6,7,8} However, these can also occur with many drugs: steroids, anticoagulants, beta blockers, anti-inflammatories, many psychotropic drugs, sedative hypnotics, opioids.^{6,7} Objectivity and consistency of terminology would lead us to use the same terminology for the same process, yet many physicians use the more pejorative terms of addiction, dependency, drug seeking and withdrawal when referring to the benzodiazepines.

Chronic use of a benzodiazepine for treating a medical condition is not an addiction. It is more appropriately considered dependence. Unfortunately, these terms are often used interchangeably. DSM-5 **does not** consider benzodiazepines taken appropriately under medical supervision a Substance Use Disorder.⁷ Its **essential feature is "continual use of the substance despite significant substance-related problems.**"⁷

Pharmacological criteria requires tolerance, "a markedly increased dose of the substance to achieve the desired effect," in addition to withdrawal.⁷ "Symptoms of tolerance and withdrawal occurring during appropriate medical treatment with prescribed medications are specifically *not* counted when diagnosing Substance Use Disorder.⁷ Normal, expected pharmacological tolerance and withdrawal during the course of medical treatment **has been known to lead to an erroneous diagnosis of addiction.**"⁷

Prevalence for Sedative, Hypnotic, or Anxiolytic Use Disorder is 0.5% or less among American adults with the exception of Native Americans and Alaska Natives at 0.8%.⁷ Medical presenters, the medical literature and the media make it seem like abuse is rampant and out of control.

Using any medication long term or even a lifetime is not addiction. Patients are **dependent** on their medications to treat any chronic medical condition of any organ system. Benzodiazepines are no different. When a person develops Panic Disorder which can lead to phobias, this author prescribes alprazolam as a first-line treatment. The average dose is 2-3mg per day with a range of 1/16-12mg per day. For Generalized Anxiety Disorder this author prescribes diazepam as a first-line treatment. The average dose is 10-20mg per day with a range of 2-60mg per day.^{6,8} This author has successfully done this for over 44 years in his private psychiatric practice with a 98+% return to a full functioning life.⁸ Panic Disorder, Agoraphobia, Social Phobia and Generalized Anxiety Disorder are usually lifetime conditions requiring lifetime treatment.

SSRIs do not cure Panic Disorder in 6 months to 2 years as first claimed by the manufacturers of paroxetine (FDA approved 1996) and sertraline (FDA approved 1997). They had to withdraw that claim. Alprazolam the last benzodiazepine produced became generic in 1993. The major anxiolytic marketing for the SSRIs began toward the end of the proprietary life of alprazolam. There was no pharmaceutical company left to counter those false claims. The manufacturers of SSRIs made billions with their supposedly non-addictive, temporarily used drugs that don't produce withdrawal. These usually have to be taken for a lifetime also.

Many Affective Disorders and Schizophrenia are also lifetime disorders requiring lifetime psychotropics. Literature directly comparing SSRIs with one another, other antidepressants and benzodiazepines is scarce.^{4,8,9,10} No pharmaceutical company would want to fund studies of their proprietary drug compared to a generic one which would most likely be shown to be more effective and less costly. The few articles that do exist do not take into account comorbid diagnoses of Affective Disorders or OCD. They're usually short term and therefore don not take into account the long term treatment that is often necessary.

Patients can become dependent on benzodiazepines and SSRIs and other antidepressants. The brain produces its own benzodiazepine.^{42,43} There are binding sites for it on the chloride ion channel and the GABA molecule. GABA also has a binding site on the chloride ion channel. When both are present the chloride channel

opens wider to allow negatively charged chloride ions to flow from outside to inside the nerve cell membrane causing it to become less excitable which translates to less anxiety.¹¹ Since Anxiety Disorders have a strong genetic predisposition one can postulate that these patients cannot produce enough of their own benzodiazepine to prevent the occurrence of an Anxiety Disorder. This can be compared to diabetes. Adding a therapeutic dose of a benzodiazepine puts that part of the brain chemistry back into balance alleviating symptoms.

Withdrawal from benzodiazepines is often misunderstood. According to the DSM-5 Benzodiazepine Discontiuance Syndrome can be divided into three categories: rebound, recurrence and withdrawal. SeeTable 1.⁷

| Symptom Category | Type of Symptom | Severity Compared to Original | <u>Course</u> |
|------------------|------------------|----------------------------------|------------------------------|
| Rebound | Same as original | More | Rapid onset, temporary |
| Recurrence | Same as original | Same | Very gradual onset, stays |
| Withdrawal | New symptom | Variable | Lasts 2-4 weeks |

Benzodiazepine Discontinuance Syndrome Table 1

Benzodiazepines can produce withdrawal or rebound discontinuance syndrome if abruptly withdrawn because their half-life is relatively short. By reducing the dose slowly there is minimal or no rebound or withdrawal. The original symptoms will return. This is **not** withdrawal as is often falsely claimed. If a more rapid discontinuation is necessary benzodiazepines can be stopped abruptly. A tapering dose equivalent of phenobarbital over 10 days will prevent seizures and withdrawal as per this authors experience.

SSRI's can also produce severe withdrawal if discontinued. This happens less frequently because their half-life is much longer. However, it happens often enough to be considered a serious problem, especially with paroxetine and the SNRI venlafaxine, since their half-life is shorter.

Birth defects in humans using benzodiazepines is somewhat controversial. Some studies show no increased incidence.^{12,13,14,15} Some show benzodiazepines to be safe.^{16,17,18} Some studies show the information to be inconclusive.^{15,19,20,21} The same rate of birth defects occurs in neonates of women who take a benzodiazepine vs those who don't.¹² They are the same wide ranging types. No one type stands out.¹² The early reference to increased incidence to cleft palate with diazepam has been later shown to be incorrect.^{18,19,22,23,24}

The seemingly higher level of benzodiazepine related birth defects vs other medications has been correlated with the higher number of women taking a benzodiazepine during pregnancy. When a birth defect occurs the first question asked the mother is to list the medications taken during pregnancy.

There is no clear correlation with neonatal lethargy, sedation or weight loss.²⁵ These can occur without the mother having taken a benzodiazepine.¹⁴ There are a few reports in the literature showing a benzodiazepine blood level in a neonate from the placental blood where this has occurred. However, other drugs, alcohol or a combination might be the cause. One also has to consider the effect on the fetus of high cortisol and adrenalin levels in untreated women with an Anxiety Disorder.

This author has treated over 2,000 patients with Anxiety Disorders in his private psychiatric practice. He finds benzodiazepines to be the most effective and least toxic medications for Anxiety Disorders. In his extensive experience and the experience of others they do **not** result in tolerance to anxiolytic effects, requiring higher dosing to achieve the initial effect as often stated.^{5,6,7,8,26,27,28,29,30,31,32,33,34,35,36}

The dosage remains stable at the patients usual therapeutic range as long as stress (physical, psychological and environmental) remains stable.^{8,26} If stress increases the dose has to be increased to go into the new therapeutic range. It remains there as long as that increased stress remains. When that stress is alleviated the dose returns to the usual therapeutic range. See Figure 1.

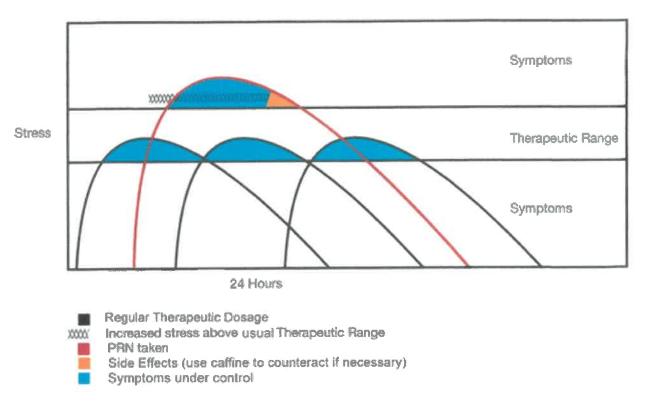


Figure 1 Benzodiazepine Dosing

Conversely, if stress decreases the dose can be decreased to a new lower therapeutic range without discontinuation syndrome.(Figure 1) Clinically this is seen when a patient becomes sedated at their usual therapeutic dose or begins skipping doses. Approximately 20% of this author's patients reduce or discontinue their dosage over time.⁸ Not all benzodiazepine users become dependent and most discontinuance symptoms are not severe.^{5,6,7,8,26} The therapeutic benefits from long-term use outweighs

the risk.²⁶ Individuals who take a therapeutic doses of a benzodiazepine rarely increase their dose, or take drugs for pleasure.^{5,6,7,8,26,34,36}

The misconception of "addiction" might come from the fact that patients do build some tolerance to the **sedating** effect after 3-5 days of a stable dose.

The dose can then be increased if necessary to a therapeutic one. Intermittent usage does not produce that tolerance. This can lead to sub-therapeutic dosing for the Anxiety Disorders. Retaining their sedative effect HS at higher doses when used for their hypnotic properties for sleep disorders is helpful.

Tolerance to sedation does not continue to occur with increasing dosage.^{6,7,8,26} If the dose goes beyond the therapeutic range sedation will remain. This is one way to find the top of therapeutic range. If anxiety symptoms remain, the bottom of therapeutic range has not been achieved. When this author's patients are at therapeutic range they tell him they don't feel like they are taking any medication: no sedation, no anxiety, no side effects.⁸

The side effect profile for benzodiazepines includes sedation, cognitive impairment, psychomotor impairment and short-term memory loss. All of these are dose related and usually occur when the therapeutic dose has been surpassed. Lowering the dose to the therapeutic range generally eliminates them. The side-effect profile for SSRI antidepressants includes insomnia, sexual dysfunction, weight gain, sedation, agitation, fatigue. Tricyclic antidepressants most commonly produce anticholinergic side effects (dry mouth, constipation) and weight gain. Lowering the dose of either of these medication types does not eliminate them. In this author's experience they can exacerbate panic attacks in about 1/3 of patients, they are ineffective in another 1/3 and they do work in the final 1/3. The ones in which they work usually have an Affective Disorder or OCD as a primary diagnosis with an Anxiety Disorder as a secondary diagnosis.^{8,9} Research does not take this into account when comparing medications which can lead to faulty conclusions.

According to the "APA Task Force Report on Benzodiazepines"⁵ and the DEA³⁴ they are used appropriately by the greater majority of patients.^{6,7,8,26,27,28,29,32,34,36} Few abuse them but abusers do so along with alcohol and street drugs at the same time. The media, public perception, non-physician mental health workers and physicians have fallen into the false belief that they are addictive and dosage has to be continually increased.^{6,8} Patients who take benzodiazepines chronically at their therapeutic dose report few if any side effects but their panic and anxiety are gone. They can then desensitize to their phobias more easily in real life situations. CBT desensitization with benzodiazepines appears more effective than CBT without medications or CBT with antidepressants. This needs more long-term study. Slow breathing or relaxation techniques don't work when a panic attack occurs in the middle of a tunnel or on top of a bridge. Patients taking a benzodiazepine can return to a fully productive life. It is therapeutically effective for patients to take PRNs to cover occasional brief periods of increased stress. If they do not, breakthrough panic attacks can occur. When that stress abates they can return to their therapeutic dose.(Figure1)

There is concern benzodiazepines are being **under prescribed or ineffectively prescribed.**^{4,5,40,44}

When using PRNs patients should take 1 or 2 pills, place them in plastic wrap and put them in their wallet which is always with them. If breakthrough anxiety or panic occurs, they have it readily available. Placing it under the tongue helps get it into the system more rapidly. This puts them in control of their illness rather than their illness controlling them. This empowerment speeds recovery to a fully functional life and helps extinguish phobias. If this stress is alleviated before the higher dose has time to metabolize and sedation occurs, the patients can then use some caffeine to titrate the sedation down. (Figure 1) Otherwise, caffeine should be avoided. It will increase anxiety and panic and reduce the effectiveness of the benzodiazepine.

If PRN use is more frequent than weekly or bi-weekly, one may consider raising the daily dosage to put the patient into a higher level of therapeutic range. It is prudent for the prescriber to look for the etiology of the increased need in areas of stress (physical, psychological and environmental). Once found, appropriate treatment should ensue.

The most common reason for treatment failure with benzodiazepines is too low a dose that is taken too infrequently.⁸ Often times this occurs because of the fear of prescribing them in the first place. Physicians who do not understand how they work and properly prescribe them come to faulty conclusions about their effectiveness. They often scare the patient by telling them the benzodiazepines are addictive and should be used sparingly. This often leads to the prescription of an SSRI, tricyclic or off label prescription of a myriad medications with more significant side effects. PRN benzodiazepines are also often needed here.

It is generally not appropriate to prescribe benzodiazepines to alcoholics or drug abusers. They are the most likely to abuse them. However, some patients who are selfmedicating with alcohol to treat their Anxiety Disorders might benefit from them. Antabuse should be given along with the benzodiazepine especially in the early stages of treatment to prevent alcohol use.

It may be potentially dangerous to combine a benzodiazepine with an opiate. This is theorized to cause respiratory depression and death. This conclusion needs more study since this combination is often taken at appropriately prescribed doses without adverse sequelae. Research literature on this speculation is sparse and opioid overdose is the more likely primary cause of death. Fentanyl is more potent and deadlier than other opiates and is often added to opiates to increase their effect. It is not included in the reports in opioid deaths. There are limited animal studies. More are definitely needed.

The conclusion about combining benzodiazepines and opiates is similar to the one regarding teratogenicity. Just because a benzodiazepine is present does not mean it is

causal to any adverse event that occurs. The negative bias toward the benzodiazepines seem to make them causal even without proof. This is speculation not science. Science must prove that speculation. Blood levels should be taken when patients OD on opiates since there are many substances that could in combination with opiates cause an adverse and deadly effect. The CDC which produces graphs and charts regarding opioid deaths uses death certificates from various practitioners of widely differing training and knowledge. They will even include a person who has filled a benzodiazepine prescription within 30 days of the OD not stating the dosage or knowing if the benzodiazepine was ingested at time of OD!

As people age they must be observed for dementia. If they have it, reduce or discontinue their dosage of benzodiazepine as needed. Clinical judgement is necessary. The myth that they cause dementia including Alzheimer's Disease is perpetuated by poorly designed research. Read the British Medical Journal article 2014; 349:g 5205 "Benzodiazepine use and risk of Alzheimer's disease: case-control study."³⁷ At the end of the article the authors themselves state this "might not be causal." Read this authors critique of that study in the BMJ. You will find it under "Response."³⁸ These critiques only appear online and are somewhat difficult to locate which minimizes their corrective effect. Psychiatric News picked up on this article in their Oct 2014 edition "Long Term Use of Benzodiazepines May Be Linked to Alzheimer's."³⁹ They did not publish this author's critique letter to them. Major TV news along with the NYTimes and other newspapers picked up on this faulty conclusion as though it was fact, needlessly scaring the public and physicians and starting a new myth. Letters to them went unheeded.

A recent study of benzodiazepines and dementia found no correlation but found they "might have protective effect against dementia."45

Patients should always have a 10-14 day supply so they won't run short and experience discontinuance syndrome if they have to cancel an appointment due to illness, weather or other unforeseen circumstances. This prevents their fear of running out of them. Insurance companies and many physicians often won't let patients have this buffer amount of their prescription. This might be causing some of the unnecessary desperation seen in patients fomenting the myth of addiction. If missing appointments happens too often consider abuse. If it is present switch to an SSRI.

In order to discontinue a benzodiazepine, slowly reduce the dosage by perhaps 10-15% every week. To discontinue more quickly, prescribe an equivalent Phenobarbital dosage and taper it over 10 days to cover withdrawal and seizures. Premorbid anxiety symptoms usually return. This is **not** withdrawal as is often incorrectly concluded. This withdrawal myth is too prevalent. Withdrawal lasts 1-4 weeks.⁷ Benzodiazepines can produce withdrawal but so can SSRIs. Proper prescribing can minimize or alleviate it.

Withdrawal can also occur with a number of other medications: steroids, anticoagulants, beta blockers, anti-inflammatories, many psychotropic drugs, sedative hypnotics, opioids.^{6,7}

If there is an increased street use of benzodiazepines, this author speculates that it may be because physicians have become fearful of prescribing them. Patients with Anxiety Disorders where SSRIs or other treatments are ineffective and benzodiazepines are may seek them on the street. This could happen when they can't find a physician willing to prescribe them or experienced enough to prescribe at proper therapeutic levels.

There are few studies comparing benzodiazepines to antidepressants in treating Anxiety Disorders. When they do occur they are usually short-term, 5-8 weeks and they don't take into account comorbid Affective Disorders or OCD. These are usually lifetime disorders that can wax and wane. Brief studies along with comorbid illness may produce inaccurate conclusions. Since we are yet unable to fix the gene(s) that cause them, lifetime treatment is often necessary.

When comparing benzodiazepines to antidepressants to treat Anxiety Disorders for side effects, efficacy and tolerability, the benzodiazepines win hands down. To perpetuate the myths of addiction, abuse and dementia scares physicians and the public from these very safe and useful medications. They have been available since 1960 and have been safely prescribed to millions of patients. They are currently underutilized. This can be corrected with knowledge and training.

New research is needed to help clear up the confusion, bias and misunderstandings regarding the benzodiazepines. This should be unbiased research that is not funded by the pharmaceutical or addiction industry. It should compare patients with Anxiety Disorders **without** comorbid Affective Disorders or OCD with the use of benzodiazepines vs antidepressants or other current medications d'jour. In addition studies are needed for patients that have been on a benzodiazepine long term and compare their incidence of dementia to patients who have not been on any psychotropic.

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Agenda Item: Request from the Virginia Interfaith Center for Public Policy

Staff Note: In the following pages, you will find email communications with Dora Muhammad, Congregation Engagement Director & Health Equity Program Manager for the Virginia Interfaith Center for Public Policy. Her request is that the Board of Medicine, in support of maternal and infant health, require its licensees to take implicit bias training. The article on "Perinatal and Other Depression in Women" that appeared in the November 2020 Board Briefs is included for your review. Public comment is anticipated.

Action: Recommend to the Board that it pursue legislation, regulation or a guidance document to address the request, or suggest another approach.

Colanthia Opher

From: Sent: To: Subject: Harp, William <william.harp@dhp.virginia.gov> on behalf of Harp, William Tuesday, May 4, 2021 4:41 PM Colanthia D. Morton Fwd: Meeting Request

------ Forwarded message ------From: **Dora Muhammad** <<u>dora@virginiainterfaithcenter.org</u>> Date: Tue, May 4, 2021 at 4:08 PM Subject: Re: Meeting Request To: Harp, William <<u>william.harp@dhp.virginia.gov</u>>

Thank you so much!



Dora Muhammad Congregation Engagement Director Health Equity Program Manager Virginia Interfaith Center for Public Policy 1716 East Franklin Street Richmond, VA 23223 (804) 643-2474 ext. 106 #LearnPrayAct #HealthCareHope #FaithfulCitizens #EndRacism



The Virginia Interfaith Center for Public Policy advocates economic, racial, social and environmental justice in Virginia's policies and practices through education, prayer, and action. VICPP is a non-partisan coalition of more than 700 faith communities working for a more just society. Learn. Pray. Act.

From: Harp, William <<u>william.harp@dhp.virginia.gov</u>> Sent: Tuesday, May 4, 2021 2:13 PM To: Dora Muhammad <<u>dora@virginiainterfaithcenter.org</u>> Subject: Re: Meeting Request

Dear Ms. Muhammad:

It has been decided that your request will be discussed by the Board of Medicine's Legislative Committee on Friday, May 21st.

The meeting will be virtual, and the Committee will take public comment at the top of the meeting. Speakers will be limited to 5 minutes.

Here is the notice of the meeting on Regulatory Town Hall. The notice says "physical location." That is being changed to "virtual." Prior to the meeting, instructions on how to join the meeting will be posted on Town Hall.

https://townhall.virginia.gov/L/ViewMeeting.cfm?MeetingID=31737

Kindest regards,

William L. Harp, MD Executive Director Virginia Board of Medicine

On Mon, May 3, 2021 at 8:48 AM Harp, William <<u>william.harp@dhp.virginia.gov</u>> wrote: Dear Ms. Muhammad:

Thank you for your message.

You may be interested in the lead article in the November 2020 Board Briefs about perinatal depression. Delegate Ibraheem S. Samirah wanted to highlight the issues of depression in women of minorities before, during and after pregnancy. The article included links to resources for practitioners. Here is the link to the November 2020 Board Briefs.

https://www.dhp.virginia.gov/media/dhpweb/docs/med/News/archive/BoardBrief91.pdf

I hope this is helpful to you.

Kindest regards, WLH

On Fri, Apr 30, 2021 at 9:32 AM Dora Muhammad <<u>dora@virginiainterfaithcenter.org</u>> wrote:

Thank you for the response and the specific guidance on options. Before I pursued legislation, we try to determine if it is necessary based on the position or protocols of the affected governmental body and what avenues are open to work with them as a stakeholder if they have the authority to make policy changes without legislation. Since the MMRT listed this recommendation under the Board and not the GA, I read that as legislative action was not necessary.

Is/would the Board welcome and support such legislation? Has it considered or been presented with the other mandates for clinical trainings that the MMRT recommended? When I spoke with the program manager in December, she was not aware whether any follow-up had been done in that regard by members of the MMRT?



Dora Muhammad Congregation Engagement Director Health Equity Program Manager Virginia Interfaith Center for Public Policy 1716 East Franklin Street Richmond, VA 23223 (804) 643-2474 ext. 106 #LearnPrayAct #HealthCareHope #FaithfulCitizens #EndRacism



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From: Harp, William <<u>william.harp@dhp.virginia.gov</u>>
Sent: Friday, April 30, 2021 9:16 AM
To: Dora Muhammad <<u>dora@virginiainterfaithcenter.org</u>>; Brown, David <<u>david.brown@dhp.virginia.gov</u>>; Yeatts,
Elaine <<u>elaine.yeatts@dhp.virginia.gov</u>>
Subject: Fwd: Meeting Request

Dear Ms. Muhammad:

Thank you for your message. I do not believe a meeting would enhance the Board's response below, but thanks for the offer.

I see 3 ways forward with your request.

1. Contact a delegate or senator in the General Assembly and have them carry a bill to require education on implicit bias for all Board of Medicine licensees.

2. File a request for rule-making. The process for developing and approving new regulations can take up to 2 years. However, if you wish to pursue this course, here is the link for filing. https://www.dhp.virginia.gov/media/dhpweb/docs/med/leg/Petition_Medicine.pdf

3. The Board of Medicine can publish how to access educational courses on implicit bias in its newsletter that goes to all licensees, including nurse practitioners. Any information you can provide to the Board about courses would be most appreciated.

I hope this is helpful to you.

With kindest regards,

William L. Harp, MD Executive Director Virginia Board of Medicine

------ Forwarded message ------From: **Dora Muhammad** <<u>dora@virginiainterfaithcenter.org</u>> Date: Fri, Apr 23, 2021 at 5:25 PM Subject: Meeting Request To: <u>medbd@dhp.virginia.gov</u> <<u>medbd@dhp.virginia.gov</u>> Cc: Coco.Morton@dhp.virginia.gov <Coco.Morton@dhp.virginia.gov>

Good afternoon Mr. Harp,

I would like to schedule a meeting with you to discuss one of the primary recommendations that is a part of our maternal health PUSH campaign and get your feedback on the feasibility of its implementation at the Virginia Board of Medicine. It is establishing a requirement of implicit bias training for all health professionals licensed by the Board. The Virginia Maternal Mortality Review Team, in its 2019 report, included a recommendation to the Board to mandate a set of clinical trainings to improve the maternal mortality rates of Black women. This would only partially improve birth outcomes for Black women in Virginia. I would like to discuss with you the significant impact that a mandate for implicit bias training would bear on their maternal mortality.

For the past several years, I have led this campaign which has involved several key elements such as planning and coordinating the Governor's Office's maternal health listening tour stop in my county, a statewide petition to Dr. Carey, and organizing a maternal health coalition to give testimony before the General Assembly. Our PUSH campaign achieved a major success during this year's legislative session of the General Assembly. I drafted a budget amendment that would enact the federal option under CHIP that would provide for coverage of prenatal care to undocumented expectant mothers, an overlooked and marginalized group of women excluded from access to these essential services.

Like the General Assembly, the Virginia Board of Medicine holds a unique position to leverage its authority to help reverse the tragic rising trend of pregnancy-related deaths of Black women in Virginia. Attached are my policy briefs on prenatal care and implicit bias as a quick reference. I look forward to hearing from you!

4



Dora Muhammad Congregation Engagement Director Health Equity Program Manager Virginia Interfaith Center for Public Policy 1716 East Franklin Street Richmond, VA 23223 (804) 643-2474 ext. 106 #LearnPrayAct #HealthCareHope

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Virginia Board of Medicine

9960 Mayland Drive, Suite 300

Henrico, VA 23233

804-367-4600

The Virginia Board of Medicine currently licenses: Acupuncturists, Athletic Trainers, Behavior Analysts, Assistant Behavior Analysts, Doctors of Chiropractic, Doctors of Medicine and Surgery, Doctors of Osteopathic Medicine and Surgery, Doctors of Podiatry, Genetic Counselors, Interns & Residents, Midwives, Nurse Practitioners*, Occupational Therapists, Occupational Therapy Assistants, Physician Assistants, Polysomnographic Technologists, Radiological Technologists, Radiological Technologists-Limited, Radiologist Assistants, Respiratory Therapists, Surgical Assistants & Surgical Technologists (*Jointly with the Board of Nursing)

Elaine J. Yeatts Senior Policy Analyst Department of Health Professions (804) 367-4688

VIRGINIA BOARD OF MEDICINE

PERINATAL AND OTHER DEPRESSION IN WOMEN

The 2020 Session of the General Assembly passed HB 42 which requires the Board of Medicine to "annually issue a communication to every practitioner licensed by the Board who provides primary, maternity, obstetrical, or gynecological health care services reiterating the standard of care pertaining to prenatal or postnatal depression or other depression. Such communication shall encourage practitioners to screen every patient who is pregnant or who has been pregnant within the previous five years for prenatal or postnatal depression or other depression, as clinically appropriate and shall provide information to practitioners regarding the factors that may increase susceptibility of certain patients to prenatal or postnatal depression or other depression or other depression, including racial and economic disparities, and encourage providers to remain cognizant of the increased risk of depression for such patients."

HB 42 echoes the recommendation of the 2016 US Preventive Services Task Force that pregnant women and postpartum women should be screened for depression, and it adds women that have been pregnant in the last 5 years. The bill seeks to be preventive, so it encourages practitioners to identify women at risk for depression. Screening and identification is important since many women do not seek treatment for depression. The practitioner is in the important position of being able to refer women at risk for depression to counseling and for further evaluation. This initiative is particularly relevant for minority women, a group that has not been screened as often.

Remember that postpartum depression can cause intense feelings of sadness, anxiety or despair that prevent new mothers from being able to do their daily tasks. Practitioners should be aware of the risk factors for perinatal depression, factors that can be clinical or social. Here are some to keep in mind.

Clinical Risk Factors

- Personal or family history of depression
- History of physical or sexual abuse
- Unplanned or unwanted pregnancy
- Current stressful life events
- Pregestational or gestational diabetes
- Complications during pregnancy



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Social Risk Factors

- Low socioeconomic status
- Lack of social or financial support
- Adolescent parenthood

Additionally, you should know that 1 in 7 women has perinatal depression. Preexisting depression, psychiatric illness prior to pregnancy, and symptoms during pregnancy are the strongest predictors of perinatal depression. Data show that a previous episode of postpartum depression predicts a second episode 50% of the time. A previous episode of postpartum psychosis predicts a recurrence 80-90% of the time. African-American women meet criteria for depression more than other ethnic groups and are 3 times more likely to die from pregnancy-related causes. And 1 in 3 migrant women from low and middle income countries have perinatal mental health issues.

It is recommended that women who exhibit 1 or more of the following should be referred for counseling or further evaluation.

- History of depression
- Current depressive symptoms
- Low income
- Adolescent or single parenthood
- Recent intimate partner violence
- Elevated anxiety symptoms
- History of significant negative life events

A useful tool to help with the identification of postpartum depression is the Edinburgh Postnatal Depression Scale. You can find it at:

https://www.fresno.ucsf.edu/pediatrics/downloads/edinburghscale.pdf

And for women that are no longer in the perinatal period, the Patient Health Questionnaire-9 and the Beck Depression Inventory BDI) are useful tools. You can find them at:

https://www.apa.org/depression-guideline/patient-health-questionnaire.pdf

https://www.ismanet.org/doctoryourspirit/pdfs/Beck-Depression-Inventory-BDI.pdf

The following 2 questions are recommended as a quick screen for a past history of depression, a significant risk factor. If the answers are "yes" for a pregnant or postpartum woman, consider referral for counseling or further evaluation.



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- Was there ever a period of time when you were feeling depressed or down or when you lost interest in pleasurable activities most of the day, nearly every day, for at least 2 weeks?
- Has a health care professional ever told you that you were depressed? Have you ever taken a medication for depression?

In all cases, interventions should be tailored to the risk.

References

Massachusetts General Hospital Center for Women's Mental Health

- Perinatal Depression: How Do We Define High Risk? (Part 1) February 27, 2019 Ruta Nonacs, MD, PhD
- Perinatal Depression: How Do We Define High risk? (Part 2) March 20, 2019 Ruta Nonacs, MD, PhD

Perinatal depression screening practices in a large health system: identifying current state and assessing opportunities to provide more equitable care – Archives of Women's Mental Health, May 5, 2020 – Abbey Sidebottom et al.

Racial Disparities in Perinatal Depression in an Underserved Los Angeles County Population [30P] – Obstetrics and Gynecology, May 6, 2017 – Anna K. Celaya, MD, MPH et al.

Research Gaps in Perinatal Mental Health: U.S. Racial & Ethnic Disparities and Neglected Global Populations - Mental Health Task Force at the Harvard Chan School, August 19, 2016 – Sarah Hodin, MPH, CD (DONA), LCCE **Agenda Item:** Accreditation Council for Continuing Education (ACCME) Project

Staff Note: In the following pages, you will find email communication with the staff of ACCME describing its project of collecting CME for physicians. Please read the information sheets and the PowerPoint presentation in advance of the meeting. Public comment from ACCME and perhaps others is anticipated.

Action: To recommend that the Board join in this project at this time, or not.

Colanthia Opher

| From: | Harp, William <william.harp@dhp.virginia.gov> on behalf of Harp, William</william.harp@dhp.virginia.gov> |
|--------------|--|
| Sent: | Monday, May 10, 2021 6:45 PM |
| То: | Colanthia D. Morton |
| Subject: | Fwd: ACCME invite to VBM for CME data collaborative |
| Attachments: | About ACCME.pdf; Medical Board Licensing Pilot Overview.pdf; PARS_for_VA Board.pdf |

Don't think I sent this. It's for Legislative.

----- Forwarded message ------From: Marcie Bonilla <<u>mbonilla@accme.org</u>> Date: Mon, May 10, 2021 at 4:59 PM Subject: RE: ACCME invite to VBM for CME data collaborative To: Dr. Graham McMahon <<u>gmcmahon@accme.org</u>>, Harp, William <<u>william.harp@dhp.virginia.gov</u>> Cc: Blanton Marchese <<u>blanton@essems.com</u>>

Good afternoon, Dr. Harp and Mr. Marchese,

I've attached some documents for the Virginia Board of Medicine's review. We're excited at the prospect of working with you, so please feel free to let us know of any questions you may have in advance of your meeting on Friday.

Best regards,

Marcie

Marcie Bonilla |she|her|hers

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From: Dr. Graham McMahon <gmcmahon@accme.org> Sent: Monday, May 10, 2021 11:10 AM To: Harp, William <william.harp@dhp.virginia.gov> Cc: Blanton Marchese <<u>blanton@essems.com</u>>; Marcie Bonilla <<u>mbonilla@accme.org</u>> Subject: RE: ACCME invite to VBM for CME data collaborative

Hi William – do you know what time you'd like me to join? 10-15 mins would be enough I imagine.

Graham

From: Harp, William
Sent: Monday, May 10, 2021 9:11 AM
To: Dr. Graham McMahon <<u>gmcmahon@accme.org</u>>
Cc: Blanton Marchese <<u>blanton@essems.com</u>>; Marcie Bonilla<<u>mbonilla@accme.org</u>>
Subject: Re: ACCME invite to VBM for CME data collaborative

Time for comment might be available at the meeting, which will be virtual.

On Mon, May 10, 2021 at 9:55 AM Dr. Graham McMahon <gmcmahon@accme.org> wrote:

Super. Will do.

Marcie, cc'd, is going to get you some resources to enclose in your materials.

Happy to call in anytime to discuss it with your colleagues.

Graham

On May 10, 2021, at 8:40 AM, Harp, William <<u>william.harp@dhp.virginia.gov</u>> wrote:

Actually, we need them by this Wednesday to be able to get the packet out on Thursday. So the sooner the better.

You don't have to send encyclopedic info at this time, just enough for the Board members to understand the project and to consider it. It might be good to include a basic information sheet and the results so far in NC and ME.

Hope this helps.

WLH

On Mon, May 10, 2021 at 9:34 AM Dr. Graham McMahon <gmcmahon@accme.org> wrote:

Sure thing - I'll put some materials together. Do you need them before Friday so you can circulate in advance?

Graham

On May 10, 2021, at 8:25 AM, Harp, William <<u>william.harp@dhp.virginia.gov</u>> wrote:

Dear Dr. McMahon:

Thank you for your message.

The Board's Legislative Committee will be meeting next Friday, the 21st.

If you could provide some explanatory documents to include in the agenda packet by this Wednesday that could serve as the basis of an informed discussion, it would be much appreciated.

With kindest regards,

William L. Harp, MD

Executive Director

Virginia Board of Medicine

On Fri, May 7, 2021 at 9:25 PM Dr. Graham McMahon <<u>gmcmahon@accme.org</u>> wrote:

Hi William,

ACCME is now collecting and verifying CME data for each physician, using data from our colleagues at FSMB. This allows us to offer a centralized national transcript for each licensee to a state licensing board. We described the system in a poster at the recent FSMB meeting – see <u>here</u>.

This data would allow your staff to check CME completions centrally and/or complete your audits of CME through the data system in minutes rather than by having to contact the physician and count pdfs of their certs.

As a national regulator we're not charging anyone (licensing board, physician, accredited CME providers) for the service, so it's completely free. The system is secure and abides by data protection regs as you'd expect.

The pilot project with North Carolina and Maine has gone well, and California and Maryland have asked to join the project on the next round. I could add another state to the next round and wondered if you would like to learn more and consider having Virginia join in on a timeline that works for you? Interested?

Best regards,

Graham

Graham McMahon, MD, MMSc (he, him, his)

President & CEO

Accreditation Council for Continuing Medical Education

401 North Michigan Avenue, Suite 1850

Chicago, IL 60611 Phone: (312) 527-9200

gmcmahon@accme.org www.accme.org



Accreditation Council[™] for Continuing Medical Education *learn well*

The Accreditation Council for Continuing Medical Education (ACCME) is the national regulator and accrediting body for continuing medical education in the United States.

ACCME accredits organizations that offer continuing medical education, creating a framework that supports, inspires, and motivates educators to achieve their full potential. We set the standards for education that accelerates learning, change, and growth in healthcare. Our standards reflect the values of our educator community and respond to the evolving healthcare environment. As a result, clinicians and teams can drive improvement in their practice and optimize the care, health, and wellness of their patients.

Our community of more than 1,600 CME providers offers physicians and healthcare teams an array of resources to promote quality, safety, and the evolution of healthcare. There are approximately 170,000 accredited CME activities for physicians to choose. Those activities accounted for over 18,000,000 physician interactions. Accredited CME offers clinicians, educators, and health leaders the power and capacity to address many of the challenges we face in our changing healthcare environment.

ACCME accredits organizations in the US and around the world. Accredited CME providers represent a range of organizations from national physician membership organizations to rural hospitals. Some specialize in local, community-based health issues, others focus on national and international health priorities, and others advance interprofessional continuing education (IPCE) and team-based care.

The State Medical Board pilot was a limited proof-of-concept involving three state medical boards and a small group of accredited CME providers trying out the system for a handful of their activities. During the pilot, CME participation was reported for hundreds of activities, accounting for over 52,000 physician completions of accredited CME.

ACCME is excited to be able to expand the pilot into a fully operation program, the ACCME and State Medical Boards Collaboration. Reporting will be open for all accredited CME providers and all State Medical Boards this summer. Please reach out to Marcie Bonilla at <u>mbonilla@accme.org</u> to get started.

Accreditation Council for Continuing Medical Education

ACCME and State Medical Board Collaboration

Overview

The ACCME collaborated with several state medical boards on a voluntary, pilot program that enabled a small group of CME providers to report physician participation in accredited CME to the Boards via ACCME's Program and Activity Reporting System (PARS). This pilot project was designed to examine the feasibility of and response to the sharing of this information, and determine if it is valuable to the physician, the accredited provider, and to the state boards. The pilot was a success, and ACCME is operationalizing the program.

The Maine Board of Licensure in Medicine, Maine Board of Osteopathic Licensure, Tennessee Board of Medical Examiners and North Carolina Medical Board participated in the pilot. During the pilot, CME participation was reported for hundreds of activities, accounting for over 52,000 physician completions of accredited CME. The Medical Board of California will be joining the collaboration in Summer 2021, and any other interested board is invited to join.

Benefits to state medical boards

The goal of the collaboration is to simplify the reporting of CME credit

by providing state medical boards with one primary source system to use to validate the completion of CME requirements by their licensed physicians. The board can download CME participation reports or search for individual physicians to verify physician-reported CME participation.

Benefits to CME Providers

Participating in the pilot allows CME providers to engage a variety of learners in their CME activities. It also increases the value of the education and credit earned for their learners, by reducing the reporting burden of their learners. Entering the learner participation data in PARS, a system they are already familiar with, helps to provide alignment between the CME and licensing systems.

Benefits to Licensed Physicians

The ACCME and the Boards are engaging in this collaboration because they share the goal of reducing regulatory burdens on physician learners. Having the CME provider report CME participation is a value-add for the learners participating in the activity.



What the Accredited CME Providers do

When a physician attends an accredited CME activity, the CME provider asks them to provide their name, state license number (or national provider identifier) and the day and month of their birth. The CME provider also secures permission from the physician to provide this information to ACCME and their state medical board. The provider will upload this data into the system they already use to report CME activities, ACCME's Program and Activity Reporting System (PARS). In addition to the licensee information, they provide the activity name, amount of CME credit earned and completion date. This information will then be available for the board to search, view and download.

What the State Medical Board does

ACCME works with data provided by the FSMB to validate that the ACCME is matching completion records submitted by the CME providers to the correct licensees. The Board does not need to provide ACCME with licensee data.

The state medical boards should communicate with their physician licensees so that they are aware of the opportunity to have their CME reported directly by the accredited CME providers.

ACCME will provide training and log in credentials for state medical board users to view the physician learner records submitted by the CME providers. Boards can continue to conduct random audits and use the system to verify the amount of CME earned by physicians being audited. Boards can also use the system to identify physicians who either have already met the CME credit requirements or who may need a reminder that more CME is needed to meet their re-licensure deadline.

Timeline

ACCME is currently undertaking improvements to our technical systems, based on what we learned during the pilot. The upgraded system will be available in the summer of 2021. The process to onboard any new State Medical Boards that want to join is simple and quick.

Cost to participate

There is no charge to participate in the ACCME and State Medical Boards Collaboration for the Medical Boards, CME providers or physicians.

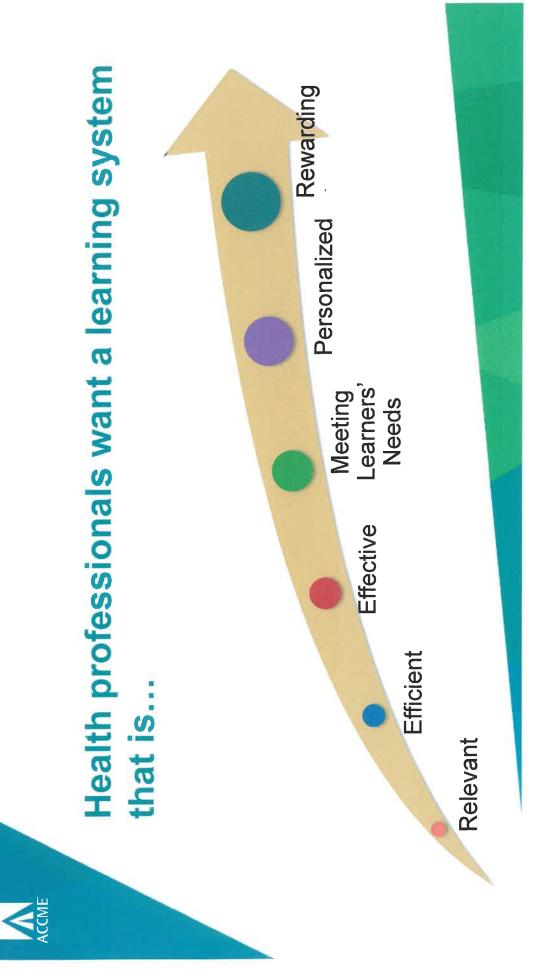
SIMPLIFYING CME DATA SHARING

Collaboration to Serve Licensees and the Virginia Board of Medicine

Accreditation Council CE for Continuing Medical Education learn well

Graham McMahon MD, MMSc CEO, ACCME







ACCMIE

| Accredited CME Providers | Over 1,600 |
|--------------------------|-----------------|
| Activities | Over 170,000 |
| Physician Interactions | Over 18,000,000 |





ACCME AND STATE MEDICAL BOARDS COLLABORATION **Collaboration Goals**

For State Medical Boards

- Simplify the reporting of CME credit for MD and DO licensees
- Simplify the review of licensees for having met re-licensing requirements or disciplinary re-instatement requirements
- Reduce the reporting burden for their licensed physicians
- Provide assurance that the CME credits reported for physicians are primary source verified
- Provide a unified system for all State Medical Boards to use for verifying the CME participation for their licensees



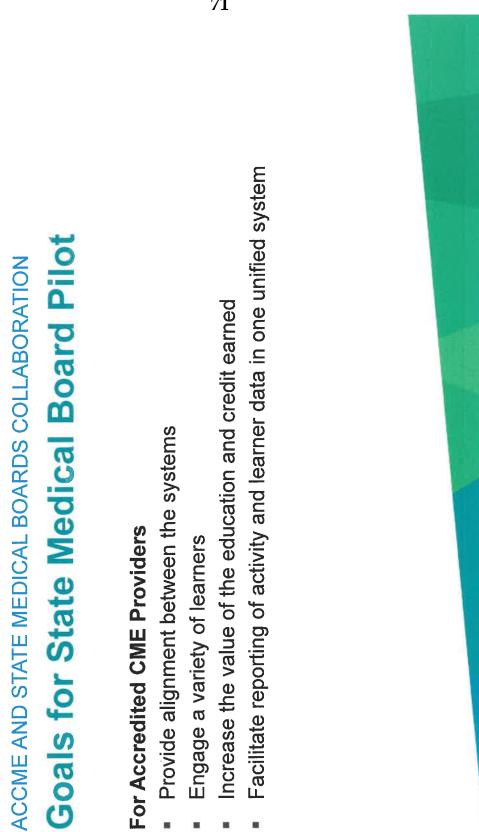
ACCME AND STATE MEDICAL BOARDS COLLABORATION

Goals for State Medical Board Pilot

For Clinicians

- Add value to the credit earned by having it automatically reported to licensing board(s)
- Facilitate finding relevant educational programs for their location, practicetype and interest
- Reduce the burden of tracking and reporting CME credits earned





ACCME

ACCME AND STATE MEDICAL BOARDS COLLABORATION

ACCME

How does it work?

The accredited provider enters data about an upcoming activity in PARS.

Licensees register to participate in the activity and provide their license number and/or NPI. The accredited provider determines that the licensee has satisfactorily completed the activity The accredited provider reports the completion data into PARS.

Accredited CME providers already use ACCME's Program and Activity Reporting System (PARS) to enter information about their CME activities.

CME providers can now enter verified participation information about your physician licensees into PARS.

You can be assured that the information that you see in PARS is primary source. No self-reported data is in the system.

There is no cost to participate in this program to the State Medical Boards, the physicians or the CME providers.





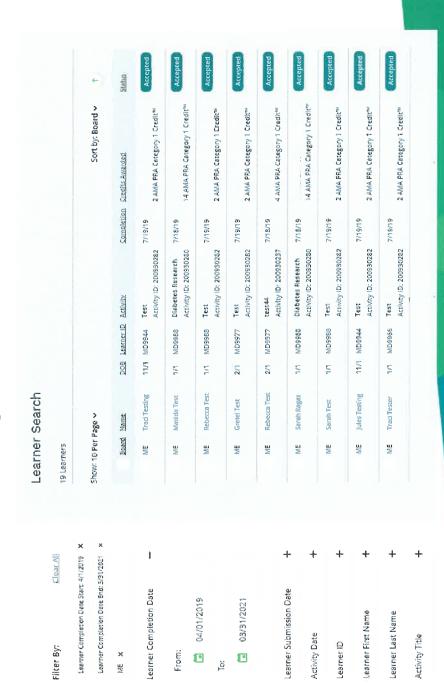
ACCME





ACCME





Search for all licensees in a given timeframe



Search for a specific licensee in a given timeframe

ACCME



See a summary of learners submitted per activity

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| | Required fee | CommunityPopulation Health - Objective measurement (e.g., observed, tested) |

Drill down to see details of the activities

ACCME



Contact me gmcmahon@accme.org

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Agenda Item: Physician Assistant Licensure Compact

Staff Note: The Federation of State Medical Boards requests comment from its member boards on the PA Licensure Compact. The draft version of the Compact is included for your review.

Action: To provide comment on the draft version, or not.

Commonwealth of Virginia Mail - FSMB Seeks Comment: Physician Assistants Licensure Compact 82



Harp, William <william.harp@dhp.virginia.gov>

FSMB Seeks Comment: Physician Assistants Licensure Compact

1 message

Maggie Quinn <mquinn@fsmb.org> To: Maggie Quinn <mquinn@fsmb.org> Mon, May 10, 2021 at 9:14 AM

Dear Colleagues,

The Federation of State Medical Boards, supported by a grant under the U.S. Health and Human Services, Health Resources and Services Administration ("HRSA") License Portability Grant Program, has worked with the Council of State Governments' National Center for Interstate Compacts ("CSG NCIC"), the American Academy of PAs, and the National Commission on Certification of Physician Assistants to develop the Physician Assistants Licensure Compact ("Compact"), for which it is seeking review and feedback.

FSMB was awarded this grant to further support the Interstate Medical Licensure Compact and develop a license portability model for PAs. PAs engage in telemedicine and practice across state lines on a regular basis, but do not currently have a portability model to facilitate interstate practice. In November 2019, FSMB hosted a two-day meeting in Washington, DC, bringing together stakeholders to identify the elements necessary to make a PA licensure portability model successful. The meeting included representatives from state medical boards, PA boards, PA professional associations, representatives from other health care professional licensing compacts, and other experts. A drafting committee was then formed and met several times, supported by CSG NCIC who drafted formal legislative language.

The Compact establishes its purpose and definitions, the duties of states participating in the Compact, the requirements for exercising a privilege to practice through the Compact, and procedures for adverse actions. It also provides for the formation of a Physicians Assistants Compact Commission and a rulemaking process.

The Physician Assistants Licensure Compact language is available here:

https://www.fsmb.org/siteassets/communications/pa-licensure-compact-43021.pdf

2021 Commonwealth of Virginia Mail - FSMB Seeks Comment: Physician Assistants Licensure Compact 83 Please email comments to Maggie Quinn at mquinn@fsmb.org by **June 14, 2021**.

Thank you in advance for taking time to respond to this call for comments.

Lisa Robin

Chief Advocacy Officer

Federation of State Medical Boards

2101 L Street NW | Suite 800 | Washington, DC 20037

202-463-4006 direct | 817-602-1112 mobile

lrobin@fsmb.org | www.fsmb.org



PHYSICIAN ASSISTANTS LICENSURE COMPACT

84

Section 1. Purpose

In order to strengthen access to health care, and in recognition of the advances in the delivery of health care, the member states of the Interstate Physician Assistants ("PA") Licensure Compact have allied in common purpose to develop a comprehensive process that complements the existing authority of state regulatory boards to license and discipline PAs, seeks to enhance the portability of a license to practice as a PA while safeguarding the safety of patients. The Compact allows medical services to be provided by PAs via the mutual recognition of the Licensee's Home State license by other Compact Member States. The Compact also adopts the prevailing standard for licensure and affirms that the practice and delivery of health care services by the PA occurs where the patient is located at the time of the patient encounter, and therefore, requires the PA to be under the jurisdiction of the State Licensing Board where the patient is located. State Licensing Boards that participate in the Compact retain the jurisdiction to impose an Adverse Action against a Privilege to Practice to practice in that State issued to a PA through the procedures in the Compact.

Section 2. Definitions

In this compact:

"Current Significant Investigative Information" means Investigative Information that a Licensing Board, after an inquiry or investigation that includes notification and an opportunity for the PA to respond, if required by State law, has reason to believe is not groundless and, if proved true, would indicate more than a minor infraction.

"Privilege to Practice" means the authorization granted by a remote State to allow a licensee from another member state to practice as a PA to provide health care and other licensed activity to a patient located in the remote state under the member state's laws and rules and shall be the equivalent of a license in the remote state.

"Home State" means the member state that is the Licensee's Primary State of Residence or employment.

"Remote State" means a member state other than the home state, where a licensee is exercising or seeking to exercise the Privilege to Practice.

[Other defined terms here]

"State" means any state, commonwealth, district, or territory of the United States.

Section 3. State Participation in the Compact

A. To participate in the Compact a Member State shall:

- License PAs.
- Participate in the Compact Commission's Data System.
- Have a mechanism in place for receiving and investigating complaints against licensees.
- Notify the Commission, in compliance with the terms of the Compact and its rules, of any adverse action or investigation against a licensee.
- Conduct FBI fingerprint based criminal background checks of initial applicants and use the results in making licensure decisions concerning the issuance of a privilege to practice.
- Comply with the rules of the Compact Commission.
- Utilize passage of a recognized national exam such as the NCCPA PANCE as a requirement for PA licensure.
- Require continuing education for license renewal.
- Grant the privilege to practice to a holder of a valid, unencumbered license in another member state.
- B. Member states may charge a fee for granting the Privilege to Practice.

A single State license issued to an individual not residing in that State does not confer the Privilege to Practice.

A member state's requirements for issuance of a single-state license are not affected by the terms of this compact.

Section 4. Compact Privilege to Practice

- A. To exercise the Privilege to Practice, a Licensee must:
- 1. Graduate from an accredited PA program.
- 2. Hold current NCCPA Certification.
- 3. Have no felony or misdemeanor convictions.
- 4. Have a social security number or national provider identifier (NPI).
- 5. Hold a license in the Home State which must be a member of the Compact.
- 6. Have no encumbrance on any State license currently held, and no adverse actions against any license or Privilege to Practice within the previous two (2) years.

- 7. Notify the Compact Commission that the licensee is seeking the privilege to practice in a remote State.
- 8. Meet any jurisprudence requirements in the remote state(s) and pay any fees.
- 9. Report to the Commission any adverse action taken by a non-member state within 30 days after the action is taken.
- B. The compact privilege is valid until the expiration of the home state license. The licensee must comply with all the requirements of Section 4. A. above to maintain the compact privilege in the remote state(s).
- C. A licensee providing medical services in a remote state under the privilege to practice shall function within the laws, regulations, and scope of practice of the remote state.
- D. A licensee providing medical services in a remote state is subject to that state's regulatory authority. A remote state may, in accordance with due process and that state's laws, remove a licensee's privilege to practice in the remote state for a specific period of time, impose fines, and/or take any other necessary actions to protect the health and safety of its citizens. The licensee may be ineligible for a privilege to practice in any Compact State until the specific time for removal has passed and all fines are paid.
- E. If a home state license is encumbered, the licensee shall lose the compact privilege in any remote state until the following occur:
 - 1. The home state license is no longer encumbered; and
 - 2. Two (2) years have elapsed from the date of the adverse action.

Section 5. Active-Duty Military Personnel or Their Spouses

Active-Duty Military or Public Health Service Commissioned Corps personnel, or the spouse of such personnel, shall designate a Home State where the individual has a current license in good standing. The individual may retain the Home State designation during the period the service member is on active duty. Subsequent to designating a Home State, the individual shall only change their Home State through application for licensure in the new State.

Section 6. Adverse Actions

- A. A Home State shall have exclusive power to impose adverse action against a PA's license issued by the Home State.
- B. In addition to the other powers conferred by State law, a Remote State shall have the authority, in accordance with existing State due process law, to:
 - 1. Take Adverse Action against a PA's Privilege to Practice within that Member State.
 - 2. Issue subpoenas for both hearings and investigations that require the attendance and testimony of witnesses as well as the production of evidence. Subpoenas issued by a Licensing Board in a Member State for the attendance and testimony of witnesses or the production of evidence from another Member State shall be enforced in the latter State by any court of competent jurisdiction, according to the practice and procedure of that court applicable to subpoenas issued in proceedings pending before it. The issuing authority shall pay any witness fees, travel expenses, mileage and other fees required by the service statutes of the State in which the witnesses or evidence are located.
- C. For purposes of taking Adverse Action, the Home State shall give the same priority and effect to reported conduct received from a Member State as it would if the conduct had occurred within the Home State. In so doing, the Home State shall apply its own State laws to determine appropriate action.
- D. The Home State shall complete any pending investigations of a PA who changes Primary State of Residence during the course of the investigations. The Home State, where the investigations were initiated, shall also have the authority to take appropriate action(s) and shall promptly report the conclusions of the investigations to the PA Licensure Compact Commission Data System. The Data System administrator shall promptly notify the new Home State of any Adverse Actions.

- E. A Member State, if otherwise permitted by State law, may recover from the affected PA the costs of investigations and disposition of cases resulting from any Adverse Action taken against that PA
- F. A Member State may take Adverse Action based on the factual findings of the Remote State, provided that the Member State follows its own procedures for taking the Adverse Action.
- G. Joint Investigations
 - In addition to the authority granted to a Member State by its respective State PA laws and regulations or other applicable State law, any Member State may participate with other Member States in joint investigations of Licensees.
 - 2. Member States shall share any investigative, litigation, or compliance materials in furtherance of any joint or individual investigation initiated under the Compact.
- H. If an Adverse Action is taken by the Home State against a PA's license, the PA's Privilege to Practice in all other Member States shall be deactivated until all encumbrances have been removed from the State license. All Home State disciplinary orders that impose Adverse Action against a PA's license shall include a Statement that the PA's Privilege to Practice is deactivated in all Member States during the pendency of the order.
- I. If a Member State takes Adverse Action, it shall promptly notify the administrator of the Data System. The administrator of the Data System shall promptly notify the Home State of any Adverse Actions by Remote States.
- J. Nothing in this Compact shall override a Member State's decision that participation in an Alternative Program may be used in lieu of Adverse Action.

Section 7. Establishment of the Physician Assistants Licensure Compact Commission

The Compact Member States hereby create and establish a joint public agency known as the

Physician Assistants Licensure Compact Commission:

- 1. The Commission is an instrumentality of the Compact States.
- 2. Venue is proper and judicial proceedings by or against the Commission shall be brought solely and exclusively in a court of competent jurisdiction where the principal office of the

Commission is located. The Commission may waive venue and jurisdictional defenses to the extent it adopts or consents to participate in alternative dispute resolution proceedings.

- 3. Nothing in this Compact shall be construed to be a waiver of sovereign immunity.
- B. Membership, Voting, and Meetings
 - 1. Each Member State shall have and be limited to one (1) delegate selected by that Member State's Licensing Board.
 - 2. The delegate shall be either:
 - a. A current PA member of the Licensing Board, PA Council/Committee, or public member; or
 - b. An administrator of the Licensing Board.
 - 3. Any delegate may be removed or suspended from office as provided by the laws of the State from which the delegate is appointed.
 - 4. The Member State Licensing Board shall fill any vacancy occurring in the Commission within 90 days.
 - 5. Each delegate shall be entitled to one (1) vote with regard to the promulgation of Rules and creation of bylaws and shall otherwise have an opportunity to participate in the business and affairs of the Commission. A delegate shall vote in person or by such other means as provided in the bylaws. The bylaws may provide for delegates' participation in meetings by telephone or other means of communication.
 - 6. The Commission shall meet at least once during each calendar year. Additional meetings shall be held as set forth in the bylaws.
 - 7. The Commission shall establish by Rule a term of office for delegates.
- C. The Commission shall have the following powers and duties:
 - 1. Establish a Code of Ethics for the Commission;
 - 2. Establish the fiscal year of the Commission;
 - 3. Establish bylaws;

- 4. Maintain its financial records in accordance with the bylaws;
- 5. Meet and take such actions as are consistent with the provisions of this Compact and the bylaws;
- Promulgate uniform Rules to facilitate and coordinate implementation and administration of this Compact. The Rules shall have the force and effect of law and shall be binding in all Member States;
- Bring and prosecute legal proceedings or actions in the name of the Commission, provided that the standing of any State PA Licensing Board to sue or be sued under applicable law shall not be affected;
- 8. Purchase and maintain insurance and bonds;
- 9. Borrow, accept, or contract for services of personnel, including, but not limited to, employees of a Member State;
- 10. Hire employees, elect or appoint officers, fix compensation, define duties, grant such individuals appropriate authority to carry out the purposes of the Compact, and establish the Commission's personnel policies and programs relating to conflicts of interest, qualifications of personnel, and other related personnel matters;
- 11. Accept any and all appropriate donations and grants of money, equipment, supplies, materials and services, and receive, utilize and dispose of the same; provided that at all times the Commission shall avoid any appearance of impropriety and/or conflict of interest;
- 12. Lease, purchase, accept appropriate gifts or donations of, or otherwise own, hold, improve or use, any property, real, personal or mixed; provided that at all times the Commission shall avoid any appearance of impropriety;
- 13. Sell, convey, mortgage, pledge, lease, exchange, abandon, or otherwise dispose of any property real, personal, or mixed;
- 14. Establish a budget and make expenditures;
- 15. Borrow money;

- 16. Appoint committees, including standing committees composed of members, State regulators, State legislators or their representatives, and consumer representatives, and such other interested persons as may be designated in this Compact and the bylaws;
- 17. Provide and receive information from, and cooperate with, law enforcement agencies;
- 18. Establish and elect an Executive Committee; and
- 19. Perform such other functions as may be necessary or appropriate to achieve the purposes of this Compact consistent with the State regulation of PA licensure and practice.
- D. The Executive Committee

The Executive Committee shall have the power to act on behalf of the Commission according to the terms of this Compact.

- 1. The Executive Committee shall be composed of nine members:
 - a. Seven voting members who are elected by the Commission from the current membership of the Commission;
 - b. One ex-officio, nonvoting member from a recognized national PA professional association; and
 - c. One ex-officio, nonvoting member from a recognized national PA certification organization.
- 2. The ex-officio members will be selected by their respective organizations.
- 3. The Commission may remove any member of the Executive Committee as provided in bylaws.
- 4. The Executive Committee shall meet at least annually.
- 5. The Executive Committee shall have the following duties and responsibilities:
 - Recommend to the entire Commission changes to the Rules or bylaws, changes to this Compact legislation, fees paid by Compact Member States such as annual dues, and any Commission Compact fee charged to Licensees for the Privilege to Practice;
 - b. Ensure Compact administration services are appropriately provided, contractual or otherwise;

- c. Prepare and recommend the budget;
- d. Maintain financial records on behalf of the Commission;
- e. Monitor Compact compliance of Member States and provide compliance reports to the Commission;
- f. Establish additional committees as necessary; and
- g. Perform other duties as provided in Rules or bylaws.
- E. Meetings of the Commission
 - 1. All meetings shall be open to the public, and public notice of meetings shall be given in the same manner as required under the Rulemaking provisions in Section 10.
 - 2. The Commission or the Executive Committee or other committees of the Commission may convene in a closed, non-public meeting if the Commission or Executive Committee or other committees of the Commission must discuss:
 - a. Non-compliance of a Member State with its obligations under the Compact;
 - The employment, compensation, discipline or other matters, practices or procedures related to specific employees or other matters related to the Commission's internal personnel practices and procedures;
 - c. Current, threatened, or reasonably anticipated litigation;
 - d. Negotiation of contracts for the purchase, lease, or sale of goods, services, or real estate;
 - e. Accusing any person of a crime or formally censuring any person;
 - f. Disclosure of trade secrets or commercial or financial information that is privileged or confidential;
 - g. Disclosure of information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy;
 - h. Disclosure of investigative records compiled for law enforcement purposes;

- i. Disclosure of information related to any investigative reports prepared by or on behalf of or for use of the Commission or other committee charged with responsibility of investigation or determination of compliance issues pursuant to the Compact; or
- j. Matters specifically exempted from disclosure by federal or Member State statute.
- If a meeting, or portion of a meeting, is closed pursuant to this provision, the Commission's legal counsel or designee shall certify that the meeting may be closed and shall reference each relevant exempting provision.
- 4. The Commission shall keep minutes that fully and clearly describe all matters discussed in a meeting and shall provide a full and accurate summary of actions taken, and the reasons therefore, including a description of the views expressed. All documents considered in connection with an action shall be identified in such minutes. All minutes and documents of a closed meeting shall remain under seal, subject to release by a majority vote of the Commission or order of a court of competent jurisdiction.
- F. Financing of the Commission
 - 1. The Commission shall pay, or provide for the payment of, the reasonable expenses of its establishment, organization, and ongoing activities.
 - 2. The Commission may accept any and all appropriate revenue sources, donations, and grants of money, equipment, supplies, materials, and services.
 - 3. The Commission may levy on and collect an annual assessment from each Member State or impose fees on other parties to cover the cost of the operations and activities of the Commission and its staff, which must be in a total amount sufficient to cover its annual budget as approved by the Commission each year for which revenue is not provided by other sources. The aggregate annual assessment amount shall be allocated based upon a formula to be determined by the Commission, which shall promulgate a Rule binding upon all Member States.
 - 4. The Commission shall not incur obligations of any kind prior to securing the funds adequate to meet the same; nor shall the Commission pledge the credit of any of the Member States, except by and with the authority of the Member State.
 - 5. The Commission shall keep accurate accounts of all receipts and disbursements. The receipts and disbursements of the Commission shall be subject to the audit and

accounting procedures established under its bylaws. However, all receipts and disbursements of funds handled by the Commission shall be audited yearly by a certified or licensed public accountant, and the report of the audit shall be included in and become part of the annual report of the Commission.

- G. Qualified Immunity, Defense, and Indemnification
 - The liability of the executive director and employees of the interstate commission or representatives of the interstate commission, acting within the scope of such person's employment or duties for acts, errors, or omissions occurring within such person's state, may not exceed the limits of liability set forth under the constitution and laws of that state for state officials, employees, and agents. The interstate commission is considered to be an instrumentality of the states for the purposes of any such action.
 - 2. The interstate commission shall defend the executive director, its employees, and subject to the approval of the attorney general or other appropriate legal counsel of the member state represented by an interstate commission representative, shall defend such interstate commission representative in any civil action seeking to impose liability arising out of an actual or alleged act, error, or omission that occurred within the scope of interstate commission employment, duties, or responsibilities, or that the defendant had a reasonable basis for believing occurred within the scope of interstate commission may not exceed the limits of liability set forth under the constitution and laws of that state for state officials, employees, and agents and neither expands nor limits the protections under that state's law.
 - 3. To the extent not covered by the state involved, member state, or the interstate commission, the representatives or employees of the interstate commission shall be held harmless in the amount of a settlement or judgment, including attorney's fees and costs, obtained against such persons arising out of an actual or alleged act, error, or omission that occurred within the scope of interstate commission employment, duties, or responsibilities, or that such persons had a reasonable basis for believing occurred within the scope of interstate commission employment, duties, provided that this subdivision may not exceed the limits of liability set forth under the constitution and laws of that state for state officials, employees, and agents and neither expands nor limits the protections under that state's law.

Section 8. Data System

- A. The Commission shall provide for the development, maintenance, and utilization of a coordinated data and reporting system containing licensure, Adverse Action, and Investigative Information on all licensed PAs in Member States.
- B. A Member State shall submit a uniform data set to the Data System on all PAs to whom this Compact is applicable (utilizing a unique identifier) as required by the Rules of the Commission, including:
- 1. Identifying information;
- 2. Licensure data;
- 3. Adverse Actions against a license or Privilege to Practice;
- 4. Non-confidential information related to Alternative Program participation;
- 5. Any denial of application for licensure, and the reason(s) for such denial;
- 6. Other information that may facilitate the administration of this Compact, as determined by the Rules of the Commission; and
- 7. Current Significant Investigative Information.
- C. Current Significant Investigative Information and other Investigative Information pertaining to a Licensee in any Member State will only be available to other Member States.
- D. The Commission shall promptly notify all Member States of any Adverse Action taken against a Licensee or an individual applying for a license. Adverse Action information pertaining to a Licensee in any Member State will be available to any other Member State.
- E. Member States contributing information to the Data System may designate information that may not be shared with the public without the express permission of the contributing State.
- F. Any information submitted to the Data System that is subsequently required to be expunded by the laws of the Member State contributing the information shall be removed from the Data System.

Section 9. Rulemaking

- A. The Commission shall exercise its Rulemaking powers pursuant to the criteria set forth in this Section and the Rules adopted thereunder. Rules and amendments shall become binding as of the date specified in each Rule or amendment.
- B. The Commission shall promulgate reasonable Rules in order to effectively and efficiently achieve the purposes of the Compact. Notwithstanding the foregoing, in the event the Commission exercises its Rulemaking authority in a manner that is beyond the scope of the purposes of the Compact, or the powers granted hereunder, then such an action by the Commission shall be invalid and have no force and effect.
- C. If a majority of the legislatures of the Member States rejects a Rule, by enactment of a statute or resolution in the same manner used to adopt the Compact within 4 years of the date of adoption of the Rule, then such Rule shall have no further force and effect in any Member State.
- D. Rules or amendments to the Rules shall be adopted at a regular or special meeting of the Commission.
- E. Prior to promulgation and adoption of a final Rule or Rules by the Commission, and at least thirty (30) days in advance of the meeting at which the Rule will be considered and voted upon, the Commission shall file a Notice of Proposed Rulemaking:
 - 1. On the website of the Commission or other publicly accessible platform; and
 - 2. On the website of each Member Licensing Board or other publicly accessible platform or the publication in which each State would otherwise publish proposed Rules.
- F. The Notice of Proposed Rulemaking shall include:
 - 1. The proposed time, date, and location of the meeting in which the Rule will be considered and voted upon;
 - 2. The text of the proposed Rule or amendment and the reason for the proposed Rule;
 - 3. A request for comments on the proposed Rule from any interested person; and
 - 4. The manner in which interested persons may submit notice to the Commission of their intention to attend the public hearing and any written comments.

- G. Prior to adoption of a proposed Rule, the Commission shall allow persons to submit written data, facts, opinions, and arguments, which shall be made available to the public.
- H. The Commission shall grant an opportunity for a public hearing before it adopts a Rule or amendment if a hearing is requested by:
 - 1. At least twenty-five (25) persons;
 - 2. A State or federal governmental subdivision or agency; or
 - 3. An association or organization having at least twenty five (25) members.
- I. If a hearing is held on the proposed Rule or amendment, the Commission shall publish the place, time, and date of the scheduled public hearing. If the hearing is held via electronic means, the Commission shall publish the mechanism for access to the electronic hearing.
 - All persons wishing to be heard at the hearing shall notify the executive director of the Commission or other designated member in writing of their desire to appear and testify at the hearing not less than five (5) business days before the scheduled date of the hearing.
 - 2. Hearings shall be conducted in a manner providing each person who wishes to comment a fair and reasonable opportunity to comment orally or in writing.
 - 3. All hearings will be recorded. A copy of the recording will be made available on request.
 - Nothing in this section shall be construed as requiring a separate hearing on each Rule. Rules may be grouped for the convenience of the Commission at hearings required by this section.
- J. Following the scheduled hearing date, or by the close of business on the scheduled hearing date if the hearing was not held, the Commission shall consider all written and oral comments received.
- K. If no written notice of intent to attend the public hearing by interested parties is received, the Commission may proceed with promulgation of the proposed Rule without a public hearing.
- L. The Commission shall, by majority vote of all members, take final action on the proposed Rule and shall determine the effective date of the Rule, if any, based on the Rulemaking record and the full text of the Rule.

- M. Upon determination that an emergency exists, the Commission may consider and adopt an emergency Rule without prior notice, opportunity for comment, or hearing, provided that the usual Rulemaking procedures provided in the Compact and in this section shall be retroactively applied to the Rule as soon as reasonably possible, in no event later than ninety (90) days after the effective date of the Rule. For the purposes of this provision, an emergency Rule is one that must be adopted immediately in order to:
 - 1. Meet an imminent threat to public health, safety, or welfare;
 - 2. Prevent a loss of Commission or Member State funds;
 - 3. Meet a deadline for the promulgation of an administrative Rule that is established by federal law or Rule; or
 - 4. Protect public health and safety.
- N. The Commission or an authorized committee of the Commission may direct revisions to a previously adopted Rule or amendment for purposes of correcting typographical errors, errors in format, errors in consistency, or grammatical errors. Public notice of any revisions shall be posted on the website of the Commission. The revision shall be subject to challenge by any person for a period of thirty (30) days after posting. The revision may be challenged only on grounds that the revision results in a material change to a Rule. A challenge shall be made in writing and delivered to the chair of the Commission prior to the end of the notice period. If no challenge is made, the revision will take effect without further action. If the revision is challenged, the revision may not take effect without the approval of the Commission.

Section 10. Oversight, Dispute Resolution, and Enforcement

A. Oversight

 The executive, legislative, and judicial branches of State government in each Member State shall enforce this Compact and take all actions necessary and appropriate to effectuate the Compact's purposes and intent. The provisions of this Compact and the Rules promulgated hereunder shall have standing as statutory law.

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- All courts shall take judicial notice of the Compact and the Rules in any judicial or administrative proceeding in a Member State pertaining to the subject matter of this Compact which may affect the powers, responsibilities, or actions of the Commission.
- 3. The Commission shall be entitled to receive service of process in any such proceeding and shall have standing to intervene in such a proceeding for all purposes. Failure to provide service of process to the Commission shall render a judgment or order void as to the Commission, this Compact, or promulgated Rules.
- B. Default, Technical Assistance, and Termination
 - If the Commission determines that a Member State has defaulted in the performance of its obligations or responsibilities under this Compact or the promulgated Rules, the Commission shall:
 - a. Provide written notice to the defaulting State and other Member States of the nature of the default, the proposed means of curing the default and/or any other action to be taken by the Commission; and
 - b. Provide remedial training and specific technical assistance regarding the default.
 - 2. If a State in default fails to cure the default, the defaulting State may be terminated from the Compact upon an affirmative vote of a majority of the Member States, and all rights, privileges and benefits conferred by this Compact may be terminated on the effective date of termination. A cure of the default does not relieve the offending State of obligations or liabilities incurred during the period of default.
 - 3. Termination of membership in the Compact shall be imposed only after all other means of securing compliance have been exhausted. Notice of intent to suspend or terminate shall be given by the Commission to the governor, the majority and minority leaders of the defaulting State's legislature, and each of the Member States.
 - 4. A State that has been terminated is responsible for all assessments, obligations, and liabilities incurred through the effective date of termination, including obligations that extend beyond the effective date of termination.
 - 5. The Commission shall not bear any costs related to a State that is found to be in default or that has been terminated from the Compact, unless agreed upon in writing between the Commission and the defaulting State.

- 6. The defaulting State may appeal the action of the Commission by petitioning the U.S. District Court for the District of Columbia or the federal district where the Commission has its principal offices. The prevailing member shall be awarded all costs of such litigation, including reasonable attorney's fees.
- C. Dispute Resolution
 - Upon request by a Member State, the Commission shall attempt to resolve disputes related to the Compact that arise among Member States and between member and non-Member States.
 - 2. The Commission shall promulgate a Rule providing for both mediation and binding dispute resolution for disputes as appropriate.
- D. Enforcement
 - 1. The Commission, in the reasonable exercise of its discretion, shall enforce the provisions and Rules of this Compact.
 - 2. By majority vote, the Commission may initiate legal action in the United States District Court for the District of Columbia or the federal district where the Commission has its principal offices against a Member State in default to enforce compliance with the provisions of the Compact and its promulgated Rules and bylaws. The relief sought may include both injunctive relief and damages. In the event judicial enforcement is necessary, the prevailing member shall be awarded all costs of such litigation, including reasonable attorney's fees.
 - 3. The remedies herein shall not be the exclusive remedies of the Commission. The Commission may pursue any other remedies available under federal or State law.

Section 11. Date of Implementation of the Physician Assistants Compact Commission

A. The Compact shall come into effect on the date on which the Compact statute is enacted into law in the seventh Member State. The provisions, which become effective at that time, shall be limited to the powers granted to the Commission relating to assembly and the promulgation of Rules. Thereafter, the Commission shall meet and exercise Rulemaking powers necessary to the implementation and administration of the Compact.

- B. Any State that joins the Compact subsequent to the Commission's initial adoption of the Rules shall be subject to the Rules as they exist on the date on which the Compact becomes law in that State. Any Rule that has been previously adopted by the Commission shall have the full force and effect of law on the day the Compact becomes law in that State.
- C. Any Member State may withdraw from this Compact by enacting a statute repealing the same.
 - 1. A Member State's withdrawal shall not take effect until six (6) months after enactment of the repealing statute.
 - 2. Withdrawal shall not affect the continuing requirement of the withdrawing State's PA Licensing Board to comply with the investigative and Adverse Action reporting requirements of this act prior to the effective date of withdrawal.
- D. Nothing contained in this Compact shall be construed to invalidate or prevent any PA licensure agreement or other cooperative arrangement between a Member State and a non-Member State that does not conflict with the provisions of this Compact.
- E. This Compact may be amended by the Member States. No amendment to this Compact shall become effective and binding upon any Member State until it is enacted into the laws of all Member States.

Section 12. Construction and Severability

This Compact shall be liberally construed to effectuate the purposes thereof. The provisions of this Compact shall be severable and if any phrase, clause, sentence or provision of this Compact is declared to be contrary to the constitution of any party State or of the United States or the applicability thereof to any government, agency, person or circumstance is held invalid, the validity of the remainder of this Compact and the applicability thereof to any government, agency, person or circumstance shall not be affected thereby. If this Compact shall be held contrary to the constitution of any party State, the Compact shall remain in full force and effect as to the remaining party States and in full force and effect as to all severable matters.

Section 13. Binding Effect of Compact

- A. A Licensee providing medical services under the Privilege to Practice shall function within the laws and regulations of the Remote State.
- B. Nothing herein prevents the enforcement of any other law of a Member State that is not inconsistent with the Compact.
- C. Any laws in a Member State in conflict with the Compact are superseded to the extent of the conflict.
- D. Any lawful actions of the Commission, including all Rules and bylaws promulgated by the Commission, are binding upon the Member States.
- E. All agreements between the Commission and the Member States are binding in accordance with their terms.
- F. In the event any provision of the Compact exceeds the constitutional limits imposed on the legislature of any Member State, the provision shall be ineffective to the extent of the conflict with the constitutional provision in question in that Member State.



SUPPLEMENTAL INFORMATION



Maternal Health Policy Brief November 2020



According to the World Health Organization, maternal mortality declined more than 40% worldwide between 1900 and 2014. During that same period, U.S. maternal mortality rates increased by approximately 26%. The U.S. is the only high resource nation with a consistently rising rate despite spending more money per capita on maternal health than any other country in the world.

In the absence of risk factors such as age over 35 years, lack of health insurance, inadequate or no prenatal care, and less than high school education, Black mothers are experiencing higher rates of pregnancy associated deaths (PADs). Increasing evidence indicates that racism across multiple levels of the U.S. health system not race—is a key cause of these disparities in maternal mortality.

Virginia

In its 2020 Scorecard on maternal health released November 2020, the March of Dimes graded Virginia a "C" on the state's preterm birth rates, which are 54% higher for Black women among all other women.

COVERAGE

Access to Care: Prenatal Care for All Mothers

Virginia's Maternal Mortality Review Team (MMRT) published recommendations in August 2019 to address the results of its review of pregnancy associated deaths.

Their review found that tobacco use was the leading cause of death in cases with chronic conditions (30.5%), followed by complications from previous pregnancies (29.1%), depression (20.1%), and inadequate prenatal care (18%). However, in cases without chronic conditions, a noted shift is inadequate prenatal care was the leading cause (19.9%), followed by previous complications (19.8%) and tobacco use (19.2%).

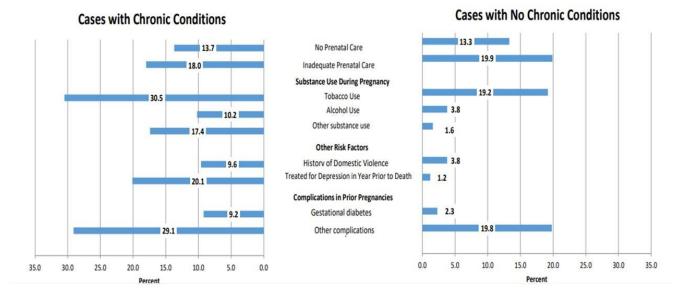
Nearly 70 percent of all women experiencing a pregnancy associated death (PAD) had at least one chronic condition, with a significant number with more than one. The report ranked chronic conditions linked to pregnancy associated deaths. Endocrine disorders were the leading indicator (43.8%), followed by mental illness (35.8%), and substance abuse (29.6%).

The implication of this data reinforces the fundamental impact of prenatal care on the mortality of healthy expectant mothers. According to the Association of Maternal & Child Health Programs, women who do not receive prenatal care are three to four times more likely to die from pregnancy-related complications than those who do receive care. The likelihood is even higher for women with high-risk pregnancies.

The U.S. prenatal care model recommends 13 to 14 visits with an obstetrician or a midwife, starting between weeks eight and 10 of pregnancy. Routine tests during these phases of pregnancy can lead to early detection, treatment, and management of certain medical conditions. Access to prenatal care for all mothers is an essential first step to eliminating racial disparities in maternal health outcomes.

REFERENCES

Virginia Maternal Mortality Review Team Report, "Chronic Disease in Virginia Pregnancy Associated Deaths, 1999-2012: Need for Coordinated Care," August 2019.





Association of Maternal & Child Health Programs, "Opportunities to Optimize Access to Prenatal Care through Health Transformation," September 2016.

Association of Reproductive Health Professionals, "Maternal Mortality in the United States: A Human Rights Failure," March 2011.



Maternal Health Policy Brief November 2020



According to the World Health Organization, maternal mortality declined more than 40% worldwide between 1900 and 2014. During that same period, U.S. maternal mortality rates increased by approximately 26%. The U.S. is the only high resource nation with a consistently rising rate despite spending more money per capita on maternal health than any other country in the world.

In the absence of risk factors such as age over 35 years, lack of health insurance, inadequate or no prenatal care, and less than high school education, Black mothers are experiencing higher rates of pregnancy associated deaths (PADs). Increasing evidence indicates that racism across multiple levels of the U.S. health system not race—is a key cause of these disparities in maternal mortality.

Virginia

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CARE SETTING

Coordination of Care: Cultural Competency & Implicit Bias Training

Virginia's Maternal Mortality Review Team published recommendations in August 2019 to address the results of its review of cases of pregnancy associated deaths.

White women died more frequently, however, the maternal mortality ratio for Black women was significantly higher. Nearly 70 percent of all women experiencing a pregnancy associated death (PAD) had at least one chronic condition, with a significant number with more than one. While nearly 55% of maternal deaths occurred after the 42-day postpartum period, the rate jumps to 62% of women with a chronic condition.

Provider-related factors were the most prevalent contributors to mortality amongst all PADs (51%) and amongst only women with a chronic condition (44%). Examples of the most prevalent provider-related contributors to mortality include "delay in or lack of diagnosis, treatment or follow-up" and "failure to refer or seek consultation." Its recommendations included training to improve clinical standards (screening, management, treatment, intervention, referral) all health care providers licensed by the Board of Medicine and all providers of care to women of childbearing age should be required to receive and maintain. Improving clinical standards should contribute to better overall health outcomes for Black mothers. However, as evidenced by the comprehensive clinical overhaul that the State of California completed to address maternal mortality, clinical interventions and changes may reduce the total number of deaths *but not the disparity* between the mortality percentage rates of Black women and their counterparts. Eliminating disparities that are resulting in Black women dying three to four times more than their counterparts requires addressing cultural competency and implicit bias in health care settings. The following are several biases that research has linked to health care disparities for Black patients and that cultural competency and implicit bias training for health care providers will work to end.

- a. Adultification: When compared to white girls starting at age 5, Black girls are seen to need less protection, need less nurturing, need less support, need less comfort, and are more independent. These perceptions contribute to stereotyping and dismissal of Black adult patients experiencing pain and symptoms at a clinical setting.
- b. Superhumanization: Whites associate magical powers (i.e. ghost, spirit, paranormal) with Black people and therefore do not think that they experience pain.
- c. Scarcity: The perception of the scarcity of resources (real or manipulated) leads to increased discrimination, as evidenced by data showing that faces of mixed-race individuals were seen as Black significant enough to affect the distribution of resources to them. These disparities of allocation widen during economic stress. The data illustrates the socioeconomic context of disparities as relates to clinical treatment.

REFERENCES

Virginia Maternal Mortality Review Team Report, "Chronic Disease in Virginia Pregnancy Associated Deaths, 1999-2012: Need for Coordinated Care," August 2019.

| | Cases Witho | ic Disease | Cases with Chronic Disease | | | |
|-------|-------------|------------|----------------------------|--------|------|-------|
| Race | Number | % | Ratio | Number | % | Ratio |
| White | 97 | 48.3 | 9.2 | 240 | 56.2 | 25.1 |
| Black | 86 | 42.8 | 27.4 | 164 | 38.4 | 51.4 |
| Other | 18 | 8.9 | 14.6 | 23 | 5.4 | 18.6 |

Georgetown Law Center, "Girlhood Interrupted: The Erasure of Black Girl Childhood" report, 2017

Northwestern University (Illinois) and University of Virginia (Charlottesville) "A Superhumanization Bias in Whites' Perceptions of Blacks" research article, October 2014

Next Meeting Date of the Legislative Committee is

September 3, 2021



Please check your calendars and advise staff of any known conflicts that may affect your attendance.



If you are not a state employee, you are eligible for a \$50.00 per diem and reimbursement of your mileage.

The travel regulations require that "travelers must submit the Travel Expense Reimbursement Voucher with 30 days after completion of their trip". (CAPP Topic 20335, State Travel Regulations, p.7)

In order for the agency to be in compliance with the state travel regulations, please submit your request for today's meeting no later than

June 21, 2021

See Co-Co for guidelines on submitting your travel voucher electronically.