Board Meeting of the Virginia Board of Medicine

June 22, 2017
8:30 a.m.

Department of Health Professions

Board of Medicine

Thursday, June 22, 2017 @ 8:30 a.m.
Perimeter Center
9960 Mayland Drive, Suite 201
Board Room 2
Henrico, VA 23233

Other Reports

New Business:

1. Regulatory and Legislative Issues – Dr. Harp and Jennifer Deschenes

VIRGINIA BOARD OF MEDICINE
FULL BOARD MINUTES

February 16, 2017 | Department of Health Professions | Henrico, VA 23233

CALL TO ORDER: Dr. Allison-Bryan called the meeting of the Board to order at 8:40 AM.

ROLL CALL: Mr. Heaberlin called the roll. A quorum was established.

MEMBERS PRESENT:
Barbara Allison-Bryan, MD, President
Kevin O'Connor, MD, Vice-President
Ray Tuck, DC, Secretary-Treasurer
Syed Ali, MD
David Archer, MD
Randy Clements, DPM
Lori Conklin, MD
Alvin Edwards, PhD
David Giammittorio, MD
The Honorable Jasmine Gore
Jane Hickey, JD
Maxine Lee, MD
Wayne Reynolds, DO
David Taminger, MD
Svinder Toor, MD
Kenneth Walker, MD

MEMBERS ABSENT: Isaac Koziol, MD

STAFF PRESENT:
William L. Harp, MD, Executive Director
Jennifer Deschenes, JD, Deputy Executive Director, Discipline
Barbara Matusiak, MD, Medical Review Coordinator
Alan Heaberlin, Deputy Executive Director, Licensing
Colanthia Morton Opher, Operations Manager
Sherry Gibson, Administrative Assistant
David Brown, DC, DHP Director
Elaine Yeatts, DHP Senior Policy Analyst
Erin Barrett, JD, Assistant Attorney General

OTHERS PRESENT:
Scott Johnson, JD, MSV
Lauren Bates-Rowe, MSV
Claudette Dalton, MD, FSMB
Lisa Robin, Vice-President, FSMB
Steven Heretick, JD, FSMB
Shiri Hickman, JD, FSMB
Thomas Reach, MD, Watauga Recovery Center

Mercer May, AATOD
Ed Ohlinger, AATOD
David Cassise, AATOD
Nick Reuter, Indivior
Cheri Lindberg, MD, Indivior
Hannah Newman, VCU
Timothy Bunton, MD, Virginia Addiction Treatment Access Coalition
Carey Cox, VATAC
Joel Andrus, US Oncology
Hughes Melton, MD, Virginia Department of Health
Sara Heisler, VHHA
Brad Bachman, American Society of Addiction Medicine
Debra O'Beirne, MD, Fairfax County CSB and VaSAM
Peter Breslin, MD, VA Addiction Treatment Access Coalition
Julie Galloway, MSV
Cal Whitehead, Commonwealth Strategy Group
Dave Garland

EMERGENCY EGRESS PROCEDURES

Dr. O'Connor provided the emergency egress procedures for Conference Room 2.

APPROVAL OF THE OCTOBER 20, 2016 MINUTES

Dr. Tuck moved to accept the minutes of October 20, 2016 as written. The motion was seconded and carried unanimously.

ADOPTION OF THE AGENDA

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

PUBLIC COMMENT ON AGENDA ITEM

Scott Johnson, MSV
Mercer May
Nick Reuter
Timothy Bunton, MD
Hughes Melton, MD
Debra O'Beirne, MD
Peter Breslin, MD
Dave Garland

DHP DIRECTOR'S REPORT

Dr. Brown took the opportunity to thank all who had contributed to the development of the opioid regulations that the Board would be discussing later in the meeting. He had high praise for Dr. Allison-Bryan and Dr. O'Connor whose leadership has been key to this effort.

FSMB PRESENTATION

Steve Heretick, JD of the Federation of State Medical Boards (FSMB) introduced the FSMB colleagues accompanying him, Claudette Dalton, MD, Lisa Robin, VP and Shiri Hickman, JD. Mr. Heretick provided an overview of the history of the FSMB. The FSMB is a 503(c)(6) corporation now over 100 years old. It is located in Euless, TX and also has an office for advocacy in Washington, DC. The FSMB is made up of over 70 member boards. It is striving to become a voice in international medicine as it continues to be an advocate and educator for state medical boards.

Lisa Robin also contributed to the presentation. She has been at the Federation for 25 years. FSMB continues to grow and offer more services to state medical boards, physicians, and the public. It has continued to enhance its comprehensive and unique physician database. This database is created from numerous sources including individual state boards, the National Commission on Certification of Physician Assistants, medical specialty boards, the National Board of Medical Examiners, NPI data and the Social Security death master file. This Information is used in support of disciplinary alerts and verifications. Key elements of this data include individual board disciplinary information, USMLE scores and attempts, American Board of Medical Specialties and American Osteopathic Association board certifications.

Ms. Robin reviewed the 2016 Medical Regulatory Trends and Actions. This included an overview of DOCINFO, a service launched in August that provides the public with the ability to search for a doctor's public disciplinary action.

She invited all to attend the FSMB Annual Meeting April 20-22, 2017 in Fort Worth. The FSMB is now recognized as an accredited CME provider.

She provided a Policy and Advocacy Update, noting new opioid guidelines, new white papers regarding "Duty to Report" and "Compounding of Drugs by Physicians", and several workgroups including "Telemedicine Consultation" and "Marijuana & Medical Regulation."

Ms. Robin reviewed the key principles of the Interstate Medical Licensure Compact. The Compact has been adopted in 18 states, and 6 other states have introduced legislation. The Compact is a voluntary program for physicians and state boards. The Compact will begin processing licenses in the next week or two.

Dr. O'Connor asked Ms. Robin if she could explain the difference between "licensure by compact" and "licensure by endorsement." Ms. Robin noted that licensure by compact is very similar to licensure by endorsement. There are certain qualifiers that must be verified by a physician's home state. Once these qualifiers have been verified, the home state will send a "letter of qualification" to the board of the state in which the applicant is seeking licensure.

It should be noted that Mr. Heretick was very complimentary of the Virginia Board of Medicine and the work it has done over the years.

REPORT OF OFFICERS AND EXECUTIVE DIRECTOR

PRESIDENT'S REPORT

Dr. Allison-Bryan reported on her attendance at the Council of State Governments on Interstate Compacts meeting in December 2016. She noted that this meeting was about interstate compacts in general. She then explained that the intent of the Interstate Medical Licensure Compact is to enhance license portability, provide greater access to care for patients, and support the practice of telemedicine. She said the Board's Legislative Committee thoroughly reviewed the Interstate Medical Licensure Compact in 2016. She further noted that the Board has the authority to promulgate regulations to expedite the licensing process and has proposed regulations for licensure by endorsement. She stated that compacts are a contract and supersede state laws. She ended by saying that one issue the Virginia Board has with the Interstate Medical Licensure Compact is that it requires all complaints to be reported to the Commission. This requirement conflicts with current Virginia statute regarding the confidentiality of complaint information.

VICE-PRESIDENT'S REPORT

Dr. O'Connor thanked Dr. Walker and his workgroup for their efforts in completing the proposed guidance document on the use of buprenorphine for office-based treatment of opioid addiction.

SECRETARY-TREASURER'S REPORT

Dr. Tuck did not have a report.

EXECUTIVE DIRECTOR'S REPORT

- Revenue and Expenditures Report

Dr. Harp gave an updated financial report covering the first two quarters of FY2017, as well as the Board's cash position. The Board had an $11,685,000 on December 31, 2016.

Dr. Harp said the Board is in good shape in regards to its FY2017 budget and expenditures. So far this year the Board's direct expenditures have been $1.5 million dollars. The largest allocated expenditures have been the Enforcement Division, DATA, the Administrative Proceedings Division and Finance.

This report was for informational purposes only and did not require any action.

- Patient Care Disciplinary Case Processing Times

Dr. Harp covered the performance reports for DHP and the Board of Medicine. In the second quarter

of FY2017, the Board's case clearance rate was 95%. Cases older than 250 days were down to 14%. Due to the great efforts of the Board members and Dr. Matusiak, the percentage of cases closed in less than 250 days was 95%. The median time for closure of patient care cases during the second quarter was 6 days.

- Health Practitioners Monitoring Program (HPMP) The Monitoring Program Committee took the following actions January 27, 2017 on Board of Medicine licensees and applicants: one respiratory therapist stay vacated, one physician dismissed/deemed ineligible, and one occupational therapy assistant dismissed due to resignation. Three physicians and one athletic trainer successfully completed the program. The Board of Medicine currently has 107 licensees/applicants in HPMP, which is approximately 25% of the total HPMP participants.

This report was for informational purposes only and did not require any action.

COMMITTEE AND ADVISORY BOARD REPORTS

- Committee Appointments and Advisory Board Reports

Dr. Reynolds moved to accept the minutes en bloc. The motion was seconded and carried unanimously.

OTHER REPORTS

Assistant Attorney General

Ms. Barrett provided an update on the status of several Board appeals.

Board of Health Professions

Dr. Allison-Bryan had no report as BHP's last meeting in December was cancelled.

Podiatry Report

Dr. Clements had no report.

Chiropractic Report

Dr. Tuck had no report.

Committee of the Joint Boards of Nursing and Medicine

The December 7, 2016 minutes were included in the packet.

NEW BUSINESS

1. REGULATORY AND LEGISLATIVE ISSUES

- Chart of Regulatory Actions

Ms. Yeatts reviewed the chart on the status of regulations for the Board as of February 15, 2017.

This report was for informational purposes only and did not require any action by the Board.

- Report of 2017 General Assembly

Ms. Yeatts reviewed the following bills currently pending in the Virginia General Assembly:

- HB 1484 Occupational therapists: Board of Medicine shall amend regulations governing licensure;
- HB 2164 Drugs of concern; drug of concern;
- SB 880 Genetic counselors; licensing; grandfather clause;
- SB 1009 Telemedicine, practice of; prescribing controlled substances;
- SB 1027 Cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide;
- SB 1046 Board of Medicine; requirements for licensure;
- SB 1178 Buprenorphine without naloxone; prescription limitations;
- SB 1180 Opioids and buprenorphine; Boards of Dentistry and Medicine to adopt regulations for prescribing;
- SB 1403 Cannabidiol; Board of Pharmacy to deschedule or reschedule upon certain publication;

- **Guidance Document 90-56 (Nurse Practitioner Practice Agreements)**

  Ms. Yeatts reviewed the guidance document and noted revisions made by the Board of Nursing (BON) at their meeting on January 24, 2017. Ms. Yeatts explained that the Board of Medicine needs to either approve the changes made or recommend further revisions to send back to the BON.

  Dr. Walker moved to adopt Guidance Document 90-56 as presented. The motion was seconded and carried unanimously.

- **Regulatory Action on Pain Management and Prescribing Buprenorphine**

  Ms. Yeatts explained that the proposed regulations for review by the Board were emergency regulations. She explained the process of implementing emergency regulations and the process by which they will move from emergency regulations to final regulations. She then led the Board

through the review of the proposed regulations for any suggested edits, deletions, additions and revisions.

Section 18VAC85-21-10 Applicability. This section was approved with no revisions.

Section 18VAC85-21-20. Definitions. This section was approved with no revisions.

Section 18VAC85-21-30. Evaluation of the acute pain patient.

Dr. Toor asked if the PMP must be checked if the physician is planning to prescribe for more than 7 days. Ms. Yeatts stated "yes", that is what is required by the Code.

The section was approved with no revisions.

Section 18VAC85-21-40. Treatment of acute pain with opioids.

Dr. Archer stated he did not believe the last sentence in this section is needed. Dr. Allison-Bryan noted that the last sentence was included to assist emergency room practitioners. There was a brief discussion among the Board members about whether to include "urgent care centers" in this section. Dr. Allison-Bryan stated that she believed it was not necessary to add "urgent care centers."

Regarding section 18VAC85-21-40(2), Dr. Lee asked if another prescription after could be written after the first 14 days.

Dr. Allison-Bryan stated that the rationale for writing a second prescription should be documented in the treatment record.

Dr. O'Connor noted that documentation was a key element of these regulations. Since the Board is charged with enforcing them, documentation is essential to the Board's task of determining whether the standard of care was met or not.

Regarding section 18VAC85-21-40(D), Dr. Archer stated that he did not believe this section was needed but would defer to the Board.

Scott Johnson quickly noted that MSV withdrew its objection to this section.

Dr. Melton noted that ASAM's guidelines note that in some instances buprenorphine may be used in the treatment of pain.

Dr. Archer asked if these regulations allowed buprenorphine to be used for other purposes, and that this section appeared to be restricting a physician's ability to prescribe.

Dr. Allison-Bryan stated that the purpose of the regulations was to assist physicians in treating opioid-dependent patients and to provide the Board with a tool to discipline physicians whose practices do not meet the standard of care.

This section as approved with the proposed staff revisions.

Section 18VAC85-21-50. Medical records for acute pain. This section was approved with the proposed staff revisions.

Section 18VAC85-21-60. Evaluation of the chronic pain patient.

This section was approved with the proposed staff revisions.

Section 18VAC85-21-70. Treatment of chronic pain with opioids.

Dr. Allison-Bryan noted that the second and third sentences of section 18VAC85-21-70(C) should be removed because they may be better suited for a guidance document. Dr. Brown agreed that a focused guidance document may be helpful and that the language under consideration of striking does track the language in other guidance documents.

Dr. Walker noted that subsection C states that buprenorphine may be prescribed for chronic pain but there was no mention of the mono-product. Dr. Melton stated that there is only one FDA-approved mono-product for pain that is not likely to be abused.

The Board requested that the second two sentences of 18VAC85-21-70(C) be removed and approved the rest of the section with the proposed staff revisions.

Section 18VAC85-21-80. Treatment plan for chronic pain. This section was approved with the proposed staff revisions.

Section 18VAC85-21-90. Informed consent and agreement for treatment for chronic pain. This section was approved with the proposed staff revisions.

18VAC85-21-100. Opioid therapy for chronic pain.

Dr. O'Connor noted that the language in subsection (D) requiring a urine drug screen or serum medication level at the initiation of chronic pain management and every three months for the first year of treatment may be burdensome. Dr. Allison-Bryan requested the term "annually" in section (D) be changed to "every six months."

Regarding subsection (E), Dr. Archer asked for clarification regarding the clause at the end of the section "treatment if indicated."

Dr. Melton replied that the treatment indicated would include options to refer the patient elsewhere.

Dr. Ali stated that once a patient presents with opioid addiction, the patient would be referred for treatment.

Dr. Walker asked for a clear definition of "opioid use disorder." Dr. Melton responded that opioid use disorder is when the opioid is being used for a purpose other than how it was intended to be used.

The section was approved with the proposed Board and staff revisions.

18VAC85-21-120. Medical records for chronic pain. This section as approved with the proposed staff revisions.

18VAC85-21-130. General provisions pertaining to prescribing of buprenorphine for addiction treatment.

Dr. Walker asked why "a licensed mental health provider" had been revised to "an appropriate mental health provider."

Dr. Allison-Bryan responded that there were not enough licensed mental health providers who treat addiction. However, there are several health care professions which are not licensed, but are able to provide appropriate treatment.

Ms. Yeatts suggested that the language, "shall refer the patient to an appropriate mental health service provider as defined in 54.1-2400.1" may satisfy the Board's concern.

The Board agreed and approved this section with the proposed staff revisions.

18VAC85-21-140. Patient assessment and treatment planning or addiction treatment. This section was approved with the proposed staff revisions.

18VAC85-21-150. Treatment with buprenorphine for addiction treatment.

The Board discussed whether to strike or maintain item number 3 in subsection (A). Dr. Melton stated that he supported this item. Dr. Harp noted that "opiate treatment programs" in subsection (B) should be edited to say "opioid treatment programs." Language in subsection (I) was revised to coincide with the revision made in subsection (D) of 18VAC85-21-100. This section was approved with the proposed staff revisions.

18VAC85-21-160. Special populations in addiction treatment. This section was approved with no revisions.

18VAC85-21-170. Medical records for opioid addiction treatment. This section was approved with no revisions.

Dr. Reynolds moved to approve the proposed "*Regulations Governing Opioid Prescribing for Pain and Prescribing of Buprenorphine.*"

The motion was seconded and carried unanimously.

Licensing Report

Mr. Heaberlin provided a report on applications received and licenses issued. This report was for informational purposes only.

Discipline Report

Ms. Deschenes provided an update on case review. This report was for informational purposes only.

Appointment of a Nominating Committee

Dr. Allison-Bryan asked for volunteers to serve on the Nominating Committee to develop a slate of officers for the June Board's consideration. She appointed volunteers Jane Hickey, Deborah DeMoss Fonseca, Dr. Kenneth Walker, and as Chair, Dr. Wayne Reynolds.

Announcements

There were no announcements.

ADJOURNMENT

Dr. Allison-Bryan adjourned the meeting at 12:30 p.m.

Barbara Allison-Bryan, MD
President, Chair

William L. Harp, MD
Executive Director

Alan Heaberlin
Recording Secretary

Virginia's Physician Workforce: 2016

Healthcare Workforce Data Center

January 2017

Virginia Department of Health Professions
Healthcare Workforce Data Center
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233
804-367-2115, 804-527-4466(fax)
E-mail: ***HWDC@dhp.virginia.gov***

Follow us on Tumblr: ***www.vahwdc.tumblr.com***

31,504 Physicians voluntarily participated in this survey. *Without their efforts the work of the center would not be possible. The Department of Health Professions, the Healthcare Workforce Data Center, and the Board of Medicine express our sincerest appreciation for your ongoing cooperation.*

Thank You!

Virginia Department of Health Professions

David E. Brown, D.C.
Director

Lisa R. Hahn, MPA
Chief Deputy Director

Healthcare Workforce Data Center Staff:

Dr. Elizabeth Carter, Ph.D.	*Yetty Shobo, Ph.D.*	Laura Jackson	Christopher Coyle
Executive Director	*Deputy Director*	*Operations Manager*	*Research Assistant*

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Norfolk

Kenneth Walker, MD
Pearisburg

Executive Director

William L. Harp, MD

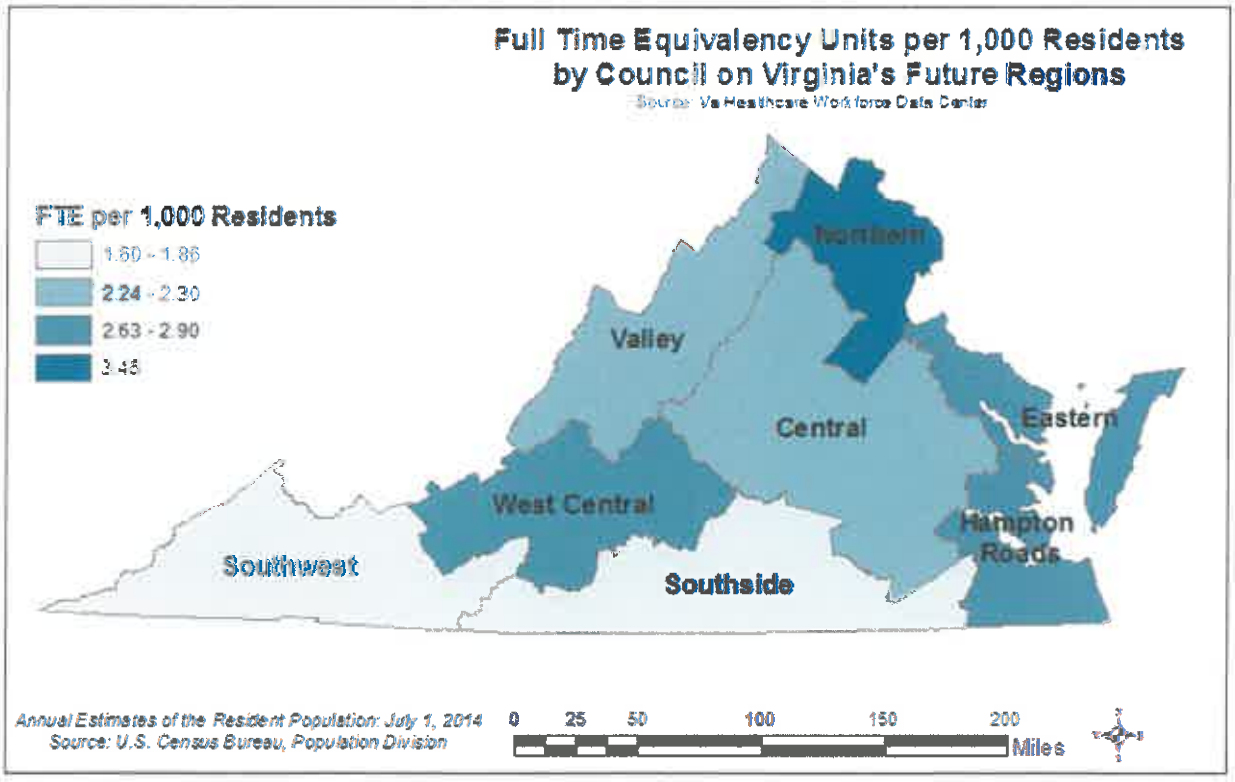
Contents

At a Glance

The Physician Workforce: At a Glance:

The Workforce		Background		Current Employment	
Licensees:	43,089	Rural Childhood:	18%	Employed in Prof.:	95%
Virginia's Workforce:	25,060	Med. School in VA:	21%	Hold 1 Full-time Job:	70%
FTEs:	25,389	Residency in VA:	27%	Satisfied?:	93%
Survey Response Rate		**Top Certifications**		**Job Turnover**	
All Licensees:	73%	Internal Medicine:	28%	Switched Jobs in 2016:	5%
Renewing Practitioners:	86%	Family Medicine:	15%	Employed over 2 yrs:	72%
Demographics		**Finances**		**Primary Roles**	
% Female:	37%	Median Inc.:	$200k-$225k	Patient Care:	83%
Diversity Index:	53%	Health Benefits:	68%	Administration:	5%
Median Age:	51	Median Ed Debt:	$0k	Education:	1%

Source: Va Healthcare Workforce Data Center



Results in Brief

31,504 physicians voluntarily took part in the 2016 Physician Workforce Survey. The Virginia Department of Health Professions' Healthcare Workforce Data Center (HWDC) administers the survey during the license renewal process, which takes place on a respondent's birth month during even-numbered years for physicians. These survey respondents represent 73% of the 43,089 physicians who are licensed in the state and 86% of renewing practitioners.

The HWDC estimates that 25,060 physicians participated in Virginia's workforce during the survey period, which is defined as those who worked at least a portion of the year in the state or who live in the state and intend to return to work in the profession at some point in the future. Virginia's physician workforce provided 25,389 "full-time equivalency units" during the survey time period, which the HWDC defines simply as working 2,000 hours a year (or 40 hours per week for 50 weeks with 2 weeks off).

37% of all physicians are female, although this percentage increases to 51% among physicians who are under the age of 40. Overall, the median age of the physician workforce is 51. In a random encounter between two physicians, there is a 53% chance that they would be of different races or ethnicities, a measure known as the diversity index. This percentage is just slightly below the statewide average of 55%. Meanwhile, the physician workforce who are under the age of 40 is actually more diverse than Virginia's overall population.

18% of all physicians grew up in a rural area, but only 15% of these professionals currently work in non-Metro areas of the state. Overall, just 7% of Virginia's physicians work in non-Metro areas of the state. 21% of the physician workforce went to medical school in Virginia, while 27% undertook their initial residency in the state.

Virginia Commonwealth University, the University of Virginia, and the Eastern Virginia Medical School were the three most common medical schools attended by Virginia's physician workforce. The majority of all physicians carry no educational debt. However, the median debt load among those professionals who are under the age of 40 is between $70,000 and $80,000.

95% of physicians are currently employed in the profession, and involuntary unemployment is nearly nonexistent at the moment. Nearly three-quarters of Virginia's physicians hold one full-time position, while another 13% hold multiple positions. 72% of physicians have been at their primary work location for at least two years, while 15% of all physicians started work at a new location at some point in the past year.

The median annual income for Virginia's physician workforce is between $200,000 and $225,000. 63% of Virginia's physician workforce receives a salary at their primary work location, while 19% earn their income from the proceeds of their own business or practice. 93% of physicians indicated they are satisfied with their current employment situation, including 61% who indicated they are "very satisfied".

54% of all physicians work at a for-profit establishment, while 10% work for the federal government. Group private practices currently employ 38% of all physicians in Virginia, the most of any establishment type in the state. The inpatient departments of hospitals (15%) and solo private practices (12%) are also common establishment types for Virginia's physician workforce.

83% of all physicians serve a patient care role, meaning that they spend at least 60% of their time in this activity. The typical physician treats approximately 50 to 75 patients per week at their primary work location, and 59% of all physicians are currently accepting new patients at their primary work location.

One-third of all physicians expect to retire by the age of 65. 8% of the current workforce expects to retire in the next two years, while half of the current workforce expects to retire by 2036. Over the next two years, just 1% of all physicians expect to leave the profession, and 3% expect to leave the state to practice medicine elsewhere. Meanwhile, 9% of Virginia's physician workforce expects to increase patient care within the next two years, and 4% expect to pursue additional educational opportunities.

Summary of Trends

There were very few changes in survey results in the 2016 survey compared to the 2014 survey. However, there was a significant increase in the number and percent of survey respondents, indicating more physicians are seeing the value in this report. Virginia's licensed physicians and workforce also increased; there were 1,046 more licensed physicians in 2016 and 855 more physicians in the workforce. Although there are more licensed physicians, slightly lower full time equivalency (FTE) units were reported. 25,704 FTEs were reported in 2014 compared to 25,389 FTEs reported in 2016. This decline is due to slightly lower hours of work reported by physicians in the survey. For example, 15% of physicians reported working 60 to 69 hours in 2016 compared to 16% in the 2014 survey.

The most recent survey results also indicate there is slightly more gender and racial diversity in Virginia's physician population. The percent of physicians that was female increased from 36% to 37%, a trend that is likely to continue as females become the majority in the field in the future as indicated by physicians under age 40 who are 51% female. The racial and ethnic diversity index also increased from 51% to 53% for all physicians although it dropped slightly from 60% to 59% for those under age 40.

The educational and rural background results were nearly identical in both surveys. However, slightly more physicians reported certification. For example, the percent reporting certification in Internal Medicine increased from 23% in 2014 to 28% in 2016.

The median income increased slightly for physicians; the median income was $175k-$200k in the 2014 survey whereas it was $200k to $225k in the 2016 survey. Although the median income increased, there was a 1% drop in the percent of physicians who reported they were at least satisfied with their current employment situation. A slightly higher percent of physicians reported working in the non-profit sector; 28% work in the non-profit sector in 2016 compared to 26% in 2014.

The geographical distribution of physicians was very similar in the two surveys. Additionally, retirement and future plans of physicians were very similar in both surveys.

Survey Response Rates

A Closer Look:

Licensees		
License Status	**#**	**%**
Renewing Practitioners	36,640	85%
New Licensees	2,444	6%
Non-Renewals	4,005	9%
All Licensees	**43,089**	**100%**

Source: Va. Healthcare Workforce Data Center

HWDC surveys tend to achieve very high response rates. 86% of renewing physicians submitted a survey. These represent 73% of physicians who held a license at some point in 2016.

Response Rates	
Completed Surveys	31,504
Response Rate, all licensees	73%
Response Rate, Renewals	86%

Source: Va. Healthcare Workforce Data Center

Response Rates			
Statistic	**Non Respondents**	**Respondent**	**Response Rate**
By Age			
Under 35	1,871	1,647	47%
35 to 39	1,942	3,711	66%
40 to 44	1,432	4,218	75%
45 to 49	1,209	4,415	79%
50 to 54	995	3,992	80%
55 to 59	975	3,826	80%
60 to 64	958	3,919	80%
65 and Over	2,203	5,776	72%
Total	**11,585**	**31,504**	**73%**
New Licenses			
Issued in 2016	2,444	0	0%
Metro Status			
Non-Metro	428	1,423	77%
Metro	5,520	18,221	77%
Not in Virginia	5,636	11,853	68%

Source: Va. Healthcare Workforce Data Center

Definitions

1. **The Survey Period:** The survey was conducted throughout 2016 on the birth month of each respondent.
2. **Target Population:** All physicians who held a Virginia license at some point in 2016.
3. **Survey Population:** The survey was available to physicians who renewed their license online. It was not available to those who did not renew, including physicians newly licensed in 2016.

At a Glance:

Workforce

2016 Physician Workforce:	25,060
FTEs:	25,389

Utilization Ratios

Licensees in VA Workforce:	58%
Licensees per FTE:	1.70
Workers per FTE:	0.99

Source: Va. Healthcare Workforce Data Center

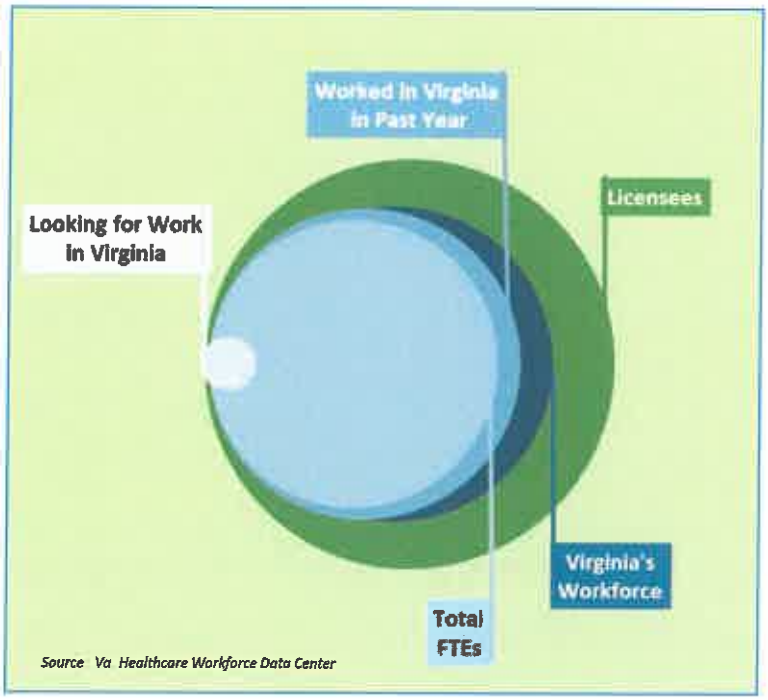
Definitions

1. **Virginia's Workforce:** A licensee with a primary or secondary work site in Virginia at any time in the past year or who indicated intent to return to Virginia's workforce at any point in the future.
2. **Full Time Equivalency Unit (FTE):** The HWDC uses 2,000 (40 hours for 50 weeks) as its baseline measure for FTEs.
3. **Licensees in VA Workforce:** The proportion of licensees in Virginia's Workforce.
4. **Licensees per FTE:** An indication of the number of licensees needed to create 1 FTE. Higher numbers indicate lower licensee participation.
5. **Workers per FTE:** An indication of the number of workers in Virginia's workforce needed to create 1 FTE. Higher numbers indicate lower utilization of available workers.

Virginia's Physician Workforce		
Status	**#**	**%**
Worked in Virginia in Past Year	24,775	99%
Looking for Work in Virginia	285	1%
Virginia's Workforce	**25,060**	100%
Total FTEs	**25,389**	
Licensees	**43,089**	

Source: Va. Healthcare Workforce Data Center

This report uses weighting to estimate the figures in this report. Unless otherwise noted, figures refer to the Virginia Workforce only. For more information on HWDC's methodology visit: www.dhp.virginia.gov/hwdc



A Closer Look:

Age & Gender						
Age	Male		Female		Total	
	#	% Male	#	% Female	#	% in Age Group
Under 35	809	49%	830	51%	1,639	7%
35 to 39	1,559	49%	1,651	51%	3,209	14%
40 to 44	1,705	53%	1,496	47%	3,201	14%
45 to 49	1,732	57%	1,287	43%	3,020	13%
50 to 54	1,633	61%	1,033	39%	2,666	12%
55 to 59	1,713	67%	839	33%	2,551	11%
60 to 64	1,900	73%	718	27%	2,618	11%
65 +	3,283	84%	642	16%	3,924	17%
Total	**14,332**	**63%**	**8,497**	**37%**	**22,829**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Gender

% Female:	37%
% Under 40 Female:	51%

Age

Median Age:	51
% Under 40:	21%
% 55+:	40%

Diversity

Diversity Index:	53%
Under 40 Div. Index:	59%

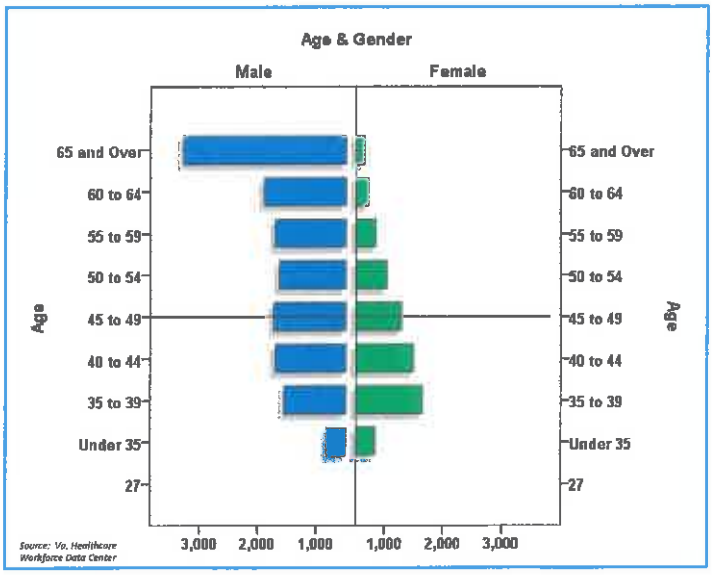
Race & Ethnicity					
Race/ Ethnicity	Virginia*	Physicians		Physicians Under 40	
	%	#	%	#	%
White	63%	14,797	66%	2,836	59%
Black	19%	1,652	7%	351	7%
Asian	6%	3,989	18%	1,048	22%
Other Race	0%	870	4%	227	5%
Two or more races	2%	341	2%	124	3%
Hispanic	9%	813	4%	188	4%
Total	**100%**	**22,461**	**100%**	**4,774**	**100%**

*Population data in this chart is from the US Census, ACS 1-yr estimates, 2011 vintage.

Source: Va. Healthcare Workforce Data Center

In a chance encounter between two physicians, there is a 53% chance that they would be of a different race/ethnicity (a measure known as the diversity index). For Virginia's population as a whole, the comparable number is 55%.

21% of all physicians are under the age of 40, and more than half of these professionals are female. In addition, there is a 59% chance that two randomly chosen physicians from this group would be of a different race or ethnicity.



At a Glance:

Childhood

Urban Childhood:	25%
Rural Childhood:	18%

Virginia Background

HS in Virginia:	21%
Med. School in VA:	21%
Init. Residency in VA:	27%

Location Choice

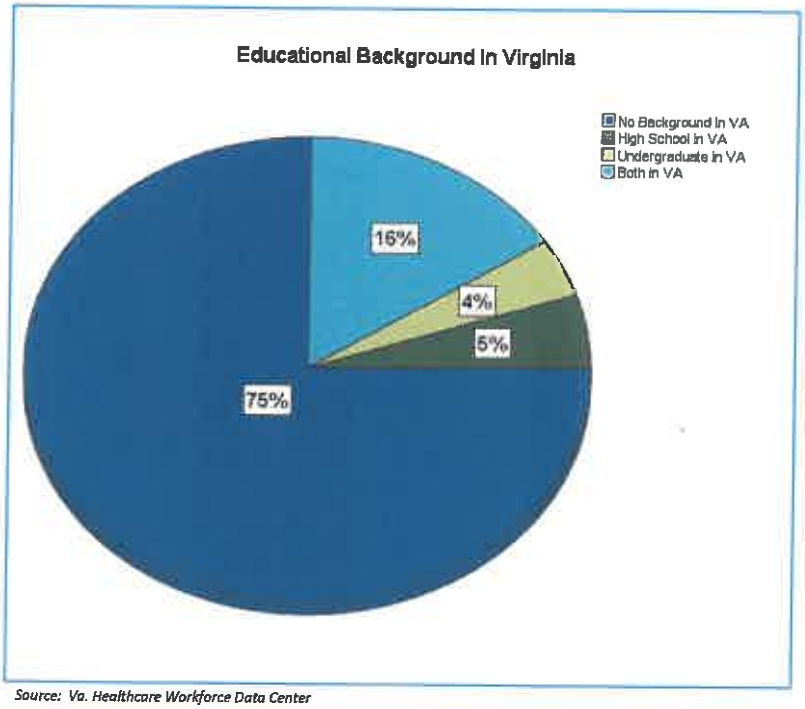
% Rural to Non-Metro:	15%
% Urban/Suburban to Non-Metro:	6%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Primary Location: USDA Rural Urban Continuum		Rural Status of Childhood Location		
Code	Description	Rural	Suburban	Urban
	Metro Counties			
1	Metro, 1 million+	14%	59%	26%
2	Metro, 250,000 to 1 million	25%	51%	24%
3	Metro, 250,000 or less	22%	58%	20%
	Non-Metro Counties			
4	Urban pop 20,000+, Metro adj	29%	45%	26%
6	Urban pop, 2,500-19,999, Metro adj	33%	44%	23%
7	Urban pop, 2,500-19,999, nonadj	42%	35%	23%
8	Rural, Metro adj	36%	42%	23%
9	Rural, nonadj	32%	40%	28%
	Overall	**18%**	**57%**	**25%**

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

18% of physicians grew up in self-described rural areas, and 15% of these professionals currently work in Non-Metro counties. Overall, 7% of Virginia's physician workforce work in non-metro counties of the state.

Top Ten States for Physician Recruitment

Rank	All Physicians			
	Medical School	#	Initial Residency	#
1	Virginia	4,551	Virginia	5,828
2	Outside U.S./Canada	4,447	Washington, D.C.	2,056
3	Pennsylvania	1,496	New York	2,000
4	Washington, D.C.	1,273	Pennsylvania	1,493
5	New York	1,256	Maryland	1,151
6	Maryland	891	North Carolina	920
7	North Carolina	745	Ohio	740
8	Ohio	552	California	675
9	Illinois	514	Michigan	528
10	Texas	449	Texas	518

Source: Va. Healthcare Workforce Data Center

21% of physicians went to medical school in Virginia, while 27% completed their initial residency in the state.

Among physicians who have been licensed in the past five years, 16% received their medical degree in Virginia, while 27% completed their initial residency in the state.

Rank	Licensed in the Past 5 Years			
	Medical School	#	Initial Residency	#
1	Outside U.S./Canada	1,139	Virginia	1,322
2	Virginia	795	New York	467
3	Pennsylvania	363	Pennsylvania	365
4	Maryland	238	Washington, D.C.	325
5	New York	227	Maryland	277
6	Washington, D.C.	219	North Carolina	198
7	North Carolina	154	Ohio	192
8	Texas	136	Texas	152
9	Illinois	135	Michigan	148
10	Ohio	129	California	144

Source: Va. Healthcare Workforce Data Center

42% of licensed physicians did not participate in Virginia's workforce in 2016. 94% of these physicians worked at some point in the past year, including 91% who currently work as physicians.

At a Glance:

Not in VA Workforce

Total:	18,063
% of Licensees:	42%
Federal/Military:	29%
VA Border State/DC:	20%

A Closer Look:

Medical Schools		
School	#	%
Virginia Commonwealth	2,385	12%
University of Virginia	1,527	8%
Eastern VA Medical School	1,088	6%
Georgetown University	622	3%
George Washington Univ.	548	3%
Uniformed Services Univ. of the Health Sciences	482	2%
Drexel University	347	2%
University of Maryland	346	2%
Jefferson Medical College	318	2%
University of North Carolina	283	1%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Top Medical Schools

VCU:	12%
UVA:	8%
East. Va. Med. School:	6%

Top Certifications

Internal Medicine:	28%
Family Medicine:	15%
Surgery:	14%

Source: Va. Healthcare Workforce Data Center

Over two-thirds of physicians do not carry any educational debt. For those with debt, median is $100K to $110K. However, among physicians who are under the age of 40, two-thirds do. Their median debt burden is between $70,000 and $80,000.

Educational Debt				
Amount Carried	All Physicians		Physicians under 40	
	#	%	#	%
None	12,915	70%	1,309	33%
$50,000 or less	1,389	8%	427	11%
$50,001-$100,000	1,154	6%	440	11%
$100,001-$150,000	951	5%	415	11%
$150,001-$200,000	751	4%	408	10%
$200,001-$250,000	599	3%	406	10%
More than $250,000	727	4%	524	13%
Total	18,485	100%	3,929	100%

Source: Va. Healthcare Workforce Data Center

Board Certifications		
Area	#	%
Internal Medicine	5,975	28%
Family Medicine	3,236	15%
Surgery[1]	3,041	14%
Pediatrics	2,530	12%
Psychiatry/Neurology	1,680	8%
Emergency Medicine	1,293	6%
Obstetrics/Gynecology	1,080	5%
Anesthesiology	1,073	5%
Radiology	1,051	5%
Ophthalmology	468	2%
At Least One Credential	21,272	85%

Source: Va. Healthcare Workforce Data Center

Over one-quarter of Virginia's physician workforce holds a board certification in Internal Medicine. Overall, 85% of Virginia's physician workforce holds at least one board certification.

[1] Includes multiple board certifications: Surgery, Colon and Rectal Surgery, Neurological Surgery, Orthopedic Surgery, Plastic Surgery, and Thoracic and Cardiac Surgery.

At a Glance:

Gov't Programs

Medicare Participant:	17%
Medicare Non-Participating Provider:	66%
Medicaid Participant:	63%

Medical Services

Meaningful Use of EHRs:	32%
CPA - NP:	15%
CPA - PA:	10%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Admitting Privileges		
Number of Facilities	#	%
Zero	9,274	43%
One	7,485	35%
Two	2,635	12%
Three	1,145	5%
Four or more	1,046	5%
Total	21,585	100%

Source: Va. Healthcare Workforce Data Center

17% of Virginia's physician workforce participates in the Medicare program, while 66% are non-participating Medicare providers, that is, they do not accept Medicare reimbursement across all services but do so on a case-by-case basis. In addition, 63% of physicians participate in Virginia's Medicaid program.

Medical Services/Activities		
Service	#	%
Achieve Meaningful Use of EHRs	7,973	32%
Collaborative Practice Agreement – Nurse Practitioner	3,838	15%
Collaborative Practice Agreement – Physician Assistant	2,495	10%
Telemedicine or Remote Consulting	2,388	10%
Participate in an Accountable Care Organization	2,334	9%
Collaborative Practice Agreement - Pharmacist	490	2%
At least One Service	10,723	43%

Source: Va. Healthcare Workforce Data Center

Gov't Program Participation		
Medicare Participating Provider		
Yes	4,098	17%
No	20,558	83%
Total	24,656	100%
Medicare Non-Participating Provider		
Yes	16,348	66%
No	8,307	34%
Total	24,656	100%
Medicaid Participating Provider		
Yes	15,432	63%
No	9,223	37%
Total	24,656	100%

Source: Va. Healthcare Workforce Data Center

Current Employment Situation

At a Glance:

Employment
Employed in Profession: 95%
Involuntarily Unemployed: <1%

Positions Held
1 Full-Time: 70%
2 or more Positions: 13%

Weekly Hours:
40 to 49: 30%
60 or more: 25%
Less than 30: 9%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Current Work Status		
Status	#	%
Employed, capacity unknown	71	<1%
Employed in a medicine or osteopathy related capacity	21,059	95%
Employed, NOT in a medicine or osteopathy related capacity	209	1%
Not working, reason unknown	0	0%
Involuntarily unemployed	25	<1%
Voluntarily unemployed	246	1%
Retired	465	2%
Total	**22,074**	**100%**

Source: Va. Healthcare Workforce Data Center

95% of physicians are currently employed in the profession, and less than 1% are involuntarily unemployed. Nearly three-quarters of all physicians currently hold one full-time job, while 13% have multiple positions. Just 30% of physicians work between 40 and 49 hours per week, while one-quarter work at least 60 hours per week.

Current Positions		
Positions	#	%
No Positions	735	3%
One Part-Time Position	2,863	13%
Two Part-Time Positions	704	3%
One Full-Time Position	15,145	70%
One Full-Time Position & One Part-Time Position	1,702	8%
Two Full-Time Positions	70	0%
More than Two Positions	377	2%
Total	**21,595**	**100%**

Source: Va. Healthcare Workforce Data Center

Current Weekly Hours		
Hours	#	%
0 hours	735	3%
1 to 9 hours	422	2%
10 to 19 hours	529	2%
20 to 29 hours	1,036	5%
30 to 39 hours	2,178	10%
40 to 49 hours	6,311	30%
50 to 59 hours	4,681	22%
60 to 69 hours	3,287	15%
70 to 79 hours	1,059	5%
80 or more hours	1,024	5%
Total	**21,261**	**100%**

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Income		
Hourly Wage	**#**	**%**
Volunteer Work Only	331	2%
Less than $50,000	690	4%
$50,000-$99,999	1,594	10%
$100,000-$149,999	2,120	13%
$150,000-$199,999	2,915	18%
$200,000-$249,999	3,122	19%
$250,000-$299,999	1,980	12%
$300,000-$349,999	1,488	9%
$350,000-$399,999	864	5%
$400,000 or more	1,503	9%
Total	**16,608**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Earnings
Median Income: $200k-$225k

Benefits
Employer Health Ins.: 68%
Employer Retirement: 64%

Satisfaction
Satisfied 93%
Very Satisfied: 61%

Job Satisfaction		
Level	**#**	**%**
Very Satisfied	13,106	61%
Somewhat Satisfied	6,851	32%
Somewhat Dissatisfied	1,143	5%
Very Dissatisfied	337	2%
Total	**21,438**	**100%**

Source: Va. Healthcare Workforce Data Center

The typical physician earned between $200,000 and $225,000 in 2016. In addition, among physicians who received either an hourly wage or a salary at their primary work location, 68% received health insurance and 64% had access to a retirement plan.

Employer-Sponsored Benefits			
Benefit	**#**	**%**	**% of Wage/Salary Employees**
Health Insurance	12,415	59%	68%
Retirement	11,864	56%	64%
Paid Vacation	11,180	53%	63%
Dental Insurance	10,334	49%	59%
Group Life Insurance	8,581	41%	50%
Paid Sick Leave	8,383	40%	48%
Signing/Retention Bonus	2,804	13%	17%
At Least One Benefit	**14,865**	**71%**	**80%**

*From any employer at time of survey.

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Underemployment in Past Year		
In the past year did you . . .?	#	%
Experience Involuntary Unemployment?	117	<1%
Experience Voluntary Unemployment?	735	3%
Work Part-time or temporary positions, but would have preferred a full-time/permanent position?	307	1%
Work two or more positions at the same time?	3,230	13%
Switch employers or practices?	1,256	5%
Experienced at least one	4,996	20%

Source: Va. Healthcare Workforce Data Center

Less than 1% of Virginia's physicians experienced involuntary unemployment at some point in the past year. By comparison, Virginia's average monthly unemployment rate was 4%.[2]

At a Glance:

Unemployment Experience 2016

Involuntarily Unemployed: <1%
Underemployed: 1%

Turnover & Tenure

Switched Jobs: 5%
New Location: 15%
Over 2 years: 72%
Over 2 yrs, 2nd location: 57%

Employment Type

Salary/Commission: 63%
Business/Pract. Income: 19%

Location Tenure				
Tenure	Primary		Secondary	
	#	%	#	%
Not Currently Working at this Location	499	2%	277	5%
Less than 6 Months	748	4%	488	9%
6 Months to 1 Year	1,339	6%	598	11%
1 to 2 Years	3,385	16%	1,090	19%
3 to 5 Years	4,523	22%	1,182	21%
6 to 10 Years	3,434	16%	798	14%
More than 10 Years	7,091	34%	1,211	21%
Subtotal	21,020	100%	5,645	100%
Did not have location	314		19,254	
Item Missing	3,726		162	
Total	25,060		25,060	

Source: Va. Healthcare Workforce Data Center

72% of physicians have worked at their primary location for more than 2 years—the job tenure normally required to get a conventional mortgage loan.

63% of physicians received a salary at their primary work location, while 19% earned income from their own business or practice.

Employment Type		
Primary Work Site	#	%
Salary/ Commission	10,883	63%
Business/ Practice Income	3,253	19%
Hourly Wage	2,110	12%
By Contract	799	5%
Unpaid	287	2%
Subtotal	17,332	100%

Source: Va. Healthcare Workforce Data Center

[2] As reported by the US Bureau of Labor Statistics. The not seasonally adjusted monthly unemployment rate ranged from 3.9% in December 2015 to 4.0% in November 2016. November's rate is from preliminary data.

Work Site Distribution

At a Glance:

Concentration

Top Region:	30%
Top 3 Regions:	73%
Lowest Region:	1%

Locations

2 or more (2016):	27%
2 or more (Now*):	26%

30% of all physicians work in Northern Virginia, the most of any region in the state. In addition, nearly one-quarter of all physicians work in Central Virginia.

A Closer Look:

Regional Distribution of Work Locations				
COVF Region	Primary Location		Secondary Location	
	#	%	#	%
Central	4,950	24%	1,035	18%
Eastern	279	1%	75	1%
Hampton Roads	4,059	19%	974	17%
Northern	6,349	30%	1,766	31%
Southside	526	3%	166	3%
Southwest	685	3%	224	4%
Valley	1,091	5%	261	5%
West Central	2,318	11%	523	9%
Virginia Border State/DC	302	1%	231	4%
Other US State	327	2%	351	6%
Outside of the US	11	0%	15	0%
Total	**20,895**	**100%**	**5,622**	**100%**
Item Missing	1,898		126	

Source: Va. Healthcare Workforce Data Center

Number of Work Locations				
Locations	Work Locations in Past Year		Work Locations Now*	
	#	%	#	%
0	283	1%	637	3%
1	15,173	71%	15,140	71%
2	2,175	10%	2,170	10%
3	2,663	13%	2,547	12%
4	443	2%	355	2%
5	235	1%	185	1%
6 or More	261	1%	198	1%
Total	**21,232**	**100%**	**21,232**	**100%**

*At the time of survey completion, December 2016.

Source: Va. Healthcare Workforce Data Center

26% of all physicians currently have multiple work locations, while 27% of physicians have had at least two work locations over the past year.

Establishment Type

A Closer Look:

Location Sector				
Sector	Primary Location		Secondary Location	
	#	%	#	%
For-Profit	10,374	54%	3,165	61%
Non-Profit	5,440	28%	1,410	27%
State/Local Government	1,633	8%	351	7%
Veterans Administration	516	3%	101	2%
U.S. Military	1,235	6%	143	3%
Other Federal Government	153	1%	44	1%
Total	19,350	100%	5,215	100%
Did not have location	314		19,254	
Item Missing	5,396		592.091	

Source: Va. Healthcare Workforce Data Center

At a Glance:
(Primary Locations)

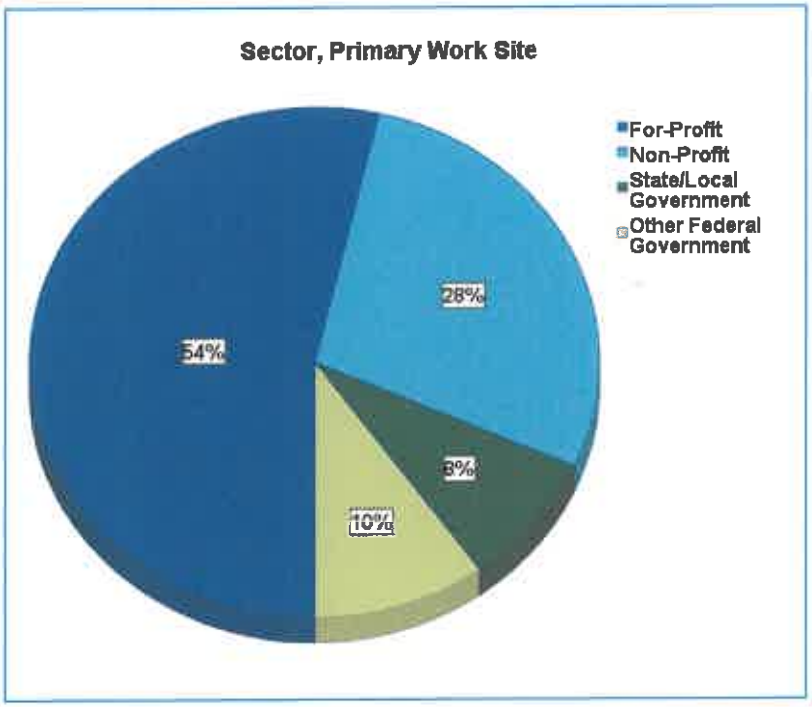
Sector

For Profit:	54%
Federal:	10%

Top Establishments

Group Private Practice:	38%
Hospital – Inpatient:	15%
Solo Private Practice:	12%

82% of all physicians work in the private sector, including 54% who work at for-profit establishments. Another 10% of Virginia's physician workforce work for the federal government.



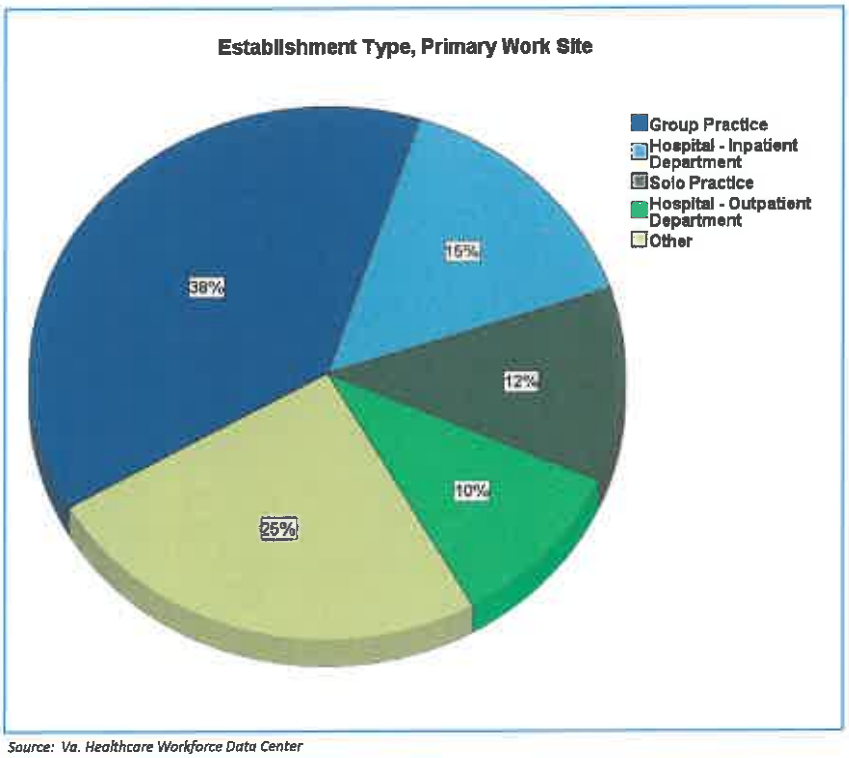
Source: Va. Healthcare Workforce Data Center

Establishment Type	Location Type: Primary Location #	Primary Location %	Secondary Location #	Secondary Location %
Group Practice	7,372	38%	1,785	34%
Hospital - Inpatient Department	2,868	15%	866	17%
Solo Practice	2,269	12%	462	9%
Hospital - Outpatient Department	1,965	10%	443	9%
Hospital - Emergency Department	1,175	6%	414	8%
Community Clinic/Outpatient Care Center	786	4%	273	5%
Medical/Osteopathic School or Parent University	667	3%	107	2%
Insurance Organization	253	1%	62	1%
Mental Health Facility	212	1%	51	1%
Nursing Home/Long-Term Care Facility	131	1%	95	2%
Outpatient Surgical Center	88	0%	75	1%
Supplier Organization	20	0%	9	0%
Other	1,437	7%	546	11%
Total	**19,245**	**100%**	**5,189**	**100%**
Did Not Have a Location	314		19,254	

Source: Va. Healthcare Workforce Data Center

Group private practices are the most common establishment type among Virginia's physicians with a primary work location. The inpatient departments of hospitals and solo private practices are also typical primary establishment types.

Group Private Practices are also the most common establishment type among physicians with a secondary work location.



Source: Va. Healthcare Workforce Data Center

Time Allocation

At a Glance:
(Primary Locations)

A Typical Physician's Time

Patient Care:	80%-89%
Administration:	1%-9%
Education:	1%-9%

Roles

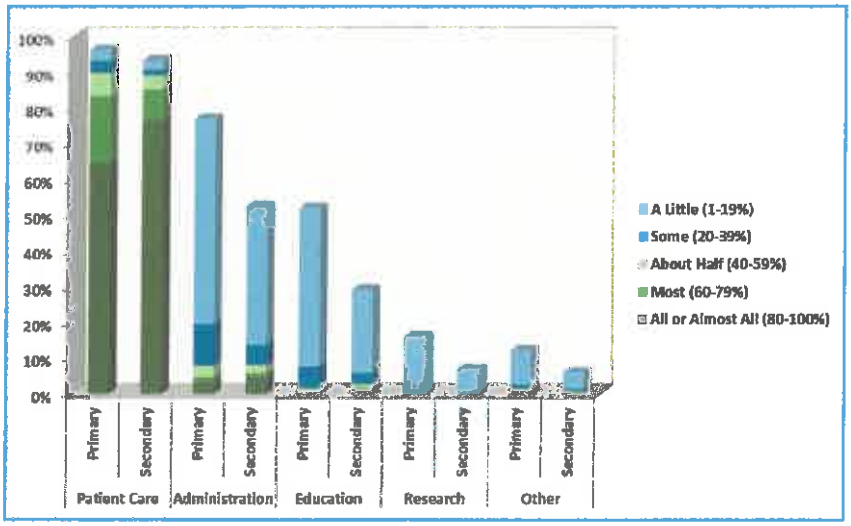
Patient Care:	83%
Administrative:	5%
Education:	1%

Patient Care Physicians

Median Admin Time:	1%-9%
Ave. Admin Time:	1%-9%

Source: Va. Healthcare Workforce Data Center

A Closer Look:



Source: Va. Healthcare Workforce Data Center

The typical physician spends most of their time in patient care activities. In fact, 83% of all physicians fill a patient care role, defined as spending at least 60% of their time in that activity. Another 5% of physicians fill an administrative role.

Time Allocation										
Time Spent	Patient Care		Admin.		Education		Research		Other	
	Prim Site	Sec. Site	Prim Site	Sec. Site	Prim Site	Sec. Site	Prim Site	Sec. Site	Prim Site	Sec. Site
All or Almost All (80-100%)	65%	76%	3%	5%	0%	1%	0%	0%	1%	0%
Most (60-79%)	19%	9%	1%	1%	0%	0%	0%	0%	0%	0%
About Half (40-59%)	7%	4%	3%	2%	1%	1%	0%	0%	0%	0%
Some (20-39%)	3%	2%	12%	6%	6%	3%	1%	0%	1%	1%
A Little (1-20%)	3%	3%	57%	39%	44%	23%	14%	6%	10%	4%
None (0%)	4%	7%	23%	47%	48%	71%	84%	93%	88%	93%

Source: Va. Healthcare Workforce Data Center

Patients

At a Glance:

Number of Patients/Week

Primary (Median):	50-75
Secondary (Median):	1-25

Accepts New Patients?

Primary:	59%
Secondary:	49%

Medicare/Medicaid

New Medicare Patients:	68%
New Medicaid Patients:	71%

Source: Va. Healthcare Workforce Data Center

59% of physicians are accepting new patients at their primary work location.

A Closer Look:

Patient Care Activities Predominantly Primary Care?				
Response	Primary Location		Secondary Location	
	#	%	#	%
Yes	7,643	42%	1,636	36%
No	11,341	58%	3,364	64%
Total	18,984	100%	5,000	100%
Question Inapplicable to Respondent	1,693		19,743	

Source: Va. Healthcare Workforce Data Center

Accepting New Patients?				
Response	Primary Location		Secondary Location	
	#	%	#	%
Yes				
I can accept some additional patients	6,307	32%	1,151	21%
I can accept many additional patients	5,404	27%	1,471	27%
No/Not Applicable				
I do not manage my patient load at this location	5,421	27%	1,829	34%
I do not provide patient care at this location	1,899	10%	781	15%
I cannot accept any additional patients	823	4%	146	3%
Total	19,854	100%	5,378	100%

Source: Va. Healthcare Workforce Data Center

Patients Visits Per Week				
Number of Visits	Primary Location		Secondary Location	
	#	%	#	%
None	1,787	9%	762	14%
1 to 24	3,119	16%	2,431	45%
25 to 49	4,087	20%	1,098	20%
50 to 74	4,036	20%	532	10%
75 to 99	3,101	15%	250	5%
100 to 124	2,287	11%	165	3%
125 to 149	749	4%	51	1%
150 or more	868	4%	117	2%
Total	20,034	100%	5,406	100%

Source: Va. Healthcare Workforce Data Center

The typical physician treats between 50 and 75 patients per week at their primary work location

New Patient Capacity				
Number of Patients	Primary Location		Secondary Location	
	#	%	#	%
Less than 50	4,023	35%	998	39%
50 to 99	2,594	23%	620	24%
100 to 199	1,852	16%	361	14%
200 to 299	892	8%	159	6%
300 to 399	405	4%	70	3%
400 to 499	342	3%	74	3%
500 to 749	346	3%	74	3%
750 to 999	111	1%	18	1%
1,000 or more	834	7%	214	8%
Total	11,399	100%	2,588	100%

Source: Va. Healthcare Workforce Data Center

Among physicians who are accepting new patients at their primary work location, 35% can accept no more than 50 patients, while 23% can accept between 50 and 99 new patients.

Among physicians who are accepting new patients at their primary work location, 71% are accepting new Medicaid patients and 68% are accepting new Medicare patients.

Accepting New Medicare/Medicaid Patients?				
Response	Primary Location		Secondary Location	
	#	%	#	%
Medicaid				
Yes	8,324	71%	1,872	72%
No, I am not a Medicaid provider	2,431	21%	556	21%
No, I am a Medicaid Provider, but am not accepting new Medicaid patients	992	8%	190	7%
Total	11,747	100%	2,618	100%
Medicare				
Yes	11,312	68%	-	-
No	5,245	32%	-	-
Total	16,557	100%	-	-

Source: Va. Healthcare Workforce Data Center

Status Change for New Medicaid Patients in Past Year?				
Response	Primary Location		Secondary Location	
	#	%	#	%
Yes	621	5%	143	5%
No	11,189	95%	2,507	95%
Total	11,810	100%	2,650	100%

Source: Va. Healthcare Workforce Data Center

Among physicians who are accepting new patients at their primary work location, 95% have seen no change in their status concerning new Medicaid patients over the past 12 months.

A Closer Look:

Retirement Expectations				
Expected Retirement Age	All Physicians		Physicians Over 50	
	#	%	#	%
Under age 50	207	1%	-	-
50 to 54	449	3%	45	<1%
55 to 59	1,308	7%	323	4%
60 to 64	3,842	22%	1,546	17%
65 to 69	6,057	34%	3,289	36%
70 to 74	3,035	17%	2,089	23%
75 to 79	947	5%	736	8%
80 or over	436	2%	353	4%
I do not intend to retire	1,342	8%	821	9%
Total	17,622	100%	9,202	100%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Retirement Expectations

All Physicians

Under 65:	33%
Under 60:	11%

Physicians 50 and over

Under 65:	21%
Under 60:	4%

Time until Retirement

Within 2 years:	8%
Within 10 years:	30%
Half the workforce:	By 2036

One-third of all physicians expect to retire before the age of 65, while another third plan on working until at least age 70. Among physicians who are age 50 and over, 21% still expect to retire by age 65, while 43% plan on working until at least age 70.

Within the next two years, just 1% of Virginia's physicians expect to leave the profession and 3% plan on leaving the state to practice medicine elsewhere. Meanwhile, 9% of physicians plan on increasing patient care hours, and 4% also plan to pursue additional educational opportunities.

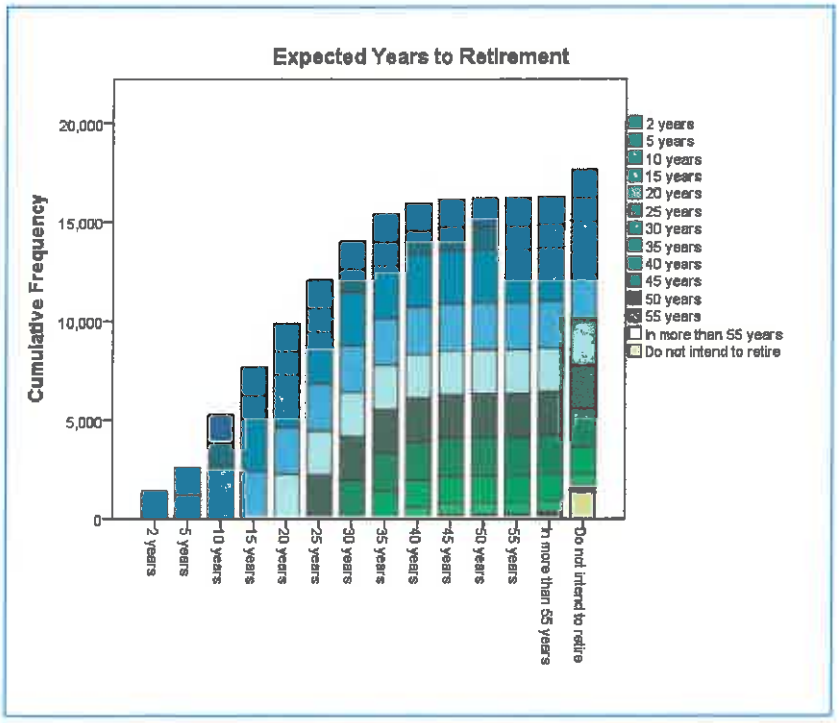
Future Plans		
Two-Year Plans:	#	%
Decrease Participation		
Leave Profession	297	1%
Leave Virginia	791	3%
Decrease Patient Care Hours	2,531	10%
Decrease Teaching Hours	166	1%
Increase Participation		
Increase Patient Care Hours	2,183	9%
Increase Teaching Hours	1,755	7%
Pursue Additional Education	1,078	4%
Return to Virginia's Workforce	97	0%

Source: Va. Healthcare Workforce Data Center

By comparing retirement expectation to age, we can estimate the maximum years to retirement for physicians. 8% of physicians expect to retire within the next two years, while 30% plan on retiring in the next ten years. Half of the current physician workforce expects to be retired by 2036.

Time to Retirement			
Expect to retire within. . .	#	%	Cumulative %
2 years	1,408	8%	8%
5 years	1,189	7%	15%
10 years	2,681	15%	30%
15 years	2,381	14%	43%
20 years	2,226	13%	56%
25 years	2,187	12%	69%
30 years	1,943	11%	80%
35 years	1,372	8%	57%
40 years	562	3%	91%
45 years	183	1%	92%
50 years	44	0%	92%
55 years	13	0%	92%
In more than 55 years	92	1%	92%
Do not intend to retire	1,342	8%	100%
Total	17,622	100%	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Using these estimates, retirements will begin to reach 10% of the current workforce starting in 2026. Retirements will peak at 15% of the workforce around the same time before declining to under 10% of the current workforce again around 2052.

Full-Time Equivalency Units

At a Glance:

FTEs

Total:	25,389
FTEs/1,000 Residents:	3.049
Average:	1.03

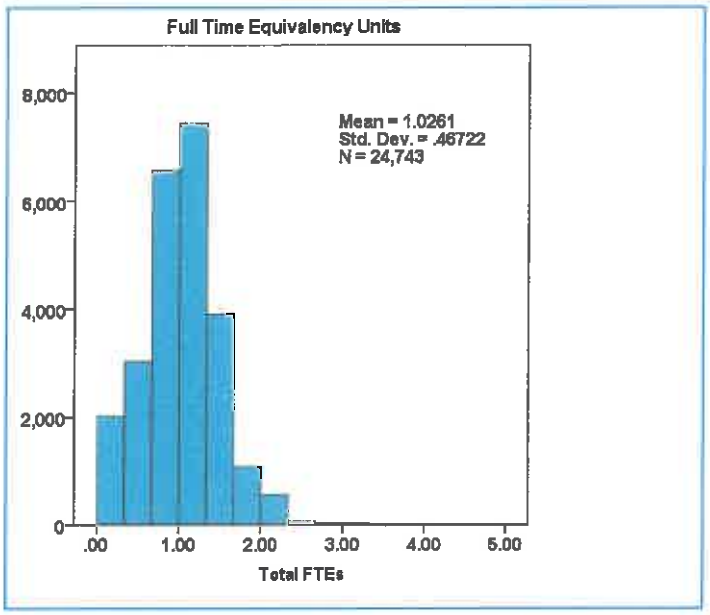
Age & Gender Effect

Age, Partial Eta^2:	Small
Gender, Partial Eta^2:	Small

Partial Eta^2 Explained:
Partial Eta^2 is a statistical measure of effect size.

Source: Va. Healthcare Workforce Data Center

A Closer Look:

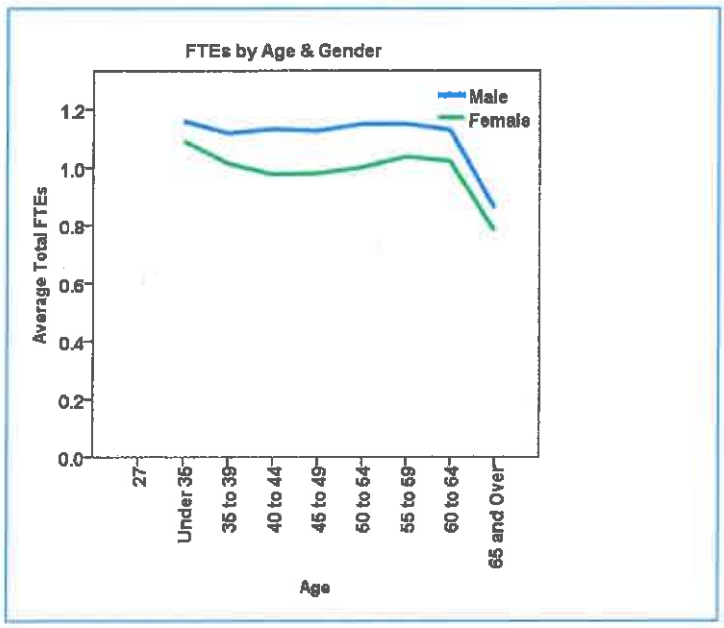


Source: Va. Healthcare Workforce Data Center

The typical physician provided 1.03 FTEs in 2016, or approximately 42 hours per week for 52 weeks. Although FTEs appear to vary by age and gender, statistical tests did not verify that a difference exists.[3]

Full-Time Equivalency Units		
Age	**Average**	**Median**
Age		
Under 30	1.12	1.09
30 to 34	1.07	1.12
35 to 39	1.05	1.01
40 to 44	1.04	1.03
45 to 49	1.07	1.05
50 to 54	1.10	1.05
55 to 59	1.07	1.06
60 and Over	0.82	0.75
Gender		
Male	1.07	1.09
Female	0.99	1.01

Source: Va. Healthcare Workforce Data Center

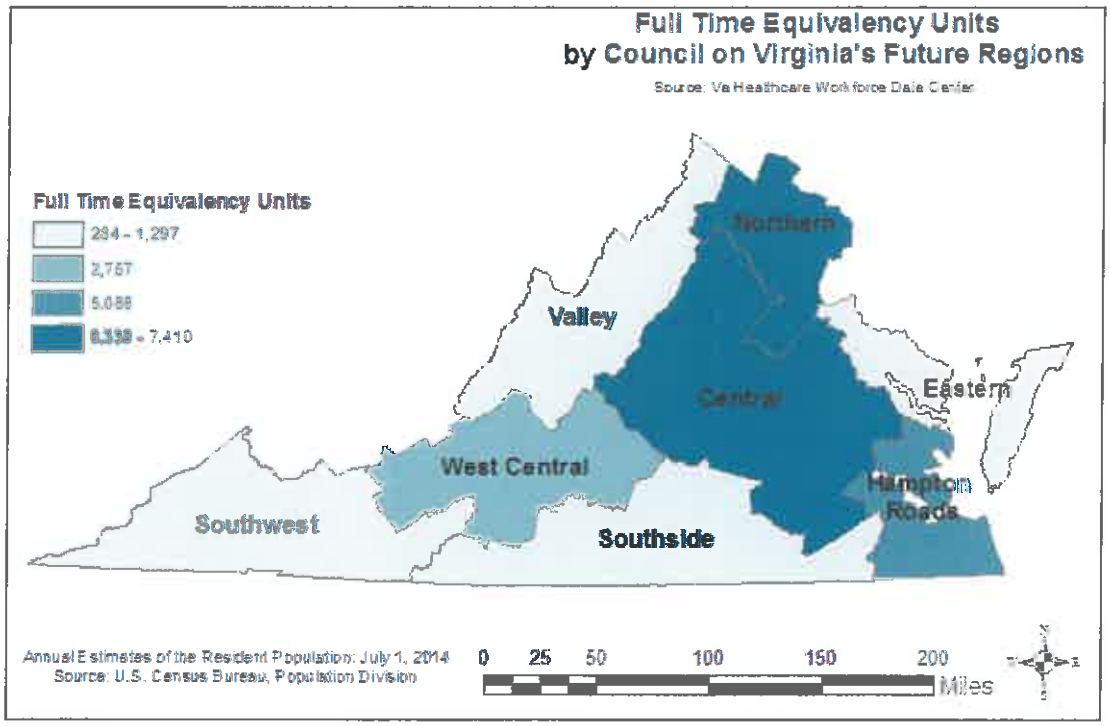


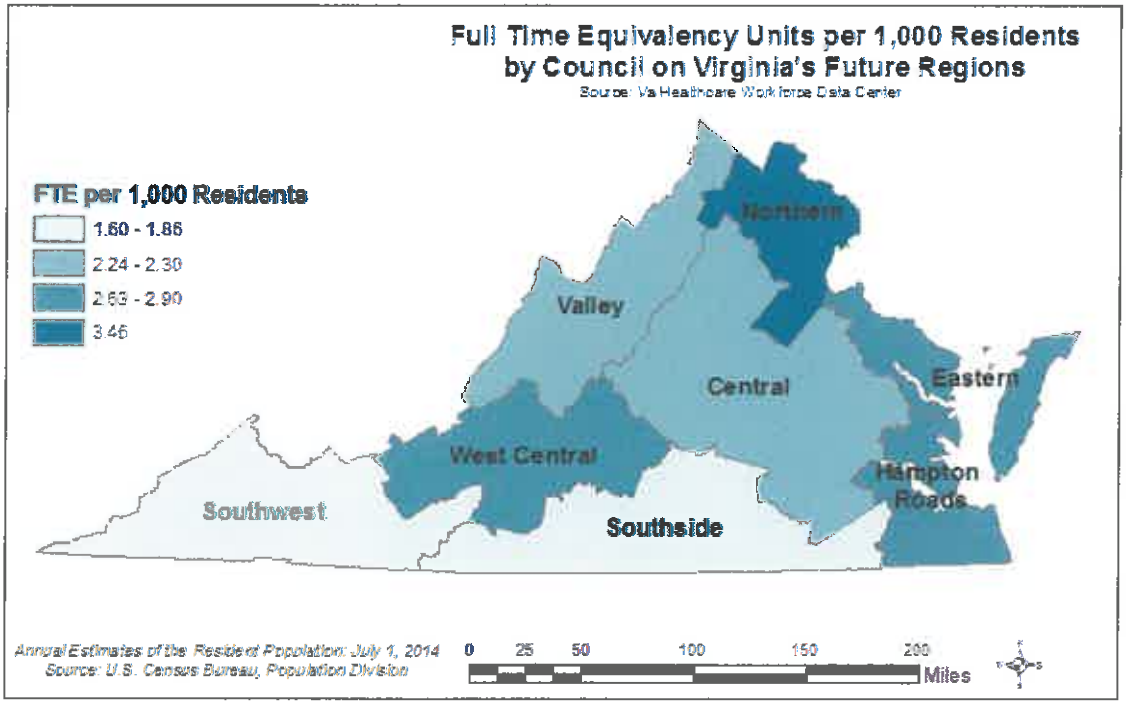
Source: Va. Healthcare Workforce Data Center

[3] Due to assumption violations in Mixed between-within ANOVA (Levene's Test was significant).

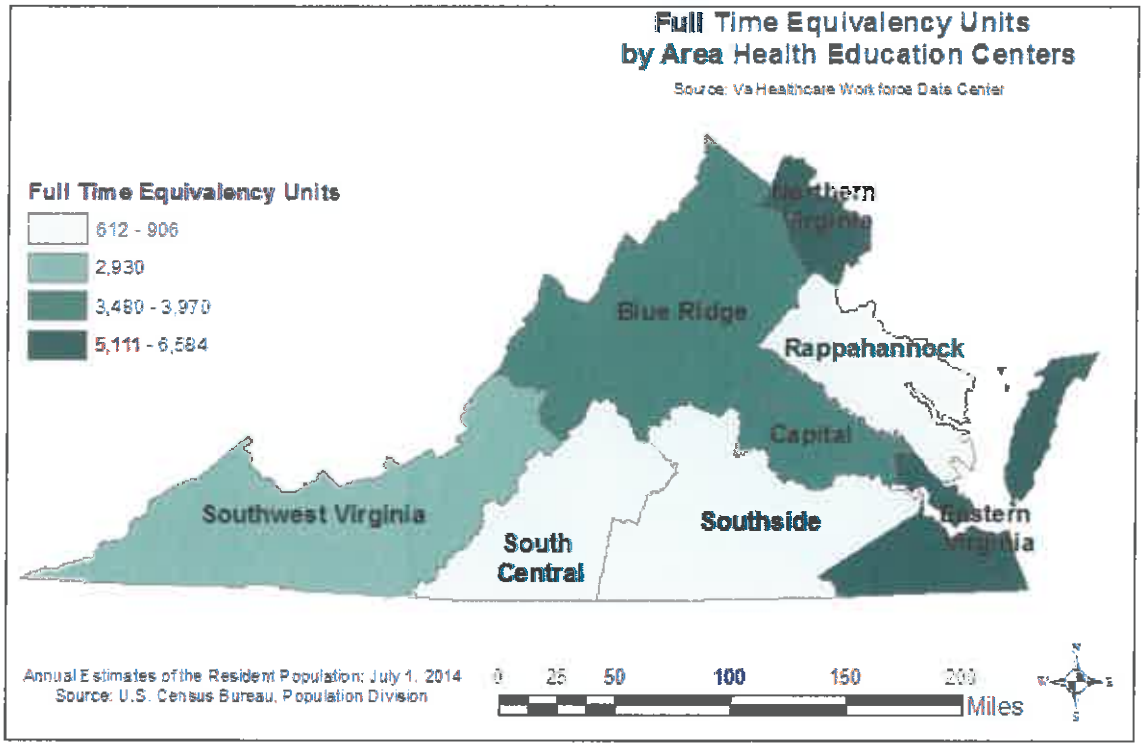
Maps

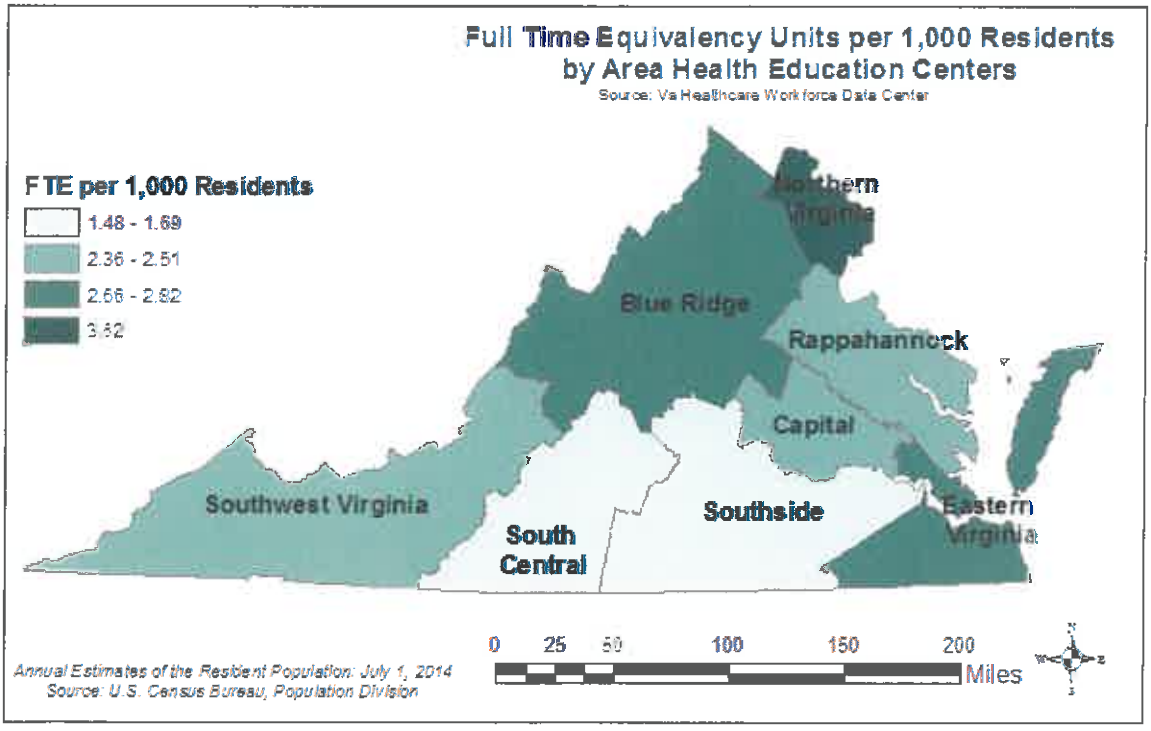
Council on Virginia's Future Regions



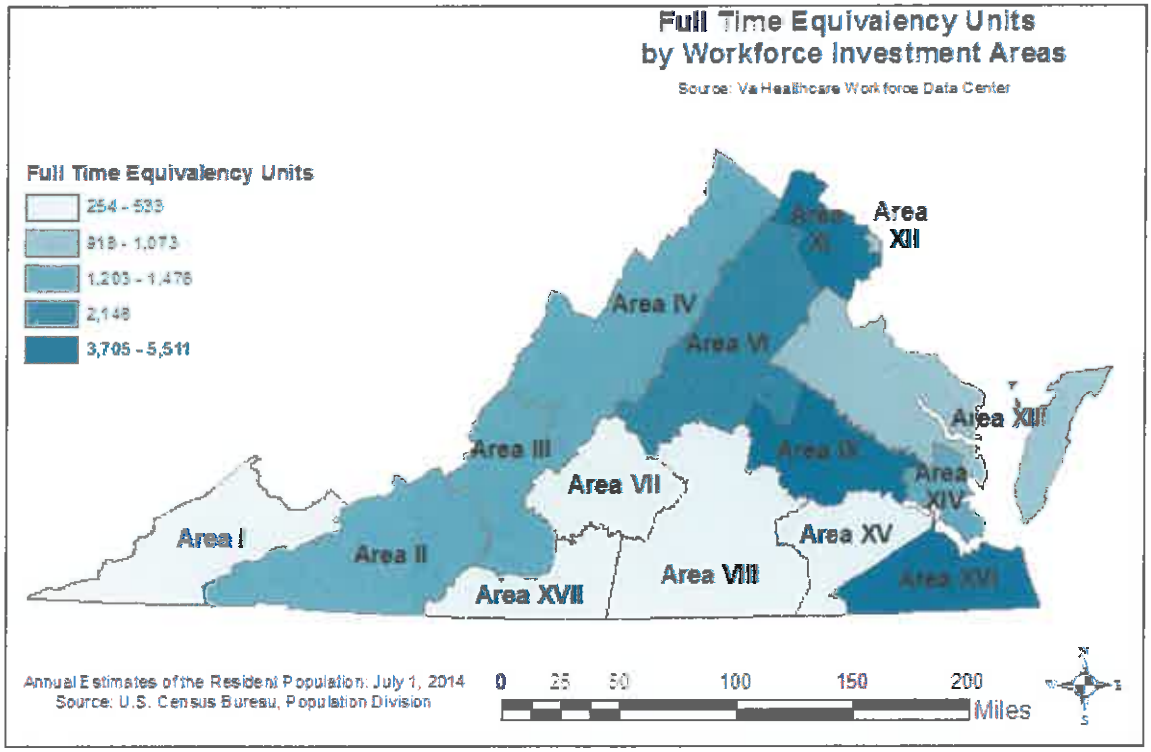


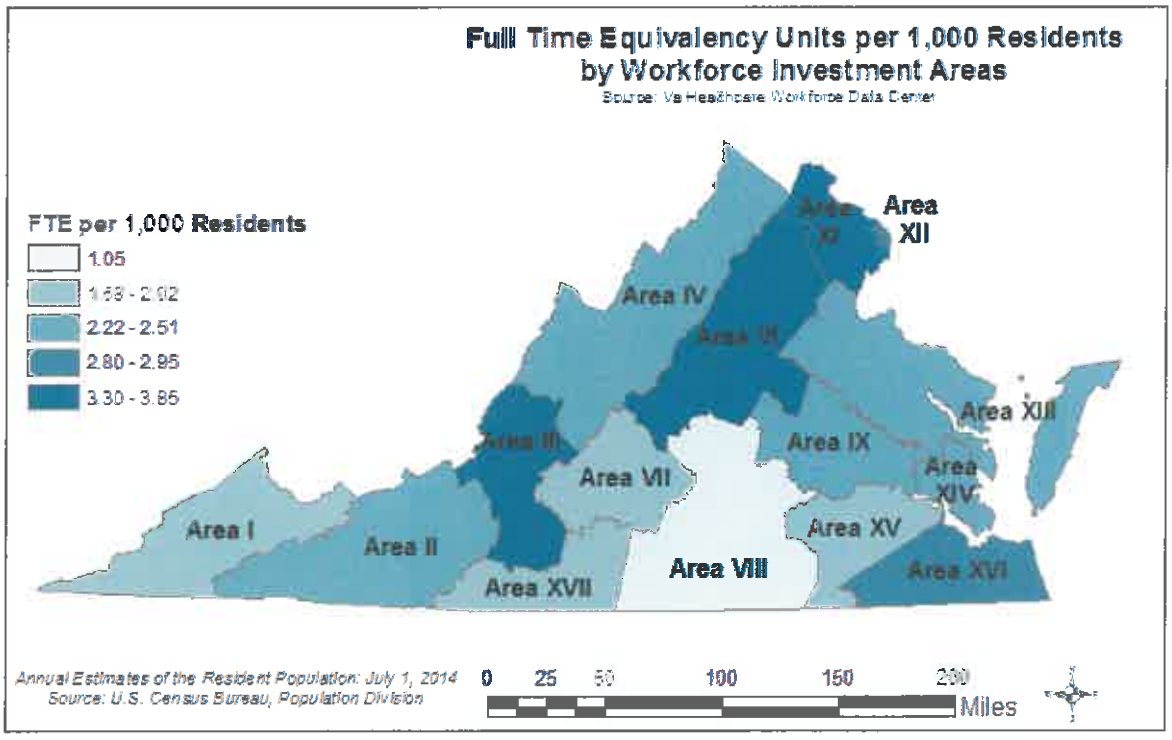
Area Health Education Center Regions



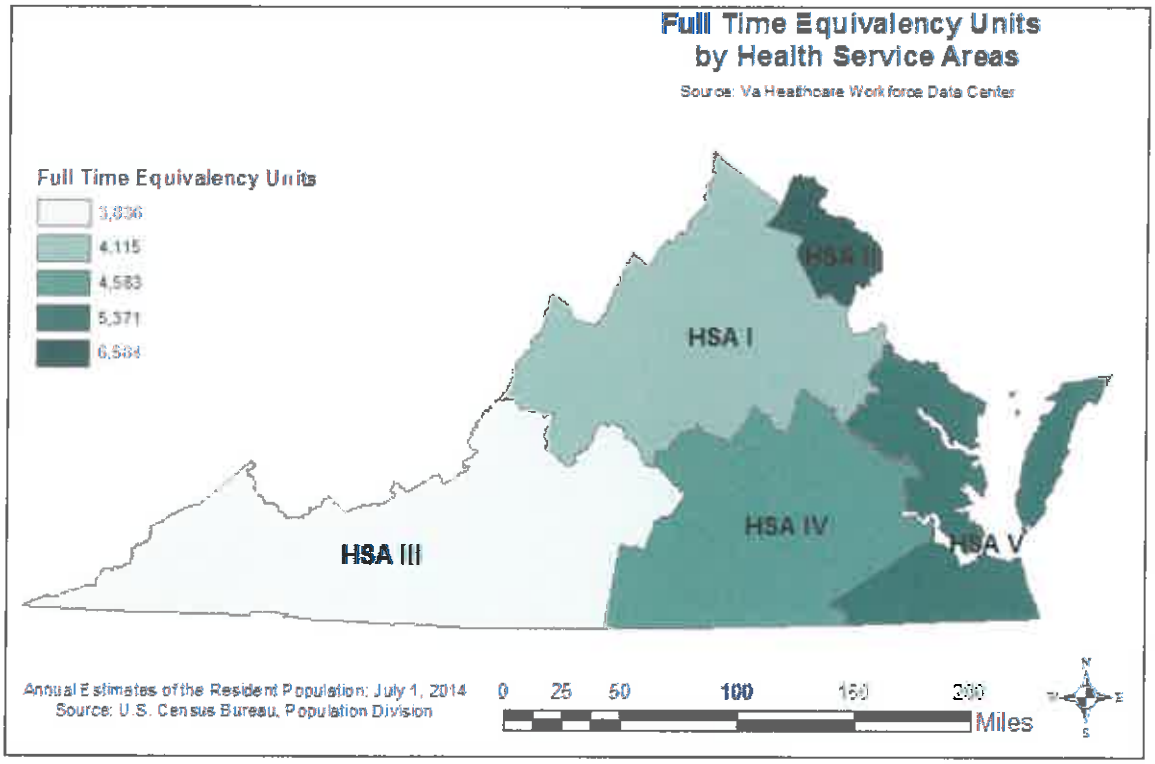


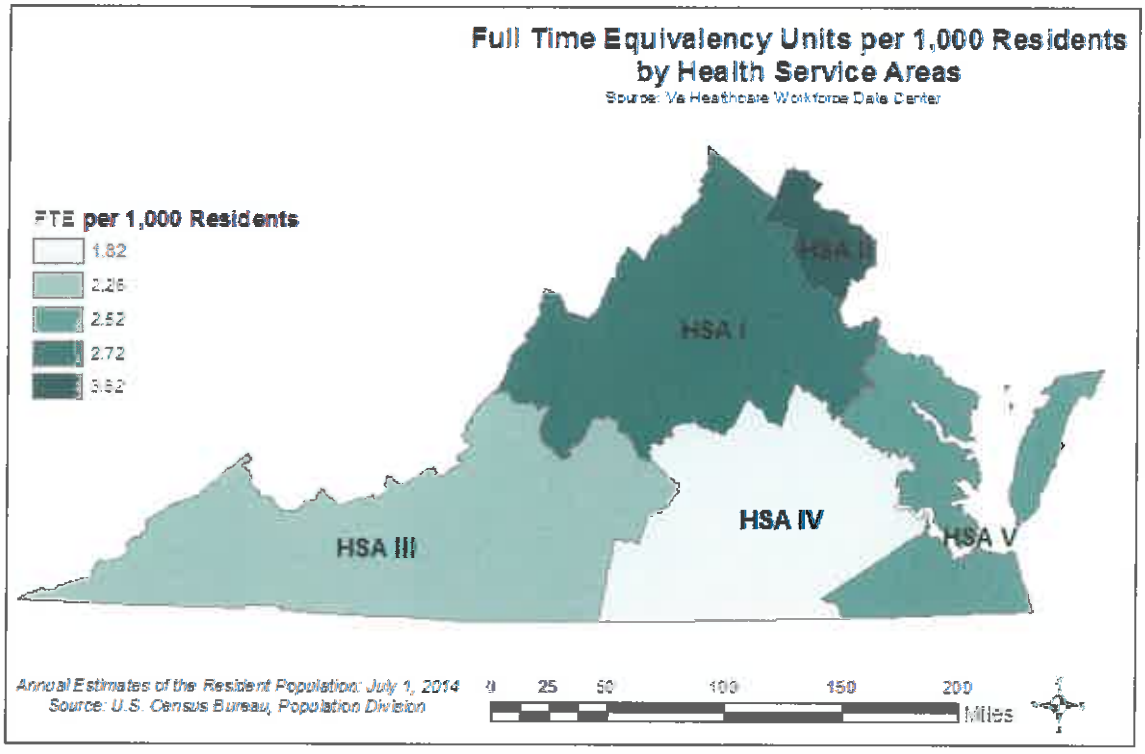
Workforce Investment Areas



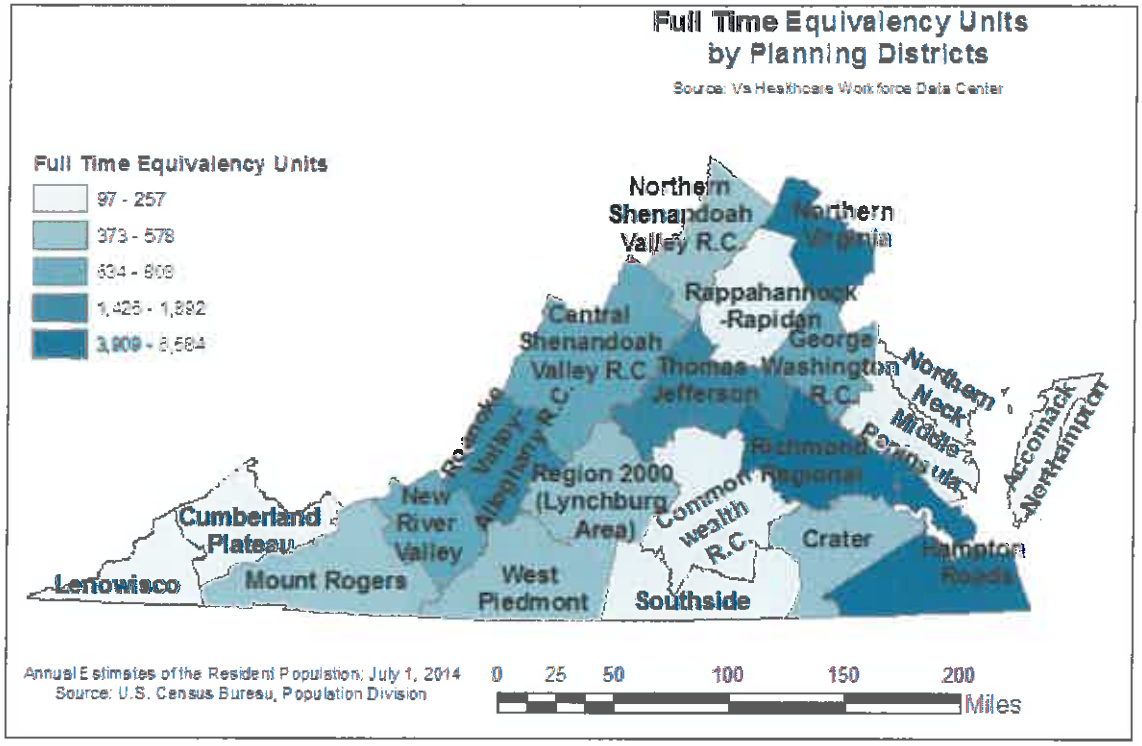


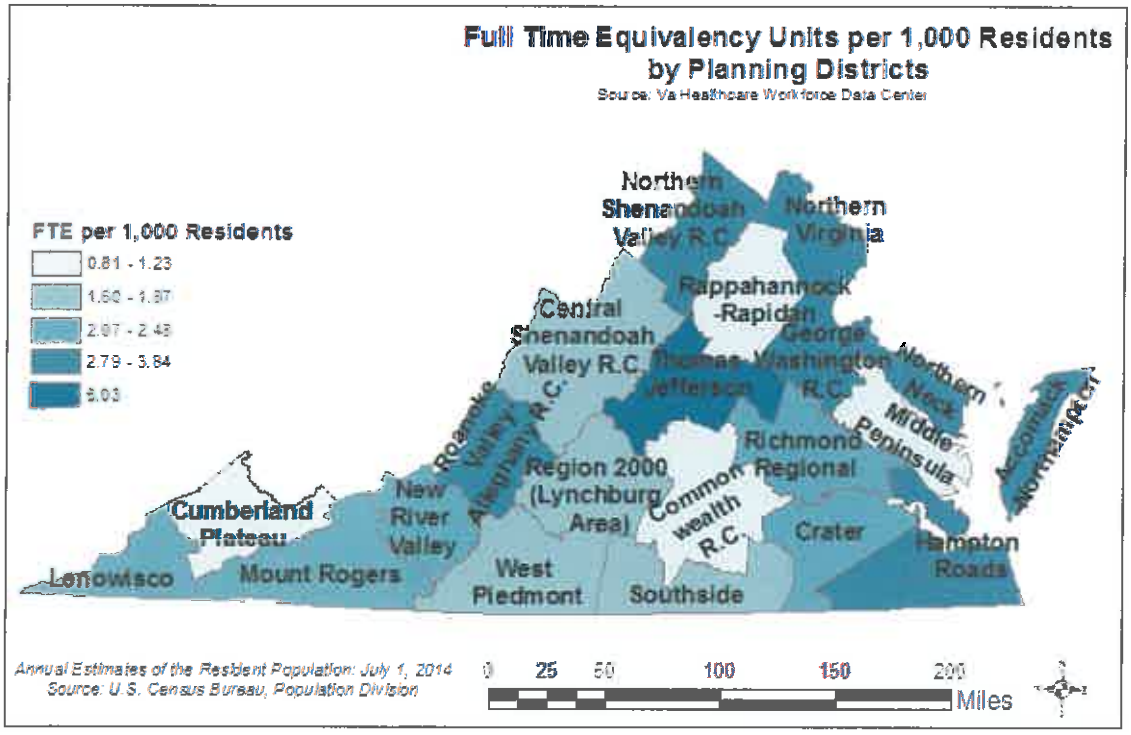
Health Services Areas





Planning Districts





Appendices

Weights

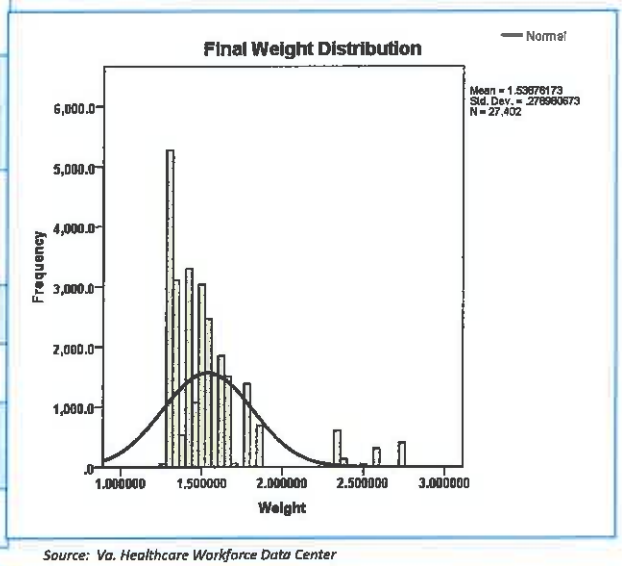
Rural Status	Location Weight #	Rate	Weight	Total Weight Min	Max
Metro, 1 million+	18,066	76.79%	1.302336	1.184949	2.033876
Metro, 250,000 to 1 million	2,211	77.88%	1.283972	1.168241	2.005197
Metro, 250,000 or less	3,464	75.84%	1.318614	1.199761	2.059299
Urban pop 20,000+, Metro adj	251	79.68%	1.255	1.14188	1.959951
Urban pop 20,000+, nonadj	0	NA	NA	NA	NA
Urban pop, 2,500-19,999, Metro adj	626	82.27%	1.215534	1.105971	1.898317
Urban pop, 2,500-19,999, nonadj	376	76.86%	1.301038	1.183768	2.031849
Rural, Metro adj	434	70.05%	1.427632	1.298951	2.229552
Rural, nonadj	164	70.12%	1.426087	1.297546	2.22714
Virginia border state/DC	8,072	69.87%	1.431206	1.302203	2.235134
Other US State	9,417	65.98%	1.515693	1.379075	2.367079

See the Methods section on the HWDC website for details on HWDC Methods:
www.dhp.virginia.gov/hwdc/

Final weights are calculated by multiplying the two weights and the overall response rate:

Age Weight x Rural Weight x Response Rate = Final Weight.

Overall Response Rate: 0.7311379



Source: Va. Healthcare Workforce Data Center

Age	Age Weight #	Rate	Weight	Total Weight Min	Max
Under 35	3,518	46.82%	2.136004857	1.898317	2.367079
35 to 39	5,653	65.65%	1.523309081	1.3538	1.688101
40 to 44	5,650	74.65%	1.339497392	1.190442	1.484405
45 to 49	5,624	78.50%	1.273839185	1.13209	1.411644
50 to 54	4,987	80.05%	1.249248497	1.110236	1.384393
55 to 59	4,801	79.69%	1.254835337	1.115201	1.390584
60 to 64	4,877	80.36%	1.244450115	1.105971	1.379075
65 and Over	7,979	72.39%	1.381405817	1.227687	1.530847

Source: Va. Healthcare Workforce Data Center

Virginia Department of Health Professions
Cash Balance
As of May 31, 2017

	102- Medicine
Board Cash Balance as of June 30, 2016	$ 10,033,194
YTD FY17 Revenue	6,866,170
Less: YTD FY17 Direct and In-Direct Expenditures	6,682,950
Board Cash Balance as May 31, 2017	10,216,414

Virginia Department of Health Professions
Revenue and Expenditures Summary
Department 10200 - Medicine
For the Period Beginning July 1, 2016 and Ending May 31, 2017

Account Number	Account Description	Amount	Budget	Amount Under/(Over) Budget	% of Budget
4002400	Fee Revenue				
4002401	Application Fee	1,103,990.00	964,775.00	(139,215.00)	114.43%
4002402	Examination Fee	1,662.00	-	(1,662.00)	0.00%
4002406	License & Renewal Fee	5,644,815.00	5,822,830.00	178,015.00	96.94%
4002407	Dup. License Certificate Fee	7,430.00	3,375.00	(4,055.00)	220.15%
4002408	Board Endorsement - In	9,392.00	-	(9,392.00)	0.00%
4002409	Board Endorsement - Out	10,565.00	49,820.00	39,255.00	21.21%
4002421	Monetary Penalty & Late Fees	87,144.00	66,450.00	(20,694.00)	131.14%
4002432	Misc. Fee (Bad Check Fee)	140.00	175.00	35.00	80.00%
	Total Fee Revenue	6,865,138.00	6,907,425.00	42,287.00	99.39%
4003000	Sales of Prop. & Commodities				
4003002	Overpayments	350.00	-	(350.00)	0.00%
4003020	Misc. Sales-Dishonored Payments	682.00	-	(682.00)	0.00%
	Total Sales of Prop. & Commodities	1,032.00	-	(1,032.00)	0.00%
	Total Revenue	6,866,170.00	6,907,425.00	41,255.00	99.40%
5011110	Employer Retirement Contrib.	152,118.15	169,778.00	17,659.85	89.60%
5011120	Fed Old-Age Ins- Sal St Emp	73,416.22	86,527.00	13,110.78	84.85%
5011140	Group Insurance	14,738.29	16,487.00	1,748.71	89.39%
5011150	Medical/Hospitalization Ins.	188,216.29	228,628.00	40,411.71	82.32%
5011160	Retiree Medical/Hospitalizatn	13,264.47	14,851.00	1,586.53	89.32%
5011170	Long term Disability Ins	6,766.23	8,307.00	1,540.77	81.45%
	Total Employee Benefits	448,519.65	524,578.00	76,058.35	85.50%
5011200	Salaries				
5011230	Salaries, Classified	1,122,031.72	1,258,544.00	136,512.28	89.15%
5011250	Salaries, Overtime	7,797.83	652.00	(7,145.83)	1195.99%
	Total Salaries	1,129,829.55	1,259,196.00	129,366.45	89.73%
5011300	Special Payments				
5011310	Bonuses and Incentives	692.50	-	(692.50)	0.00%
5011380	Deferred Compnstn Match Pmts	4,965.20	9,298.00	4,332.80	53.40%
	Total Special Payments	5,657.70	9,298.00	3,640.30	60.85%
5011530	Short-trm Disability Benefits	6,244.07	-	(6,244.07)	0.00%
	Total Disability Benefits	6,244.07	-	(6,244.07)	0.00%
5011600	Terminatn Personal Svce Costs				
5011620	Salaries, Annual Leave Balanc	561.13	-	(561.13)	0.00%
5011660	Defined Contribution Match - Hy	627.29	-	(627.29)	0.00%
	Total Terminatn Personal Svce Costs	1,188.42	-	(1,188.42)	0.00%
5011930	Turnover/Vacancy Benefits	-	-	-	0.00%
	Total Personal Services	1,591,439.39	1,793,072.00	201,632.61	88.75%
5012000	Contractual Svs				
5012100	Communication Services				
5012110	Express Services	6,315.01	5,997.00	(318.01)	105.30%
5012130	Messenger Services	74.99	-	(74.99)	0.00%
5012140	Postal Services	53,143.86	66,802.00	13,658.14	79.55%
5012150	Printing Services	338.86	3,026.00	2,687.14	11.20%

Virginia Department of Health Professions
Revenue and Expenditures Summary
Department 10200 - Medicine
For the Period Beginning July 1, 2016 and Ending May 31, 2017

Account Number	Account Description	Amount	Budget	Amount Under/(Over) Budget	% of Budget
5012160	Telecommunications Svcs (VITA)	12,103.97	10,500.00	(1,603.97)	115.28%
5012170	Telecomm. Svcs (Non-State)	1,035.00	-	(1,035.00)	0.00%
5012190	Inbound Freight Services	66.23	35.00	(31.23)	189.23%
	Total Communication Services	73,077.92	86,360.00	13,282.08	84.62%
5012200	Employee Development Services				
5012210	Organization Memberships	8,385.00	7,228.00	(1,157.00)	116.01%
5012240	Employee Trainng/Workshop/Conf	4,205.00	4,283.00	78.00	98.18%
5012250	Employee Tuition Reimbursement	-	752.00	752.00	0.00%
	Total Employee Development Services	12,590.00	12,263.00	(327.00)	102.67%
5012300	Health Services				
5012360	X-ray and Laboratory Services	181.87	2,298.00	2,116.13	7.91%
	Total Health Services	181.87	2,298.00	2,116.13	7.91%
5012400	Mgmnt and Informational Svcs				
5012420	Fiscal Services	130,657.15	119,963.00	(10,694.15)	108.91%
5012440	Management Services	1,540.29	1,797.00	256.71	85.71%
5012460	Public Infrmtnl & Relatn Svcs	31.00	-	(31.00)	0.00%
5012470	Legal Services	5,905.87	5,579.00	(326.87)	105.86%
	Total Mgmnt and Informational Svcs	138,134.31	127,339.00	(10,795.31)	108.48%
5012500	Repair and Maintenance Svcs				
5012510	Custodial Services	4,486.75	-	(4,486.75)	0.00%
5012530	Equipment Repair & Maint Srvc	1,755.00	1,705.00	(50.00)	102.93%
	Total Repair and Maintenance Svcs	6,241.75	1,705.00	(4,536.75)	366.09%
5012600	Support Services				
5012630	Clerical Services	100,658.62	67,495.00	(33,163.62)	149.13%
5012640	Food & Dietary Services	11,216.90	12,698.00	1,481.10	88.34%
5012660	Manual Labor Services	16,053.14	24,912.00	8,858.86	64.44%
5012670	Production Services	90,379.99	153,625.00	63,245.01	58.83%
5012680	Skilled Services	344,837.76	531,779.00	186,941.24	64.85%
	Total Support Services	563,146.41	790,509.00	227,362.59	71.24%
5012800	Transportation Services				
5012820	Travel, Personal Vehicle	19,466.69	25,626.00	6,159.31	75.96%
5012830	Travel, Public Carriers	4,694.72	4,170.00	(524.72)	112.58%
5012850	Travel, Subsistence & Lodging	16,013.34	21,524.00	5,510.66	74.40%
5012880	Trvl, Meal Reimb- Not Rprtble	6,604.75	7,407.00	802.25	89.17%
	Total Transportation Services	46,779.50	58,727.00	11,947.50	79.66%
	Total Contractual Svs	840,151.76	1,079,201.00	239,049.24	77.85%
5013000	Supplies And Materials				
5013100	Administrative Supplies				
5013120	Office Supplies	25,578.49	14,609.00	(10,969.49)	175.09%
5013130	Stationery and Forms	237.10	3,614.00	3,376.90	6.56%
	Total Administrative Supplies	25,815.59	18,223.00	(7,592.59)	141.66%
5013300	Manufctrng and Merch Supplies				
5013350	Packaging & Shipping Supplies	-	94.00	94.00	0.00%
	Total Manufctrng and Merch Supplies	-	94.00	94.00	0.00%
5013500	Repair and Maint. Supplies				

Virginia Department of Health Professions
Revenue and Expenditures Summary
Department 10200 - Medicine
For the Period Beginning July 1, 2016 and Ending May 31, 2017

Account Number	Account Description	Amount	Budget	Amount Under/(Over) Budget	% of Budget
5013520	Custodial Repair & Maint Matrl	33.17	-	(33.17)	0.00%
	Total Repair and Maint. Supplies	33.17	-	(33.17)	0.00%
5013600	Residential Supplies				
5013620	Food and Dietary Supplies	123.52	528.00	404.48	23.39%
5013630	Food Service Supplies	-	1,129.00	1,129.00	0.00%
	Total Residential Supplies	123.52	1,657.00	1,533.48	7.45%
5013700	Specific Use Supplies				
5013730	Computer Operating Supplies	669.00	166.00	(503.00)	403.01%
	Total Specific Use Supplies	669.00	166.00	(503.00)	403.01%
	Total Supplies And Materials	26,641.28	20,140.00	(6,501.28)	132.28%
5014000	Transfer Payments				
5014100	Awards, Contrib., and Claims				
5014130	Premiums	592.00	-	(592.00)	0.00%
	Total Awards, Contrib., and Claims	592.00	-	(592.00)	0.00%
	Total Transfer Payments	592.00	-	(592.00)	0.00%
5015000	Continuous Charges				
5015100	Insurance-Fixed Assets				
5015160	Property Insurance	-	485.00	485.00	0.00%
	Total Insurance-Fixed Assets	-	485.00	485.00	0.00%
5015300	Operating Lease Payments				
5015340	Equipment Rentals	6,256.92	7,200.00	943.08	86.90%
5015350	Building Rentals	353.76	-	(353.76)	0.00%
5015360	Land Rentals	-	100.00	100.00	0.00%
5015390	Building Rentals - Non State	127,814.72	133,528.00	5,713.28	95.72%
	Total Operating Lease Payments	134,425.40	140,828.00	6,402.60	95.45%
5015500	Insurance-Operations				
5015510	General Liability Insurance	-	1,828.00	1,828.00	0.00%
5015540	Surety Bonds	-	108.00	108.00	0.00%
	Total Insurance-Operations	-	1,936.00	1,936.00	0.00%
	Total Continuous Charges	134,425.40	143,249.00	8,823.60	93.84%
5022000	Equipment				
5022100	Computer Hrdware & Sftware				
5022170	Other Computer Equipment	3,546.73	-	(3,546.73)	0.00%
	Total Computer Hrdware & Sftware	3,546.73	-	(3,546.73)	0.00%
5022200	Educational & Cultural Equip				
5022240	Reference Equipment	141.00	829.00	688.00	17.01%
	Total Educational & Cultural Equip	141.00	829.00	688.00	17.01%
5022600	Office Equipment				
5022610	Office Appurtenances	-	125.00	125.00	0.00%
5022620	Office Furniture	1,594.35	1,857.00	262.65	85.86%
5022640	Office Machines	-	1,250.00	1,250.00	0.00%
5022680	Office Equipment Improvements	-	17.00	17.00	0.00%
	Total Office Equipment	1,594.35	3,249.00	1,654.65	49.07%
5022700	Specific Use Equipment				

Virginia Department of Health Professions
Revenue and Expenditures Summary
Department 10200 - Medicine
For the Period Beginning July 1, 2016 and Ending May 31, 2017

Account Number	Account Description	Amount	Budget	Amount Under/(Over) Budget	% of Budget
5022710	Household Equipment	228.99	-	(228.99)	0.00%
	Total Specific Use Equipment	228.99	-	(228.99)	0.00%
	Total Equipment	5,511.07	4,078.00	(1,433.07)	135.14%
	Total Expenditures	2,598,760.90	3,039,740.00	440,979.10	85.49%
	Allocated Expenditures				
30100	Data Center	855,541.64	1,092,171.08	236,629.44	78.33%
30200	Human Resources	68,375.48	202,896.27	134,520.79	33.70%
30300	Finance	313,064.37	307,063.31	(6,001.06)	101.95%
30400	Director's Office	159,225.61	180,604.71	21,379.10	88.16%
30500	Enforcement	1,681,619.41	1,716,880.52	35,261.11	97.95%
30600	Administrative Proceedings	650,256.25	818,760.24	168,503.98	79.42%
30700	Impaired Practitioners	25,751.99	24,612.76	(1,139.24)	104.63%
30800	Attorney General	164,206.88	162,067.98	(2,138.90)	101.32%
30900	Board of Health Professions	77,060.28	119,088.25	42,027.97	64.71%
31100	Maintenance and Repairs	-	3,379.12	3,379.12	0.00%
31300	Emp. Recognition Program	2,841.53	2,596.56	(244.97)	109.43%
31400	Conference Center	2,115.38	1,776.72	(338.66)	119.06%
31500	Pgm Devlpmnt & Implmentn	84,130.31	92,355.70	8,225.38	91.09%
	Total Allocated Expenditures	4,084,189.15	4,724,253.20	640,064.05	86.45%
	Net Revenue in Excess (Shortfall) of Expenditures	$ 183,219.95	$ (856,568.20)	$ (1,039,788.15)	21.39%

HPMP Monthly Census Report

Active Cases April 30, 2017

Board	Board Participants	License	Count of ID	% with this license
Nursing	275	LPN	40	9.1116
Nursing	275	RN	218	49.6583
Nursing	275	LNP	17	3.8724
			275	**62.6424**
Nursing	5	CNA	**4**	**0.9112**
Nursing	5	RMA	**1**	**0.2278**
			5	**1.1390**
Medicine	110	DO	10	2.2779
Medicine	110	Intern/Resident	10	2.2779
Medicine	110	MD	70	15.9453
Medicine	110	PA	7	1.5945
Medicine	110	Lic Rad Tech	2	0.4556
Medicine	110	DC	2	0.4556
Medicine	110	OT	2	0.4556
Medicine	110	RT	5	1.1390
Medicine	110	DPM	1	0.2278
Medicine	110	LBA	1	0.2278
			110	**25.0569**
Pharmacy	19	Pharmacist	**19**	4.3280
Dentistry	15	DDS	10	2.2779
Dentistry	15	DMD	2	0.4556
Dentistry	15	RDH	3	0.6834
			15	**3.4169**
Social Work	4	LCSW	**4**	**0.9112**
Psychology	2	LCP	**2**	0.4556
Counseling	1	LPC	**1**	0.2278
Veterinary Medicine	2	DVM	**2**	**0.4556**
Audiology & Speech-Language	**1**	SLP	**1**	**0.2278**
Physical Therapy	5	PT	2	0.4556
Physical Therapy	5	PTA	3	0.6834
			5	**1.1390**
TOTALS			**439.00**	**100.00**

From: G. Paul Nardo [mailto:GPNardo@house.virginia.gov]
Sent: Tuesday, May 23, 2017 2:46 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Cc: Bell, Richard P. <DelDBell@house.virginia.gov>
Subject: HJR 780 - Designating February, in 2018 and in each succeeding year, as Self-Care Month in Virginia

Dear Dr. Allison-Bryan:

During the 2017 Session of the Virginia General Assembly earlier this year, the Virginia House of Delegates passed a number of pieces of important legislation, including House Joint Resolution 780.

HJR 780 designates February, in 2018 and in each succeeding year, as Self-Care Month in Virginia.

Pursuant to this legislation, I have been directed to transmit a copy of HJR 780 to the Virginia Board of Medicine, so that members of the organization may be apprised of the sense of the General Assembly of Virginia in this matter.

So you may take note of this recent legislative action, I have attached for your convenience a copy of HJR 780 in a .PDF format in addition to the above hotlink to the legislation. I also am asking that you share this information with all intended recipients and/or others whom you believe may benefit from knowing of the intent of Virginia state lawmakers on this public policy matter.

If you have any questions, please let me know.

Thank you.

G. Paul Nardo

G. Paul Nardo

Clerk of the House & Keeper of the Rolls of the Commonwealth

804-698-1619 (office)
804-698-1800 (fax)
gpnardo@house.virginia.gov (email)

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Post Office Box 406
Richmond, Virginia 23218

Physical Address:
House Clerk's Office
Virginia House of Delegates
State Capitol, 3rd Floor
1000 Bank Street
Richmond, Virginia 23219

ENROLLED

HOUSE JOINT RESOLUTION NO. 780

Designating February, in 2018 and in each succeeding year, as Self-Care Month in Virginia.

Agreed to by the House of Delegates, January 31, 2017
Agreed to by the Senate, February 14, 2017

WHEREAS self-care is a lifelong daily habit of healthy lifestyle choices, good hygiene practices, prevention of infection and illness, avoiding unhealthy choices, monitoring for signs and symptoms of changes in health, knowing when to consult a health care practitioner, and knowing when it is appropriate to self-treat conditions; and

WHEREAS the U.S. Food and Drug Administration deems over-the-counter medicines safe and effective for the self-care treatment of minor acute and chronic health conditions and symptoms such as pain, the common cold, allergies, and other conditions that impact large segments of the population; and

WHEREAS over-the-counter medicines are either developed as new nonprescription medicines or switched from existing prescription medicines to provide greater empowerment to consumers; and

WHEREAS over-the-counter, nonprescription medicines are self-care products that consumers purchase in pharmacies, supermarkets, retail stores, and online; and

WHEREAS every dollar spent on over-the-counter medicines saves the United States health care system between six and seven dollars, totaling $102 billion in annual savings; and

WHEREAS nonprescription medicines help to ease the burden on health care practitioners, eliminating unnecessary medical examinations that could be avoided with appropriate self-care; and

WHEREAS Virginia benefits when its citizens practice appropriate self-care, do not unnecessarily visit health care practitioners, and are empowered by higher self-esteem, improved health, and reduced use of health care services; and

WHEREAS all Virginians are encouraged to take advantage of self-care's potential to improve personal and public health, help save personal and public funds, and strengthen the sustainability of Virginia's health care system; and

WHEREAS achieving the full potential of self-care is a shared opportunity for consumers, health care practitioners, policy makers, and regulators; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the General Assembly designate February, in 2018 and in each succeeding year, as Self-Care Month in Virginia; and, be it

RESOLVED FURTHER, That the Clerk of the House of Delegates transmit a copy of this resolution to the Virginia Board of Medicine so that members of the board may be apprised of the sense of the General Assembly of Virginia in this matter; and, be it

RESOLVED FINALLY, That the Clerk of the House of Delegates post the designation of this month on the General Assembly's website.

VIRGINIA BOARD OF MEDICINE

Committee Appointments

2016-2017

EXECUTIVE COMMITTEE (8)
Barbara Allison-Bryan, MD, President, Chair
Randy Clements, DPM
Lori Conklin, MD
Alvin Edwards, PhD
Jane Hickey, JD
Maxine Lee, MD
Kevin O'Connor, MD, Vice-President
Ray Tuck, DC - Secretary/Treasurer

LEGISLATIVE COMMITTEE (7)
Kevin O'Connor, MD, Vice-President, Chair
Syed Salman Ali, MD
Barbara Allison-Bryan, MD
David Giammittorio, MD
Jasmine Gore, The Honorable
Wayne Reynolds, DO
Svinder Toor, MD

CREDENTIALS COMMITTEE (9)
Kenneth Walker, MD, Chair
Salman Ali, MD
David Archer, MD
Deborah DeMoss Fonseca
Jane Hickey, JD
Isaac Koziol, MD
Jasmine Gore, The Honorable
Wayne Reynolds, DO
David Taminger, MD

FINANCE COMMITTEE
Barbara Allison-Bryan, MD – President
Kevin O'Connor, MD, Vice-President
Ray Tuck, Jr., DC - Secretary/Treasurer

BOARD BRIEFS COMMITTEE
William L. Harp, M.D., Ex Officio

CHIROPRACTIC COMMITTEE
Ray Tuck, Jr., DC - Secretary/Treasurer

BOARD OF HEALTH PROFESSIONS
Barbara Allison-Bryan, MD, President

COMMITTEE OF THE JOINT BOARDS OF NURSING AND MEDICINE
Lori Conklin, MD
Wayne Reynolds, DO
Kenneth Walker, MD

VIRGINIA BOARD OF MEDICINE
EXECUTIVE COMMITTEE MINUTES

Friday, April 7, 2017 Department of Health Professions Henrico, VA

CALL TO ORDER: The meeting convened at 8:30 AM.

ROLL CALL: Ms. Opher called the roll; a quorum was established.

MEMBERS PRESENT:
Barbara Allison-Bryan, MD, President, Chair
Randy Clements, DPM
Lori Conklin, MD
Alvin Edwards, PhD
Jane Hickey, JD
Maxine Lee, MD
Kevin O'Connor, MD, Vice-President

MEMBERS ABSENT: Ray Tuck, DC, Secretary-Treasurer

STAFF PRESENT:
William L. Harp, MD, Executive Director
Jennifer Deschenes, JD, Deputy Director, Discipline
Alan Heaberlin, Deputy Director, Licensure
Barbara Matusiak, MD, Medical Review Coordinator
Colanthia Morton Opher, Operations Manager
Sherry Gibson, Administrative Assistant
David Brown, DC, DHP Director
Lisa Hahn, DHP Senior Deputy Director
Elaine Yeatts, DHP Senior Policy Analyst
Erin Barrett, JD, Assistant Attorney General

OTHERS PRESENT:
Julie Galloway, MSV
Scott Johnson, JD, MSV
Eric Gish, DO, Liberty University

EMERGENCY EGRESS INSTRUCTIONS

Dr. O'Connor provided the emergency egress instructions.

APPROVAL OF MINUTES OF DECEMBER 2, 2016

Dr. Edwards moved to approve the meeting minutes of December 2, 2016 as presented. The motion was seconded and carried unanimously.

ADOPTION OF AGENDA

Dr. Edwards moved to adopt the agenda as presented. The motion was seconded and carried unanimously.

PUBLIC COMMENT

There was no public comment.

DHP DIRECTOR'S REPORT

Dr. Brown provided an update on the statistics he reported to the Full Board at its February 16, 2017 meeting. At that time, he had advised that the projection for opioid-related deaths would rise from 811 in 2015 to 1100 deaths in 2016, a 33% increase. However, it is now projected to reach closer to 1400 deaths, which will be greater than a 40% increase over 2015. As previously identified, the increase in numbers is directly related to heroin and fentanyl. Although prescription drug overdose deaths have plateaued in recent years, 80% of heroin and fentanyl deaths most likely can be traced back to a prescription for opioids for legitimate pain.

Dr. Brown said what the Board has done in creating regulations is very important, and in the long run the Board will be even more effective with evidence-based guidelines. Thanks for all those who put so much thought into the regulations, and to Dr. Harp for all his work in teeing them up and getting them drafted in an expeditious fashion.

Dr. Brown noted that there were two areas of concern – First, letters are being received from patients validating what Dr. Walker predicted at the Legislative Committee meeting, January 27, 2017. Dr. Walker had noted that, with the implementation of the regulations, some practitioners would choose to cease prescribing opioids, thereby reducing access to care for legitimate pain patients. Dr. Brown and Dr. Walker were not sure what to do about this, other than educate practitioners.

The second area of concern is the number and seriousness of comments that Dr. Harp and Board staff are receiving regarding the regulations. Do the regulations hit the mark and do what they are intended to do? A significant aspect of the regulations is the prevention of diversion of buprenorphine on the streets. HB2163 as initially written would have prohibited the prescription of buprenorphine mono-product to anyone other than pregnant women. Dr. Brown worked with the patron of the bill to ensure that the Board would be able to help determine who should and who should not be prescribed the mono-product.

Many comments the Board is receiving relate to the phenomenon of naloxone intolerance. The waivered physician community seems to be split about 50/50 on this issue.

Dr. Brown said that Dr. Harp had recently proposed language to address these concerns. Secretary Hazel thought that a deliberate approach to any change in the regulations would be the best way to go. Dr. Brown concluded by asking the Committee to consider reconvening a Regulatory Advisory Panel to review the emergency regulations and recommend revisions if warranted.

PRESENTATION: DR. GISH – LIBERTY UNIVERSITY OSTEOPATHIC MEDICAL SCHOOL

Dr. Eric Gish, Director of Osteopathic Integration, gave a brief presentation on the new osteopathic medical school in Lynchburg. Dr. Gish stated that the school's mission is to educate osteopathic physicians in a Christian environment. It prepares physicians who will dedicate themselves to excellence in practice, service toward their fellow man, lifelong learning and the advancement of medical knowledge. Dr. Gish pointed out that although the school has a Christian environment, students do not have to be Christian in order to attend. He also stated that the unwritten part of the school's mission is to encourage their students to eventually practice in the rural areas of Southside Virginia and its towns and cities--Danville, Martinsville, Lynchburg, South Boston and others. He also noted that the school has been granted the highest accreditation.

Dr. Gish stated that there are currently 3 classes of students with the first class set to graduate in 2018. The school provides training in biomedical science, pre-clinical studies, clinical studies and clinical rotation sites at Danville Regional Medical, Memorial Hospital of Martinsville, Sentara Halifax Regional Hospital, Southwestern Virginia Consortium, Bon Secours DePaul Medical Center, Palestine Regional Medical Center in Texas, and St. Anthony's Memorial Hospital in Illinois.

Dr. Lee said that she has met several Liberty students during Carilion's anesthesiology sessions. The students have been very enthusiastic and have worked collaboratively with every team member. Dr. Gish advised that, in addition to Carllion, Liberty also has a relationship with Edward Via and shares 3 training sites.

Fielding questions, Dr. Gish stated that in regards to outpatient work, the school has an onsite clinic and also partners with Central Virginia Family Physicians. Liberty's simulation center provides students with a variety of experiences, including observing a patient's passing away.

Dr. Allison-Bryan thanked Dr. Gish for his informative presentation.

EXECUTIVE DIRECTOR'S REPORT

FSMB Travel Authorization

Dr. Harp provided an update on the progress of the travel authorization requests for the FSMB Annual Meeting. Dr. Brown said that he had signed and forwarded the authorizations to the Secretary's office. It's the largest number that he has seen for travel to FSMB. He noted that Dr. Hazel is very supportive of activities that will enhance the Board members' ability to protect the public.

Revenue and Expenditures

Dr. Harp reported that the cash balance on February 28, 2017 was $11 million and that the Board is a little ahead on its revenues. Because of the surplus in the budget, a 20% reduction in renewal fees has been implemented for the upcoming biennium.

Health Practitioners Monitoring Program

Dr. Harp briefly reviewed the HPMP census report noting that Medicine always has about 25% of the total participants; at this time Medicine has 106 participants.

NEW BUSINESS

Chart of Regulatory Actions

Ms. Yeatts reviewed the status of pending regulatory matters and highlighted "Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic – licensure by endorsement", "Regulations Governing the Practice of Occupational Therapists – NBCOT certification as option for CE", and "Regulations Governing the Practice of Genetic Counselors".

This report was for informational purposes only.

Report from the 2017 General Assembly

Ms. Yeatts briefly reviewed the following legislation:

- HB 1484 Occupational therapists; Board of Medicine shall amend regulations governing licensure. Board of Medicine to amend regulations governing licensure of occupational therapists to specify Type 1 continuous learning activities. Directs the Board of Medicine to amend regulations governing licensure of occupational therapists to provide that Type 1 continuing learning activities that shall be completed by the practitioner prior to renewal of a license shall consist of an organized program of study, classroom experience, or similar educational experience that is related to a licensee's current or anticipated roles and responsibilities in occupational therapy and approved or provided by one of the following organizations or any of its components: the Virginia Occupational Therapy Association; the American Occupational Therapy Association; the National Board for Certification in Occupational Therapy; a local, state, or federal government agency; a regionally accredited college or university; or a health care organization accredited by a national accrediting organization granted authority by the Centers for Medicare and Medicaid Services to assure compliance with Medicare conditions of participation. Such regulations shall also provide that Type 1 continuing learning activities may also include an American Medical Association Category 1 Continuing Medical Education program. The bill further provides that the Board of Medicine shall not deem maintenance of any certification provided by such organization as sufficient to fulfill continuing learning requirements for occupational therapists.

- HB 2119 – Laser hair removal; limits practice. Limits practice to a properly trained person licensed to practice medicine or osteopathic medicine or licensed as a physician assistant or nurse practitioner, or to a properly trained person under the direction and supervision of a licensed doctor of medicine or osteopathic medicine or physician assistant or nurse practitioner.

- HB 2164 Drugs of concern; drug of concern. - Adds any material, compound, mixture, or preparation containing any quantity of gabapentin, including any of its salts, to the list of drugs of concern. This bill contains an emergency clause.

- SB848 Naloxone; dispensing for use in opioid overdose reversal, etc. - Dispensing of naloxone. Allows a person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for use in opioid overdose reversal and who is acting on behalf of an organization that provides services to individuals at risk of experiencing opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a controlled substances registration from the Board of Pharmacy pursuant to § 54.1-3423 to dispense naloxone to a person who has completed a training program on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber, (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, and (iii) without charge or compensation. The bill also provides that dispensing may occur at a site other than that of the controlled substance registration, provided that the entity possessing the controlled substance registration maintains records in accordance with regulations of the Board of Pharmacy. The bill further provides that a person who dispenses naloxone shall not be liable for civil damages of ordinary negligence for acts or omissions resulting from the rendering of such treatment if he acts in good faith and that a person to whom naloxone has been dispensed pursuant to the provisions of the bill may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. The bill contains an emergency clause. This bill is identical to **HB 1453**.

- SB 880 Genetic counselors; licensing; grandfather clause. - Extends the deadline from July 1, 2016, to December 31, 2018, or to within 90 days of the effective date of the relevant regulations promulgated by the Board, whichever is later, by which individuals who have at least 20 years of documented work experience practicing genetic counseling and meet other certain requirements may receive a waiver from the Board of Medicine of the requirements of a master's degree and American Board of Genetic Counseling or American Board of Medical Genetics certification for licensure as a genetic counselor.

- SB 1020 Peer recovery specialists and qualified mental health professionals; registration. - **Registration of peer recovery specialists and qualified mental health professionals.** Authorizes the registration of peer recovery specialists and qualified mental health professionals by the Board of Counseling. The bill defines "qualified mental health professional" as a person who by education and experience is professionally qualified and registered by the Board of Counseling to provide collaborative mental health services for adults or children. The bill requires that a qualified mental health professional provide such services as an employee or independent contractor of the Department of Behavioral Health and Developmental Services or a provider licensed by the

Department of Behavioral Health and Developmental Services. The bill defines "registered peer recovery specialist" as a person who by education and experience is professionally qualified and registered by the Board of Counseling to provide collaborative services to assist individuals in achieving sustained recovery from the effects of addiction or mental illness, or both. The bill requires that a registered peer recovery specialist provide such services as an employee or independent contractor of the Department of Behavioral Health and Developmental Services, a provider licensed by the Department of Behavioral Health and Developmental Services, a practitioner licensed by or holding a permit issued from the Department of Health Professions, or a facility licensed by the Department of Health. The bill adds qualified mental health professionals and registered peer recovery specialists to the list of mental health providers that are required to take actions to protect third parties under certain circumstances and notify clients of their right to report to the Department of Health Professions any unethical, fraudulent, or unprofessional conduct. The bill directs the Board of Counseling and the Board of Behavioral Health and Developmental Services to promulgate regulations to implement the provisions of the bill within 280 days of its enactment. This bill is identical to **HB 2095.**

- SB 1027 Cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide. - **Cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide.** Authorizes a pharmaceutical processor, after obtaining a permit from the Board of Pharmacy (the Board) and under the supervision of a licensed pharmacist, to manufacture and provide cannabidiol oil and THC-A oil to be used for the treatment of intractable epilepsy. The bill sets limits on the number of permits that the Board may issue and requires that the Board adopt regulations establishing health, safety, and security requirements for permitted processors. The bill provides that only a licensed practitioner of medicine or osteopathy who is a neurologist or who specializes in the treatment of epilepsy may issue a written certification to a patient for the use of cannabidiol oil or THC-A oil. The bill also requires that a practitioner who issues a written certification for cannabidiol oil or THC-A oil, the patient issued such certification, and, if the patient is a minor or incapacitated, the patient's parent or legal guardian register with the Board. The bill requires further that a pharmaceutical processor shall not provide cannabidiol oil or THC-A oil to a patient or a patient's parent or legal guardian without first verifying that the patient, the patient's parent or legal guardian if the patient is a minor or incapacitated, and the practitioner who issued the written certification have registered with the Board. Finally, the bill provides an affirmative defense for agents and employees of pharmaceutical processors in a prosecution for the manufacture, possession, or distribution of marijuana. The bill contains an emergency clause.

- SB 1046 Board of Medicine; requirements for licensure. - **Board of Medicine; requirements for licensure.** Removes provisions related to licensure of graduates of an institution not approved by an accrediting agency recognized by the Board of Medicine. Under the bill, only graduates of institutions approved by an accrediting agency recognized by the Board of Medicine are eligible for licensure.

- SB 1178 Buprenorphine without naloxone; prescription limitation. - **Prescription of buprenorphine without naloxone; limitation.** Provides that prescriptions for products containing buprenorphine without naloxone shall be issued only (i) for patients who are pregnant, (ii) when converting a patient from methadone to buprenorphine containing naloxone for a period not to exceed seven days, or

(iii) as permitted by regulations of the Board of Medicine or the Board of Nursing. The bill contains an emergency clause and has an expiration date of July 1, 2022. This bill is identical to **HB 2163.** Ms. Yeatts advised that this bill was amended to include veterinary medicine.

- SB 1180 Opioids and buprenorphine; Boards of Dentistry and Medicine to adopt regulations for prescribing. - **Boards of Dentistry and Medicine; regulations for the prescribing of opioids and buprenorphine.** Directs the Boards of Dentistry and Medicine to adopt regulations for the prescribing of opioids and products containing buprenorphine. The bill requires the Prescription Monitoring Program at the Department of Health Professions to annually provide a report to the Joint Commission on Health Care and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health on the prescribing of opioids and benzodiazepines in the Commonwealth that includes data on reporting of unusual patterns of prescribing or dispensing of a covered substance by an individual prescriber or dispenser or on potential misuse of a covered substance by a recipient. The bill contains an emergency clause.

- SB 1230 Opiate prescriptions; electronic prescriptions. - **Opiate prescriptions; electronic prescriptions.** Requires a prescription for any controlled substance containing an opiate to be issued as an electronic prescription and prohibits a pharmacist from dispensing a controlled substance that contains an opiate unless the prescription is issued as an electronic prescription, beginning July 1, 2020. The bill defines electronic prescription as a written prescription that is generated on an electronic application in accordance with federal regulations and is transmitted to a pharmacy as an electronic data file. The bill requires the Secretary of Health and Human Resources to convene a work group of interested stakeholders to review actions necessary for the implementation of the bill's provisions, to evaluate hardships on prescribers and the inability of prescribers to comply with the deadline for electronic prescribing, and to make recommendations for any extension or exemption processes relative to compliance or disruptions due to natural or manmade disasters or technology gaps, failures, or interruptions of services. The work group shall report on the work group's progress to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2017, and a final report to such Chairmen by November 1, 2018. Ms. Yeatts advised that a work group will be established to develop the guidelines.

- SB 1232 Opioids; limit on amount prescribed, extends sunset provision. - **Limits on prescription of controlled substances containing opioids.** Requires a prescriber registered with the Prescription Monitoring Program (the Program) to request information about a patient from the Program upon initiating a new course of treatment that includes the prescribing of opioids anticipated, at the onset of treatment, to last more than seven consecutive days and exempts the prescriber from this requirement if the opioid is prescribed as part of treatment for a surgical or invasive procedure and such prescription is for no more than 14 consecutive days. Current law requires a registered prescriber to request information about a patient from the Program upon initiating a new course of treatment that includes the prescribing of opioids anticipated, at the onset of treatment, to last more than 14 consecutive days and exempts the prescriber from this requirement if the opioid is prescribed as part of a course of treatment for a surgical or invasive procedure and such prescription is not refillable. The bill extends the sunset for this requirement from July 1, 2019, to July 1, 2022.

- SB 1403 Controlled substances; use of FDA-approved substance upon publication of final rule, etc. - **Board of Pharmacy to deschedule or reschedule controlled substances.** Authorizes the Board of Pharmacy (Board) to designate, deschedule, or reschedule as a controlled substance any substance 30 days after publication in the Federal Register of a final or interim final order or rule designating such substance as a controlled substance or descheduling or rescheduling such substance. Under current law, the Board may act 120 days from such publication date. The bill also provides that a person is immune from prosecution for prescribing, administering, dispensing, or possessing pursuant to a valid prescription a substance approved as a prescription drug by the U.S. Food and Drug Administration on or after July 1, 2017, in accordance with a final or interim final order or rule despite the fact that such substance has not been scheduled by the Board. The immunity provided by the bill remains in effect until the earlier of (i) nine months from the date of the publication of the interim final order or rule or, if published within nine months of the interim final order or rule, the final order or rule or (ii) the substance is scheduled by the Board or by law. This bill is identical to HB 1799.

This report was for informational purposes only.

Regulatory Action – Adoption of Final Regulations for Nurse Practitioners

Ms. Yeatts stated that a fee reduction had been approved by the Board of Nursing for all categories of nurse practitioners, and it must also be approved by the Board of Medicine.

Dr. Edwards moved to adopt the final regulations as an exempt action. The motion was seconded and carried unanimously.

Regulatory Advisory Panel for Opioid Regulations

Dr. Allison-Bryan stated that she was proud of the work the Board has done with the regulations and is impressed that acceptance of them is going as smoothly it is, considering only a few concerns had been expressed.

To deal with a number of comments about naloxone intolerance and other issues, it has been suggested to re-establish the Regulatory Advisory Panel to review the regulations and propose some minor tweaking if warranted.

After a brief discussion, Dr. Conklin moved to re-establish a Regulatory Advisory Panel for the reasons stated above. The motion was seconded and carried unanimously.

ANNOUNCEMENTS

Next meeting – August 4, 2017

There were no other announcements.

ADJOURNMENT

With no further business to conduct, the meeting adjourned at 9:28 a.m.

Barbara Allison-Bryan, MD
President, Chair

William L. Harp, MD
Executive Director

Colanthia M. Opher
Recording Secretary

VIRGINIA BOARD OF MEDICINE

LEGISLATIVE COMMITTEE MINUTES

Friday, May 19, 2017 Department of Health Professions Henrico, VA

CALL TO ORDER: The meeting convened at 8:31 a.m.

ROLL CALL: Mr. Heaberlin called the roll; a quorum was established.

MEMBERS PRESENT:
Kevin O'Connor, MD, Vice-President, Chair
Syed Salman Ali, MD
Wayne Reynolds, DO
Svinder Toor, MD
The Honorable Jasmine Gore

MEMBERS ABSENT
Barbara Allison-Bryan, MD, President
David Giammittorio, MD

STAFF PRESENT:
William L. Harp, MD, Executive Director
Jennifer Deschenes, JD, Deputy Director, Discipline
Alan Heaberlin, Deputy Director, Licensure
Barbara Matusiak, MD, Medical Review Coordinator
Colanthia Morton Opher, Operations Manager
David Brown, DC, DHP Director
Erin Barrett, JD, Assistant Attorney General

OTHERS PRESENT:
W. Scott Johnson, JD, HDJN & MSV
Ralston King, MSV
Carey Cox, VATAC
Sara Heisler, VHHA

EMERGENCY EGRESS INSTRUCTIONS

Dr. O'Connor provided the emergency egress instructions.

APPROVAL OF MINUTES of January 27, 2017

Dr. Ali moved to accept the meeting minutes as presented. The motion was seconded and carried.

ADOPTION OF AGENDA

Dr. Toor made a motion to accept the agenda as presented.

The motion was seconded and carried unanimously.

PUBLIC COMMENT

There was no public comment.

DHP DIRECTOR'S REPORT

Dr. Brown provided a brief report. He said that, in calendar year 2016, Virginia deaths related to opioid overdose were up 40% over calendar year 2015 and noted that there is no sign of this problem slowing. He commended the Regulatory Advisory Panel (RAP) for their work on the opioid regulations. He also noted that the workgroup of educators meeting next door with Dr. Hazel should be a great help in reducing opioid overdose death through prescriber education.

EXECUTIVE DIRECTOR'S REPORT

Dr. Harp did not have a report.

NEW BUSINESS

1. **Chart of Board of Medicine Regulatory Actions**

Elaine Yeatts provided a brief overview of this item. No action was required.

2. **Consideration of Recommendations from the Regulatory Advisory Panel, Supporting Documents, and Public Comment.**

Dr. O'Connor began by noting that he does not want to change the regulations based on anecdotal information.

Ms. Yeatts explained the different processes required to amend the emergency regulations and final regulations. The full Board in June will re-adopt the emergency regulations and move to adopt the full regulations to replace the emergency regulations upon their expiration. She then led the Committee through the recommendations from the RAP that met May 15, 2017.

18VAC85-21-70(C). After a brief discussion Dr. Ali moved to strike the first sentence of subsection C in the emergency regulations and to substitute the language, "Buprenorphine mono-product in tablet form shall not be prescribed for chronic pain." The motion was seconded and carried unanimously.

18VAC85-21-150(4). The Committee discussed how prescribers would be monitored to ensure they did not exceed 5% of patients being prescribed the mono-product. Dr. Harp, Dr. Brown and Ms. Deschenes all noted that the Prescription Monitoring Program (PMP) could be used to conduct prescriber audits. It was reported that Ralph Orr, PMP Director, could fashion a program to identify those that exceeded the established threshold.

Dr. Toor stated that he would like documentation on the patient's prescription that he/she is allergic to naloxone. He further asked for clarification on how the RAP chose 5% of patients as a threshold.

Dr. Harp stated that this number was agreed to by the RAP, which had believers and skeptics regarding naloxone intolerance. He stated that a member of the RAP noted his patients that were unable to tolerate the bi-product was around 5% of his total number of MAT patients.

Dr. Brown explained that having a clear percentage of patients in the regulations strengthens the hand of the Board. It will allow the PMP Advisory Panel to set the threshold for prescribers that are to be referred for investigation. A clear standard in the regulations will serve as a concrete basis for such referrals.

Dr. Ali asked Dr. Harp if the 5% number is necessary, and if it is his general belief that it is accurate that 5% of patients have problems with naloxone-containing product.

Dr. Harp stated that, according to the RAP, naloxone intolerance occurs in less than 5% of the patient population and that financial hardship is greater than 5%.

Dr. O'Connor stated that it is not the Board's purview to determine financial hardship. He favors reducing the 5% number to 3% and to strike "financial hardship" from the suggested revision. He further stated that a prescriber needs to have significant documentation in the medical record supporting why the mono-product is being prescribed.

Ms. Gore noted that she believed financial hardship should be included in the regulations. Financial hardship and the patient's ability to pay is a significant part of seeking and obtaining health care.

The Committee agreed that a 3% threshold would be enough to cover naloxone intolerance. Dr Toor made a motion to revise 18VAC85-21-150(4) to read, "For patients who have a demonstrated allergy or intolerance to naloxone, prescriptions for the mono-product shall not exceed 3% of the total prescriptions for buprenorphine written by the prescriber. Such exceptions must be clearly documented in the patient's medical record."

The motion was seconded and carried unanimously.

18VAC85-21-160(A).

Dr. Toor moved to change "shall" to "may." The motion was seconded and carried.

The Committee then began to review suggested edits to the final regulations that arose from the RAP's discussion.

18VAC85-21-10(2). The edit to include correctional facilities was discussed. Ms. Deschenes reviewed the reasons for including the revised language including correctional facilities, noting that the particular subsection dealt with acute and chronic pain, not addiction.

Dr. Ali noted that this particular population is already prone to drug-seeking behavior and exempting correctional facilities from the regulations is counterintuitive.

Ms. Deschenes said that patients in correctional facilities are administered the medication by a nurse who ensures that it is taken as prescribed.

Dr. Brown noted that the agency had not been contacted by any correctional facilities seeking such an exception.

By consensus, it was determined not to include the suggested revision in the final regulations.

18VAC85-21-30(B). A discussion was held regarding the feasibility of removing the specific Code language from this regulation.

Ms. Yeatts noted that striking the Code section language would require physicians to check the PMP if even one opioid tablet was prescribed.

The Committee agreed that this would result in an undue burden for physicians.

Dr. Brown told the Committee that the General Assembly had made it a standard to check the PMP when a prescription is written for a 7 day or greater supply of opioids.

By consensus, it was determined to leave this regulation as written.

180VAC85-21-40 & 18VAC85-21-70(5). Dr. Harp explained that the Board had gotten questions from pharmacists who have to call physicians in order to determine if the opioid prescriptions being written were legitimate, since allowable supplies differ for acute, surgical and chronic pain.

Dr. O'Connor stated that this recommendation appears to open an avenue for more complaints to the Board about physicians rather than improving patient care.

Dr. Brown noted that this particular revision is part of the final regulations which still must go out for another comment period. He noted that, without the proposed language, more calls will be made to prescribers by pharmacists who want to double-check why a prescription is being written.

Dr. Ali noted that this would be difficult to implement with physicians who write prescriptions electronically. It would be particularly difficult to document the type of pain on prescriptions generated in electronic medical records (EMR).

Dr. O'Connor said that this is not an issue about which people are complaining.

Dr. Toor moved not to include the revised language in the final regulations.

The motion was seconded and carried.

18VAC85-21-40(A)(C). This revision was requested because tramadol is an opioid and having it named separately in the regulation creates ambiguity. Dr. O'Connor said that there is no downside to leaving tramadol in the regulation as written, and by consensus it was decided tramadol would stay.

18VAC85-21-70(A)(3) & 18VAC85-21-80(C). After a brief discussion, Dr. Toor moved to strike "abuse" in the first regulation above and replace it with "misuse". He moved to strike the word "abuse" from the second regulation as well, replacing it with "misuse". The motion was seconded and carried.

3. **Draft Regulations for Licensure by Endorsement.**

Dr. Harp reviewed the "Draft Elements for Licensure by Endorsement" with the Committee.

Items under section 1 and 2 were agreed upon by consensus with no discussion.

Regarding section 3, a discussion was held on the period of practice a physician must attest to in order to be eligible for licensure by endorsement. Mr. Heaberlin suggested that, based upon his review of other states' regulations for licensure by endorsement, the Board should require 5 years of "continuous" or "active" practice defined as an average of 20 hours/week, or 640 hours a year.

Dr. Ali asked if residency and fellowships could be included in the 5 years of continuous or active practice.

Mr. Heaberlin noted that licensure by endorsement is intended to expedite licensure for physicians who have been practicing for several years and who already have a practice history. Physicians coming out of residency or fellowship are already expedited since there is less work history to be verified.

On section 4, Dr. Harp explained that North Carolina and other states that have licensure by endorsement accept the Canadian Board certifications as equivalent to the U.S. Board certifications.

For section 5, Dr. Harp explained the elements in a National Practitioner Data Bank report. The report includes medical malpractice payments, medical board history, licensure history and disciplinary actions taken by hospitals.

Dr. Ali noted the report was easy to obtain.

Dr. Harp asked if, since the NPDB report is so inclusive, would it be acceptable to the Board if only one license verification was required to document the 5 years of continuous licensure.

The Committee agreed that only one license verification would be needed. Dr. Toor also noted that the application should ask the applicant if he has ever resigned from a position or is under investigation by any other Board.

Dr. Toor moved to accept the "Draft Elements for Licensure by Endorsement" as reviewed by the Committee. The motion was seconded and carried unanimously.

ANNOUNCEMENTS

Please have your travel vouchers in by May 22nd.

The next Legislative Committee meeting will be September 8, 2017.

ADJOURNMENT

All business being completed, Dr. O'Connor adjourned the meeting at 10:07 a.m.

Kevin O'Connor, MD
Vice-President, Chair

William L. Harp, MD
Executive Director

Alan Heaberlin, Deputy Director, Licensing
Recording Secretary

<< DRAFT UNAPPROVED >>

ADVISORY BOARD ON ACUPUNCTURE
MINUTES

The Advisory Board on Acupuncture met on Tuesday, May 30, 2017 at 10:00 a.m. at the Department of Health Professions at 9960 Mayland Drive, Henrico, VA 23233.

MEMBERS PRESENT: Lynn Almloff, L.Ac., Chair
Janet L. Borges, L.Ac., Vice-Chair
Sharon Crowell, L.Ac.
Leslie Rubio, Citizen Member

MEMBERS ABSENT: Chheany Ung, M.D.

STAFF PRESENT: William L. Harp, M.D., Executive Director
Alan Heaberlin, Deputy Executive Director-Licensing
Erin Barrett, JD, Assistant Attorney General
Beulah Baptist Archer, Licensing Specialist
Colanthia Morton Opher, Operations Manager

GUESTS PRESENT: Richard Grossman, VECTRE

CALL TO ORDER

Lynn Almloff called the meeting to order.

EMERGENCY EGRESS PROCEDURES

Alan Heaberlin announced how to exit the building in case of an emergency or a drill.

ROLL CALL

Beulah Archer called the roll; a quorum was declared.

APPROVAL OF THE MINUTES FROM February 1, 2017.

Sharon Crowell moved to approve the minutes. The motion was seconded and carried.

ADOPTION OF THE AGENDA

Lynn Almloff moved to adopt the agenda. The motion was seconded and carried.

PUBLIC COMMENT ON AGENDA ITEMS

No public comment.

NEW BUSINESS

1. **Advisory Board Statement on the Acupuncture Modality of Dry Needling**

Janet Borges restated the request by Matthew Stanley in the previous Advisory Board meeting that it consider issuing a statement regarding the definition of dry needling.

Board Counsel, Erin Barrett, JD, stated that the Advisory Board on Acupuncture can only define dry needling for the profession of acupuncture, that the current modalities allowed by acupuncture are broadly stated in Virginia law and regulations that govern its practice, and that guidance documents do not speak to standards of care.

Janet Borges moved that the Advisory Board convene a closed session pursuant to section 2.2-3711(A)(7) of the Code of Virginia for consultation with the Assistant Attorney General. Additionally, it was moved that William L. Harp, MD, Alan Heaberlin, Beulah Archer and Colanthia Morton attend the closed meeting because 1) their presence in the closed meeting is deemed necessary, and/or 2) their presence will aid the Advisory Board in its consideration of this matter. Sharon Crowell seconded the motion, which passed unanimously.

Upon returning to open session, Lynn Almloff moved that "all those who certify, to the best of your knowledge that the Advisory Board on Acupuncture heard, discussed or considered only those public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act, and only such public business matters as were identified in the motion by which the closed meeting was convened." The motion was seconded by Sharon Crowell. All members unanimously said "Aye" to the certification.

Lynn Almloff moved that the Advisory Board not make any comment on dry needling. The motion was seconded and carried with Ms. Almloff, Ms. Crowell and Ms. Rubio voting "yes", and with Ms. Borges voting "no."

Announcements –Alan Heaberlin

Active Licensed—Acupuncturists-502

Inactive Licensed—Acupuncturists-7

NEXT SCHEDULED MEETING:

October 4, 2017 @ 10:00 a.m.

ADJOURNMENT

Lynn Almloff declared meeting be adjourned at 11:06 a.m.

Lynn Almloff, L.Ac., Chair

William L. Harp, M.D., Executive Director

Beulah Baptist Archer, Licensing Specialist

DRAFT UNAPPROVED

ADVISORY BOARD ON GENETIC COUNSELING
MINUTES

June 5, 2017

The Advisory Board on Genetic Counseling met on Monday, June 5, 2017, at 1:00 p.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Henrico, Virginia.

MEMBERS PRESENT:	Matthew Thomas, ScM, CGC, Chair Heather Creswick, MS, CGC, Vice Chair John Quillin, PhD, MPH, MS Lori Swain
MEMBER ABSENT:	Marilyn Foust, MD
STAFF PRESENT:	William L. Harp, M.D., Executive Director Elaine Yeatts, DHP Senior Policy Analyst Alan Heaberlin, Deputy Executive Director Colanthia Morton Opher, Operations Manager Denise Mason, Licensing Specialist
GUESTS PRESENT:	Logan B. Karns, MS, University of Virginia

CALL TO ORDER

Mr. Thomas called the meeting to order at 1:02 p.m.

EMERGENCY EGRESS PROCEDURES

Mr. Thomas announced the Emergency Egress Instructions.

ROLL CALL

The roll was called, and a quorum was declared.

APPROVAL OF MINUTES OF NOVEMBER 14, 2016

Dr. Quillin moved to approve the minutes of November 14, 2016. The motion was seconded and carried.

ADOPTION OF AGENDA

Ms. Quillin moved to approve the agenda. The motion was seconded and carried.

PUBLIC COMMENT ON AGENDA ITEMS

Ms. Karns proposed questions to the Board in regards to the University of California Berkeley Genetic Counseling Program and its accreditation at the time of her graduation.

NEW BUSINESS

1. Review of Regulations Effective June 14, 2017

Ms. Yeatts reviewed the Regulations Governing the Practice of Genetic Counselors which become effective on June 14, 2017. Heather Creswick made a motion requesting legal advice from the Office of the Attorney General regarding a legal interpretation of 18VAC85-170-60(A) to determine if a candidate for licensure who graduated from an ABCG-accredited program prior to 2013 would be eligible for licensure. The motion was seconded and carried.

Mr. Heaberlin noted that, at the full Board meeting on June 22, 2017, he would request a grace period for licensure until December 31, 2018.

2. Review of the Application Process

Mr. Heaberlin led the Advisory Board in a discussion of the application process which included instructions, forms and applications. Minor revisions were discussed for the application process and documents. Ms. Creswick made a motion to approve the revisions. The motion was seconded and carried.

ANNOUNCEMENTS

There were no announcements.

NEXT MEETING DATE

October 2, 2017 @ 1:00p.m.

ADJOURNMENT

The Advisory board meeting was adjourned at 2:36p.m.

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Matthew Thomas, Chair

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William L. Harp, M.D., Executive Director

_____
Denise Mason, Licensing Specialist

---DRAFT UNAPPROVED ---

ADVISORY BOARD ON BEHAVIOR ANALYSIS
Minutes
June 5, 2017

The Advisory Board on Behavior Analysis met on Monday, June 5, 2017 at 10:00 a.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Henrico, Virginia 23233.

MEMBERS PRESENT:	Keri Bethune, PhD, BCBA-D Kate Lewis, MS, BCBA, LBA Amanda Kusterer, BCaBA Asha Patton Smith, MD
MEMBERS ABSENT:	Gary Fletcher
STAFF PRESENT:	William L. Harp, M.D., Executive Director Alan Heaberlin, Deputy Director, Licensure Elaine Yeatts, DHP Senior Policy Analyst Denise Mason, Licensing Specialist Colanthia Morton Opher, Operations Manager
GUESTS PRESENT:	Christy Evanko, BCBA

CALL TO ORDER

Dr. Bethune called the meeting to order at 10:05 a.m.

EMERGENCY EGRESS PROCEDURES

Alan Heaberlin announced the Emergency Egress Procedures.

ROLL CALL

The roll was called by Denise Mason; a quorum was declared.

ADOPTION OF AGENDA

Ms. Kusterer moved to adopt the agenda as presented. The motion was seconded and carried.

---DRAFT UNAPPROVED ---

APPROVAL OF MINUTES OF January 30, 2017

Ms. Lewis made a motion to approve the minutes. The motion was seconded and carried.

PUBLIC COMMENT

Ms. Evanko discussed changes she would like to see in the wording of the application.

NEW BUSINESS

1. Review of the Application Process

Mr. Heaberlin noted that in Fiscal Year 2017, the Board has licensed 31 Assistant Behavior Analysts in an average of 33 days, and 209 Behavior Analysts in an average of 45 days. He then reviewed the application process including the instructions, forms and applications for Assistant Behavior Analysts and Behavior Analysts. The Advisory Board suggested several revisions to the language in these documents that would improve the process for applicants and staff. Mr. Heaberlin indicated that the changes would be made.

Announcements

Mr. Heaberlin informed the Advisory Board that there are currently 869 Behavior Analysts and 138 Assistant Behavior Analysts holding licenses with the Virginia Board of Medicine.

Next Meeting Date

The Advisory Board's next meeting will be October 2, 2017 at 10:00 a.m.

Adjournment

The meeting was adjourned at 10:46 a.m.

_____
Dr. Keri Bethune, PHD, BCBA-D

_____
William L. Harp, M.D.
Executive Director

_____
Denise W. Mason, Licensing Specialist

ADVISORY BOARD ON OCCUPATIONAL THERAPY
Minutes
June 6, 2017

The Advisory Board on Occupational Therapy met on Tuesday, June 6, 2017 at 10:00 a.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Henrico, Virginia.

MEMBERS PRESENT: Kathryn Skibek, OT, Chair
Breshae Bedward, OT, Vice-Chair
Eugenio Monasterio, M.D.
Karen Lebo

MEMBERS ABSENT: Dwayne Pitre, OT

STAFF PRESENT: William L. Harp, M.D., Executive Director
Alan Heaberlin, Deputy Director, Licensure
Elaine Yeatts, DHP Senior Policy Analyst
ShaRon Clanton, Licensing Specialist
Jennifer Deschenes, Deputy Executive Director, Discipline
Jennie Wood, Compliance/Safety Officer III

GUESTS PRESENT: Alexander Macaulay, VOTA

CALL TO ORDER

Kathryn Skibek called the meeting to order at 10:00 a.m.

EMERGENCY EGRESS PROCEDURES

Mr. Heaberlin announced the Emergency Egress Instructions.

ROLL CALL

ShaRon Clanton called the roll, and a quorum was declared.

APPROVAL OF MINUTES OF JANUARY 31, 2017.

Dr. Monasterio moved to adopt the minutes as written. The motion was seconded and carried.

ADOPTION OF AGENDA

There was an amendment to the agenda for consideration of proposed regulations. Dr. Monasterio moved to adopt the amended agenda. The motion was seconded and carried.

PUBLIC COMMENT ON AGENDA ITEMS

None

NEW BUSINESS

1. Virginia Occupational Therapy Workforce 2016

   Elizabeth Carter, PhD reviewed "Virginia's Occupational Therapy and Occupational Therapy Assistant Workforce: 2016" created by the Healthcare Workforce Data Center. Ms. Lebo commended Dr. Carter on the scope and thoroughness of the study. No action was required.

2. Request for Guidance Document Regarding Supervisory Responsibilities of an Occupational Therapist

   Jennifer Deschenes and Jennie Wood discussed questions that Board staff has received regarding the supervisory responsibilities of an Occupational Therapist. The members of the Advisory Board recommended maintaining a list of questions regarding this subject for discussion at the next meeting. Based on the discussion in October, the Advisory Board will recommend a guidance document or a set of Frequently Asked Questions. The members all agreed by affirmation.

3. Consideration of Proposed Regulations

   Elaine Yeatts requested the Advisory Board to recommend that the Board of Medicine adopt amendments to 18VAC85-80-71 in order to conform to the new law regarding continued competency. The motion was made by Ms. Bedward, seconded and carried unanimously.

   Ms. Yeatts then asked the Advisory Board to consider amending the proposed regulatory action regarding 18VAC85-80-71 by deleting subsection 3 which states "The board recognizes the maintenance of current NBCOT certification as fulfilling the requirements of this subsection". Deleting this sentence will avoid a conflict with the new law that becomes effective July 1, 2017. Ms. Yeatts noted that other amendments to this section were still viable and could move forward by fast-track action if requested by the Advisory Board. Ms. Lebo moved to recommend the proposed language as previously written with the deletion of subsection 3 for consideration of fast-track action. The motion was seconded and carried unanimously.

ANNOUNCEMENTS:

Mr. Heaberlin informed the Advisory Board that there are currently 3146 active and 33 inactive Occupational Therapists. Additionally, there are 1177 active and 7 inactive Occupational Therapy Assistants who hold licenses issued by the Virginia Board of Medicine.

NEXT MEETING DATE

October 3, 2017, 10:00 a.m.

ADJOURNMENT

The meeting of the Advisory board was adjourned at 11:19 a.m.

Kathryn Skibek, OT, Chair

William L. Harp, M.D.
Executive Director

ShaRon Clanton, Licensing Specialist

DRAFT UNAPPROVED

ADVISORY BOARD ON ATHLETIC TRAINING
MINUTES

June 8, 2017

The Advisory Board on Athletic Training met on Thursday, June 8, 2017, at 10:00 a.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Henrico, Virginia.

MEMBERS PRESENT:	Michael Puglia, AT, Chair Sara Whiteside, AT, Vice-Chair Deborah Corbatto, AT
MEMBER ABSENT:	Jeffrey Roberts, MD Trilizsa Trent, Citizen Member
STAFF PRESENT:	William L. Harp, M.D., Executive Director Elaine Yeatts, DHP Senior Policy Analyst Alan Heaberlin, Deputy Director, Licensure Denise Mason, Licensing Specialist
GUESTS PRESENT:	Matthew Gage, AT, President of VATA Scott Powers, VATA Becky Bowers-Lanier, VATA Hassan Shah, MD, VCU Srinivasa Punyala, VCU Tanner Howell, VATA

CALL TO ORDER

Mr. Puglia called the meeting to order at 10:06 a.m.

EMERGENCY EGRESS PROCEDURES

Mr. Heaberlin announced the Emergency Egress Instructions.

ROLL CALL

Denise Mason called the roll, and a quorum was declared.

APPROVAL OF MINUTES OF October 6, 2016

Mr. Puglia noted the last sentence of Section 1 under New Business had an error. The sentence was revised, and Ms. Whiteside moved to approve the amended minutes of October 6, 2016. The motion was seconded and passed.

ADOPTION OF AGENDA

Ms. Whiteside requested an additional item for the agenda, an Item number 4 "Discussion of Notification of Expired Licenses." Ms. Corbatto moved to approve the amended agenda. The motion was seconded and carried.

PUBLIC COMMENT ON AGENDA ITEMS

There was no public comment.

NEW BUSINESS

1. Athletic Trainers Who Work at Youth Sports Events

Ms. Whiteside led the Advisory Board in a discussion regarding a concern she has with Athletic Trainers providing proof of licensure when working at youth sports events. She questioned whether employers are requesting documentation of licensure from the Athletic Trainers prior to their practice at youth sports events. Ms. Whiteside explained that she cannot remember a time when she was asked to provide evidence of licensure as an Athletic Trainer. It was noted that it is the responsibility of the youth sports event promoters to obtain verification of licensure for each Athletic Trainer that will be practicing at the event.

No action was required.

2. Cross-State Border Coverage

Ms. Whiteside led the Advisory Board in a discussion regarding cross–state border coverage in regards to Athletic Trainers practicing in other jurisdictions without being licensed in that jurisdiction. The law was reviewed regarding Virginia licensure not being required for athletic trainers who come to Virginia for an event in the employ of an out-of-state team or athlete. Licensure is required for out-of-state athletic trainers that come into Virginia to work an event when hired by the event staff rather than by a specific team or athlete.

No action was required.

3. Letter from David Ross, MD Regarding Reducing Risk from Subconcussions

Dr. Harp discussed the letter from David Ross, MD regarding subconcussions. Dr. Harp said he suggested to Dr. Ross that he contact VATA to see if it was interested in getting the word out on the product he has developed to detect subconcussions. No action was required.

4. Notification of Expired Licenses

Ms. Whiteside asked the question "How is the licensee notified of that he/she has an expired license?" Mr. Heaberlin discussed the process that the Board uses to notify a licensee that it is time to renew. He said that, at this time, the Board does not notify licensees that his/her license has expired.

No action was required.

ANNOUNCEMENTS

Mr. Heaberlin informed the Advisory Board that there are currently 1,496 Athletic Trainers that hold an active license with the Board of Medicine, and 1 that holds an inactive license. At this time, 224 of the current active licenses are out-of-state.

NEXT MEETING DATE

October 5, 2017

ADJOURNMENT

The Advisory board meeting was adjourned at 10:54 a.m.

Michael Puglia, AT, Chair

William L. Harp, M.D., Executive Director

Denise Mason, Licensing Specialist

---DRAFT UNAPPROVED---

ADVISORY BOARD ON PHYSICIAN ASSISTANTS
Board of Medicine
June 8, 2017, 1:00 PM
9960 Mayland Drive, Suite 201
Richmond, VA
Training Room 2

The Advisory Board on Physician Assistants met Thursday, June 8, 2017, at 1:00 p.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Henrico, Virginia.

MEMBERS PRESENT:	Thomas Parish PA-C, Chair Portia Tomlinson, PA-C, Vice-Chair Rachel Carlson, PA-C
MEMBERS ABSENT:	James Potter, MD Citizen Member, vacant
STAFF PRESENT:	William L. Harp, MD, Executive Director R. Alan Heaberlin, Deputy Director, Licensure Elaine Yeatts, DHP Senior Policy Analyst ShaRon Clanton, Licensing Specialist
GUESTS PRESENT:	David Falkenstein, VAPA Robert Glasgow, PA-C, VAPA W. Scott Johnson-MSV Hassan Shah, MD-VCU Srinivasa Punyala, MD-VCU

Call to Order

Mr. Parish called the meeting to order at 1:05 pm.

Emergency Egress Procedures

Alan Heaberlin provided the emergency evacuation instructions.

Roll Call

Ms. Clanton called the roll, and a quorum was declared.

Approval of Minutes June 9, 2016 & February 2, 2017

Ms. Carlson moved to approve the minutes from June 9, 2016 and February 2, 2017. The motion was seconded and carried.

Adoption of Agenda

Ms. Yeatts requested the addition of a NOIRA for laser hair removal as an item on the agenda. A motion was made by Rachel Carlson, PA-C to approve the amended agenda; it was seconded and carried.

Public Comment on Agenda Items

Mr. Falkenstein discussed a proposal to amend the levels of supervision in the regulations for PA's. He also discussed amending 18VAC85-50-181 to clarify that PA's can do pharmacotherapy for weight loss.

Mr. Johnson provided websites from MSV to help with opioid prescribing.

NEW BUSINESS

1. The Advisory Board discussed a request to consider amending 18VAC85-50-10, 18VAC85-50-101 and 18VAC85-50-110 by the removing definitions and requirements for direct, general and personal supervision. Mr. Parish asked to table this item until the next meeting of the Advisory Board which was agreed to by acclamation.

2. Review of Amendments effective June 29, 2017

   Ms. Yeatts reviewed the amendments affecting 18VAC85-50-110 by noting that PA's will no longer need to seek Board approval to perform invasive procedures under continuous or general supervision. Ms. Yeatts further recommended a NOIRA to amend 18VAC85-50-181 by including the language from subsection C of Section 18VAC85-20-90 of the Regulations Governing the Medicine, Osteopathy, Podiatry and Chiropractic to clarify the authority of PA's in the pharmacotherapy of weight loss.

3. Review of Regulations for Prescribing Opioids and Buprenorphine effective March 15, 2017

   Mrs. Yeatts provided an overview of new requirements pertaining to PA's prescribing opioids.

4. Notice of Intended Regulatory Action for Laser Hair Removal

   Ms. Yeatts suggested a Notice of Intent for Regulatory Action in order to promulgate regulations for Code Section 54.1-2973.1 which takes effect on July 1, 2017. Of importance will be the definition of supervision.

   Rachel Carlson moved to recommend a NOIRA to amend 18VAC85-50-181 by including the language from subsection C of Section 18VAC85-20-90 and to recommend a NOIRA to create regulations required by Section 54.1-2973.1 of the Code of Virginia. The motion was seconded and carried.

Announcements

Mr. Heaberlin gave the current license stats for PA's. There were 3512 with active licenses, 2732 with Virginia addresses, 775 out-of-state, and 25 with inactive licenses.

Next Scheduled Meeting: October 5, 2017 @ 1:00 p.m.

Adjournment

Mr. Parish adjourned the meeting at 2:11 p.m. The motion was seconded and carried.

_____

Thomas Parish, PA-C, Chair

_____

William L. Harp, M.D., Executive Director

_____

ShaRon Clanton, Licensing Specialist

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ADVISORY BOARD ON MIDWIFERY
Minutes
June 9, 2017

The Advisory Board on Midwifery met on Friday, June 9, 2017, at 10:00 a.m., at the Department of Health Professions, Perimeter Center; 9960 Mayland Drive, Henrico, Virginia 23233.

MEMBERS PRESENT:	Kim Pekin, CPM Maya Hawthorn, CPM Natasha Jones, MSC Ami Keatts, M.D. Mayanne Zielinski, CPM
MEMBERS ABSENT:	None
STAFF PRESENT:	William L. Harp, M.D. Executive Director Alan Heaberlin, Deputy Director, Licensing Colanthia Morton, Operations Manager Beulah Baptist Archer, Licensing Specialist
GUESTS PRESENT:	Ralston King, Medical Society of VA Becky Bowers-Lanier, VMA Nicole Pugar, ACOG-NA Degra Nofsinger, CPM, VA Midwives Alliance, President

CALL TO ORDER

Kim Pekin called the meeting to order at 10:10 a.m.

EMERGENCY EGRESS PROCEDURES

Alan Heaberlin announced how to exit the building in the event of an emergency or drill.

ROLL CALL

Beulah Baptist Archer called the roll, and a quorum was declared.

APPROVAL OF THE FEBRUARY 3, 2017 MEETING MINUTES

Mayanne Zielinski moved to approve the minutes. The motion was seconded and carried.

ADOPTION OF THE AGENDA

Mayanne Zielinski moved to adopt the agenda. The motion was seconded and carried.

PUBLIC COMMENT ON AGENDA ITEMS

No public comment on agenda items.

NEW BUSINESS

1. NARM 2016 Job Analysis Survey –Kim Pekin, CPM

Elaine suggested to the Advisory Board that the members review the NARM Job Analysis Survey, their three Guidance Documents, and the regulations that Govern the Practice of Midwifery to see if any inconsistencies exist. Mayanne Zielinski moved to table the topic until the next meeting. The motion was seconded and carried. The guidance documents and regulations were provided to the members, along with the packet that contained the NARM Job Analysis Survey.

2. CPM's Ordering Ultrasounds and Lab Tests – Kim Pekin , CPM

Kim Pekin addressed the Advisory Board regarding the increased resistance licensed midwives are encountering when ordering standard obstetrical ultrasounds, biophysical profiles, and lab tests. Clint Bowen, from INOVA Hospital requested a statement from DHP stating that ordering ultrasounds is listed in the scope of practice for midwives.

Dr. Harp and Elaine Yeatts confirmed that if a statement is provided, it would need to come from the Board of Medicine. Ms. Yeatts suggested that counsel be consulted to determine if the Board could further interpret the scope of practice that appears to include the ordering of ultrasounds and other tests.

Maya Hawthorn moved to ask the Board of Medicine to review the midwifery scope of practice that includes ordering ultrasounds, non-stress tests, biophysical profiles, and lab tests and consider approving a guidance document. The motion was seconded and carried.

ANNOUNCEMENTS – Alan Heaberlin

Alan provided the totals for licensed midwives in Virginia as of June 9, 2017.

Licensed Midwives	85
Virginia addresses	63
Out-of-state addresses	22

Kim Pekin announced that UPS is now delivering newborn metabolic screenings, via next day air, to the Division of Consolidated Laboratory Services.

NEXT MEETING DATE

TBD

ADJOURNMENT

Kim Pekin adjourned the meeting.

Kim Pekin, CPM, Chair

William L. Harp, MD
Executive Director

Beulah Baptist Archer, Licensing Specialist

---DRAFT UNAPPROVED---

ADVISORY BOARD ON POLYSOMNOGRAPHIC TECHNOLOGY
Minutes
June 9, 2017

The Advisory Board on Polysomnographic Technology met on Friday, June 9, 2017 at 1:00 p.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Henrico, Virginia.

MEMBERS PRESENT:	Jonathan Clark, RPSGT, Chair Debbie Akers, RPSGT, Vice-Chair Anna Rodriquez, RPSGT Robert Vorona, M.D. Marie Quinn
MEMBERS ABSENT:	None
STAFF PRESENT:	William L. Harp M.D., Executive Director Alan Heaberlin, Deputy Director for Licensure Colanthia Morton, Operations Manager Denise Mason, Licensing Specialist
GUESTS PRESENT:	Amy Boykins, Children's Hospital of the King's Daughters

Call TO ORDER

Mr. Clark called the meeting to order at 1:07p.m.

EMERGENCY EGRESS PROCEDURES

Mr. Heaberlin announced the Emergency Egress Procedures.

ROLL CALL

The roll was called by Denise Mason; a quorum was declared.

APPROVAL OF MINUTES FROM OCTOBER 7, 2016

Ms. Rodriquez moved to adopt the minutes. The motion was seconded and carried.

ADOPTION OF AGENDA

Mr. Clark moved to adopt the agenda. The motion was seconded and carried.

PUBLIC COMMENT ON AGENDA ITEMS

Amy Boykins discussed her concerns in regards to not having enough Polysomnograhic Technologists to serve the public.

NEW BUSINESS

1. Discussion of "Proposal to add a Provisional Licensure for Polysomnographic Technologists"

Mr. Clark led the discussion of this item. Mr. Heaberlin stated that he thought that regulation similar to the Occupational Therapist License Applicant may be a better alternative than a provisional license or temporary authorization to practice. Ms. Yeatts said such a proposal would require a Code change and would need to be submitted as a recommendation/request to the Board of Medicine. Ms. Rodriquez made a motion to request that the Board of Medicine consider a legislative proposal to grant an exception to licensure for those who have completed training and are eligible to sit for the Board of Registered Polysomnographic Technologists certification examination. A motion was made that such individuals may practice for up to 6 months, or until they are licensed or receive notification of failure of the examination, whichever comes first. The motion was seconded and carried.

ANNOUNCEMENTS

Dr. Vorona invited Mr. Heaberlin to speak at the Annual Meeting of the Virginia Academy of Sleep Medicine on November 3, 2017 in Richmond. Mr. Heaberlin accepted the invitation.

Mr. Heaberlin announced that there are currently 467 licensed polysomnographic technologists in Virginia.

NEXT SCHEDULED MEETING

October 6, 2017 @ 1:00 p.m.

ADJOURNMENT

The meeting of the Advisory Board was adjourned at 2:16 p.m.

_____
Dr. Robert Vorona, Chair

_____
William Harp, Executive Director

_____
Denise W. Mason, Licensing Specialist

DRAFT UNAPPROVED

VIRGINIA BOARD OF MEDICINE
Regulatory Advisory Panel on Opioid Regulations
Minutes

Monday, May 15, 2017 | Department of Health Professions | Henrico, VA

CALL TO ORDER: The meeting convened at 9:01 a.m.

EMERGENCY EGRESS: Dr. Harp outlined how to exit the building in an emergency.

MEMBERS PRESENT:
Barbara Allison-Bryan, MD, Chair
Stephen Long, MD
Thomas Reach, MD
Paul Spector, DO
Sheila Furey, MD
Mishka Terplan, MD
Art Van Zee, MD
Mary McMasters, MD
Sarah Melton, Pharm D

MEMBERS ABSENT: None

STAFF PRESENT:
William L. Harp, MD, Executive Director
Jennifer Deschenes, JD, Deputy Executive Director, Discipline
David Brown, DC, DHP Director
Lisa Hahn, DHP, Chief Deputy
Elaine Yeatts, DHP Senior Policy Analyst
Alan Heaberlin, Deputy Director, Licensure
Colanthia Morton Opher, Operations Manager

OTHERS PRESENT:
Katherine Neuhausen, MD
Hughes Melton, MD
Mellie Randall
Ed Ohlinger, Acadia Healthcare
David Cassia, Acadia Healthcare
Ajay Manhapra, MD, VAMC-Hampton
Joshua Mount, Pharm D., Depomed, Inc
Shruti Kulkarni, JD, CLAAD
Stephen Northrup, JD, Rampey Northrup LLC

DRAFT UNAPPROVED

VIRGINIA BOARD OF MEDICINE
Regulatory Advisory Panel on Opioid Regulations
Minutes

Monday, May 15, 2017 Department of Health Professions Henrico, VA

Carey Cox, VATAC
Stephanie Galica, Adapt Pharma
Patrick Fekurils, Adapt Pharma
Vincent Nardone, MD
Nicole Pugar, JD, Williams Mullen
Gary Riddle, Indivior
Peter Breslin, MD, McShin Foundation
Sara Heisler, VHHA
Scott Johnson, JD, Medical Society of VA
Brad Bachman, American Society of Addiction Medicine & VASAM
Ralston King, Medical Society of VA
Brenda Moody
Tyler Moody
Carrie Pearson
Pamela Sickal

Dr. Allison-Bryan thanked all the Panel members for their participation and briefly reviewed the history of the emergency regulations.

She stated that the goal for the day was to review the emergency regulations and to determine whether any urgent changes needed to be made. She noted that 90% of the comments received were related to intolerance of buprenorphine-naloxone products.

WELCOME AND INTRODUCTION OF PANEL MEMBERS

Panel members, agency and board staff introduced themselves.

PRESENTATIONS

Kate Neuhausen, MD spoke in support of the regulations as they are written. She noted that the DMAS Medicaid regulations align with the Board's emergency regulations. DMAS currently covers treatment for opioid addiction which allows patients to obtain buprenorphine products from a pharmacy, supports buprenorphine mono-product for pregnant women, and believes that the current regulations will minimize diversion.

VIRGINIA BOARD OF MEDICINE
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Hughes Melton, MD spoke to the nature of addiction and the rates of buprenorphine prescribing and drug seizures across the state by district. Dr. Melton noted that buprenorphine was found in a significant number of the overdoses in southwest Virginia. He suggested keeping the regulations as strong as they are for the next six months and then review the data.

Mellie Randall, Substance Abuse Policy Director for the Department of Behavior Health and Developmental Services (DBHDS), strongly encouraged CSBs to develop the capacity to directly provide access to buprenorphine products by engaging the services of a waivered prescriber. All clinical staff would need to be trained on the use of medication-assisted treatment for opioid use disorder. DBHDS supports the language contained in the emergency regulations pertaining to restrictions on the use of the mono-product and does not support exempting OTPs from these regulations. DBHDS will continue to seek other state and federal resources to improve access to evidence-based treatment services for addiction.

PUBLIC COMMENT

Scott Johnson, JD spoke to the feedback received by the Medical Society of Virginia from its members regarding the emergency regulations, drawing the Panel's attention to 18VAC85-21-10(B)(2).

Brad Bachman, representing VASAM and ASAM, acknowledged that the regulations are meant to stop diversion, but he doesn't want the regulations to reduce access to treatment. The regulations should be in step with the ASAM National Practice Guideline for treatment and its tenets for reducing diversion of opioids.

Ralston King, Medical Society of Virginia, stated that tramadol should not be co-prescribed with other opioids.

Bonnie Moody spoke in support of her son who has been managing chronic pain with an opioid. This medication has allowed her son to be a contributing member of society, but the new regulations have required substitution with an opioid that is more expensive and not covered by Medicaid. All chronic pain sufferers are not addicts.

VIRGINIA BOARD OF MEDICINE
Regulatory Advisory Panel on Opioid Regulations
Minutes

Monday, May 15, 2017 Department of Health Professions Henrico, VA

Tyler Moody stated that he has lost a friend due to an opioid overdose. He noted his chronic pain management is with buprenorphine. He has an active, productive life as a result of buprenorphine. Why is Virginia punishing those who have an adverse reaction to naloxone? What option is available without fear of death or financial ruin other than strong, cheap heroin?

Ed Ohlinger, Acadia, said his company is familiar with overprescribing and diversion of opioids. He stated he is concerned with the approximately 300 buprenorphine patients treated in the OTP model. Mr. Ohlinger requested an exception to the regulations for OTPs in order to allow a full range of treatment services. He said the patients who are prescribed the mono-product have similar treatment plans as those in the methadone program. The regulations should include requiring a review of patients' treatment plans and investigation of complaints from doctors and law enforcement. Federally-licensed OTPS are held to a higher federal standard and should have an exemption.

Ajay Manhapra, MD is an addiction medicine physician and began his comments by addressing the question, "why opioid addiction is treated with another addictive opioid". He spoke about the effects of opioid use disorder. He noted that very few people die from using buprenorphine, but that many people die due to a lack of buprenorphine. He agrees there are pill mills but asks the Panel to please not take away options for physicians in their treatment of patients.

Shruti Kulkarni, JD noted that the emergency regulations do not restrict other, more potent medications. The regulations prevent physicians from providing a medically necessary treatment option in buprenorphine mono-product. She suggested amending the regulations to permit physicians to use their judgment and proper oversight.

Vincent Nardone, MD, Virginia Treatment Access Coalition, noted that every substance has the ability to trigger allergic reactions. He has patients who have had allergic reactions to naloxone. He suggests RAST testing for patients who claim an allergic reaction. He suggested amending the regulations to allow the mono-product for patients with objective evidence of intolerance to naloxone.

Peter Breslin, MD, McShin Foundation, stated that since the emergency regulations were enacted, he has had four patients leave his practice because he was no longer able to prescribe the mono-product. He noted that one of those patients recently died from a heroin overdose. He has another patient with hepatitis C who cannot be treated with naloxone because it is hepatotoxic. He believes the majority of physicians are doing the right thing, and the regulations should not be absolute.

Carrie Pearson said she was placed on Suboxone in 2013. While on Suboxone she was sick most of the time until she was switched to the mono-product. Immediately her health improved. She is begging for an allergy/intolerance exception in the regulations that would allow her to obtain the mono-product.

Pamela Sickal informed the panel that she had been on Subutex for a few years. She has a hypersensitivity to naloxone. She is worried that if she were to take methadone, she would abuse it. Traveling to the nearest OTP would be inconvenient. She said no other options are available to patients who are sensitive to naloxone. She believes the regulations should have restrictions on opioid prescribing, but less restrictive for buprenorphine.

Joshua Mount, PharmD spoke regarding dosing limits and that MMEs should not be used for regulating all opioids, specifically those that are atypical and multi-mechanistic.

DHP Director's Comments

Dr. Brown provided a brief history of the regulations. The General Assembly requested the Board of Medicine review the issue of diversion. He asked the Regulatory Advisory Panel to keep in mind the genesis of the regulations. He further advised that if the Panel comes to a consensus on an issue, it should be presented to the Board. Likewise, if the Panel cannot reach a consensus on an issue, the comments from the Panel should be presented to the Board for its consideration.

NEW BUSINESS

Consideration for Amendment to the Emergency Regulations

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Dr. Allison-Bryan led the Panel through a thorough discussion of the sections identified for possible revision. There were a number of revisions and edits made to reflect the expert opinion of the Panel members. Consensus on the recommendations to forward to the Legislative Committee on May 19, 2017 was attained.

Naloxone Intolerance-18VAC85-21-150

Some Panel members believed that there is a real phenomenon of naloxone intolerance and others did not. The majority of the Panel members agreed to the possibility of a physician writing mono-product for 3-5% of MAT patients in the practice IF physicians could be tracked by the PMP to identify those that exceeded the identified limit. Ralph Orr, Director of the PMP, will be asked if this condition can be met.

Financial Hardship-18VAC85-21-150

The Panel was not in favor of this issue, but thought that financial hardship could be included in the 3-5% being prescribed mono-product IF the tracking mentioned above is possible.

Nursing Mothers and Infants-18VAC85-21-160(A)

After discussion, the Panel decided that the "shall be treated with buprenorphine mono-product" should be changed to "may be treated with buprenorphine mono-product."

Hepatic Disease and Potential Hepatic Disease-18VAC85-21-150

The Panel chose not to suggest an exception for these conditions.

Dosage of Buprenorphine-18VAC85-21-150(I)

After discussion, the Panel decided not to suggest an exception to the absolute limit of 24 mg/day of buprenorphine.

Tapering Period from Buprenorphine Mono-Product-18VAC85-21-150

The Panel believed that the seven days implied in the regulations was adequate for tapering from the mono-product to nothing and chose not to recommend a change.

Subutex and Suboxone Off-Label for Pain -18VAC85-21-70(C)

The Panel decided to address this with "buprenorphine mono-product tablets shall not be used for chronic pain."

Consideration for final regulations

Dr. Allison-Bryan led the panel through a thorough discussion of identified issues for possible revision for the final regulations. A number of revisions and edits were approved by consensus, as well as a number of subsections that were not seen to need revisions and edits. Again, consensus was gained on a work product that could go forward to the Legislative Committee.

Drug Screens and Naloxone with PRN Opioids and PRN Benzodiazepines-18VAC85-21-40(B)(3), 18VAC85-21-70(B)(3) & 18VAC85-21-100(D)
The Panel did not recommend any changes at this time.

Notation on Prescriptions for Type of Pain-18VAC85-21-40(E) & 18VAC85-21-70(F)
The Panel did agree that prescribers should note on a prescription for opioids what type of pain was being treated.

OTP's and Buprenorphine Mono-Product-18VAC85-21-150
The Panel declined to make a recommendation.

State Correctional Facilities with Sole Source Pharmacies-18VAC85-21-(B)(1)
The Panel agreed to recommend that state, regional or local correctional facilities with sole source pharmacies could be excepted.

Assisted Living Day Programs with Sole Source Pharmacies-18VAC85-21-(B)(1)
The Panel declined to recommend an exception on this issue.

Removal of Tramadol to Reduce Confusion-18VAC85-21-40(C) & 18VAC85-21-70(D)
The Panel agreed to strike tramadol from these sections.

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Other Considerations

Exceptions for Full Disability and Life-Shortening Chronic Illness-18VAC85-21-10 & 18VAC85-21-70
The Panel declined to recommend these changes.

Number of Days for Acute Pain-18VAC85-21-30(B) & 18VAC85-21-69(A)(7)
The Panel agreed to recommend striking "54.1-2522.1" from the regulations.

Naloxone Prescriptions-18VAC85-21-40(B)(3) & 18VAC85-21-70(B)(3)
The Panel concluded that getting more naloxone into the community was a meritorious idea. It was suggested that the 120 MME in 40(B)(3) be deleted in favor of the diagnosis of substance misuse, prior overdose, or concomitant benzodiazepine. The decision was made to leave 120 MME/day in the section.

Definition of an Opioid-18VAC85-21-20
The Panel declined to recommend that a definition be added, although one of the Panel members said he would send definitions for "opiate" and "opioid" for consideration.

Specification of Inpatient Substance Treatment-18VAC85-21-10(B)(2)
The Panel considered inpatient substance treatment and rehab to already be covered by this section with the language "inpatient hospital admission."

Next Steps
Elaine Yeatts noted that other issues not discussed by the Regulatory Advisory Panel may arise and be addressed by the full Board after its review.

Announcements
Dr. Allison-Bryan thanked the Panel for its attention and hard work.

Dr. Harp reminded the Panel attendees to turn in expense reports to Ms. Opher.

DRAFT UNAPPROVED

VIRGINIA BOARD OF MEDICINE

Regulatory Advisory Panel on Opioid Regulations

Minutes

Monday, May 15, 2017 Department of Health Professions Henrico, VA

Adjournment

Dr. Allison-Bryan adjourned the meeting at 1:45.

Barbara Allison-Bryan, MD
Chairperson

William L. Harp, MD
Executive Director

Alan Heaberlin
Deputy Director Licensure

Expert admissibility standards to consider:

Traditional Virginia Standard:

To qualify to serve as an expert witness, an individual:

> must possess sufficient knowledge, skill, or experience regarding the subject matter of the testimony to assist the trier of fact in the search for the truth. Generally, a witness possesses sufficient expertise when, through experience, study or observation the witness acquires knowledge of a subject beyond that of persons of common intelligence and ordinary experience.

Virginia Medical Malpractice Standard:

To qualify to serve as an expert witness, an individual:

> [a]ny health care provider who is licensed to practice in Virginia shall be presumed to know the statewide standard of care in the specialty or field of practice in which he is qualified and certified....A witness shall be qualified to testify as an expert on the standard of care if he demonstrates expert knowledge of the standards of the defendant's specialty and of what conduct conforms or fails to conform to those standards and if he has had active clinical practice in either the defendant's specialty or a related field of medicine within one year of the date of the alleged act or omission forming the basis of the action.

Virginia Department of Health Professions

APPROVED

Board of Health Professions Full Board Meeting

February 23, 2017
10:00 a.m. - Board Room 4
9960 Mayland Dr, Henrico, VA 23233

In Attendance	Robert J. Catron, Citizen Member
	Helene D. Clayton-Jeter, OD, Board of Optometry
	Marvin Figueroa, Citizen Member
	Yvonne Haynes, LCSW, Board of Social Work
	Allen R. Jones, Jr., DPT, PT
	Derrick Kendall, NHA, Board of Long-Term Care Administrators
	Ryan Logan, Board of Pharmacy
	Martha S. Perry, MS, Citizen Member
	Herb Stewart, PhD, Board of Psychology
	Laura P. Verdun, MA, CCC-SLP, Board of Audiology & Speech-Language Pathology
	James D. Watkins, DDS, Board of Dentistry
	James Wells, RPH, Citizen Member
	Junius Williams, Jr, MA, Board of Funeral Directors and Embalmers
Absent	Barbara Allison-Bryan, MD, Board of Medicine
	Kevin Doyle, Ed.D., LPC, LSATP, Board of Counseling
	Mark Johnson, DVM, Board of Veterinary Medicine
	Trula E. Minton, MS, RN, Board of Nursing
	Jacquelyn M. Tyler, RN, Citizen Member
DHP Staff	David E. Brown, D.C., Director DHP
	Elizabeth A. Carter, Ph.D., Executive Director BHP
	Kathy Siddall, Business Planning & Research Director DHP
	Elaine Yeatts, Senior Policy Analyst DHP
	Ralph Orr, Program Manager, Prescription Monitoring Program
	Jaime Hoyle, Executive Director, Boards of Counseling, Psychology & Social Work DHP
	Diane Powers, Communications Director DHP
	Matt Treacy, Communications Associate DHP
	Laura L. Jackson, Operations Manager BHP
Presenters	Neal Kauder and Kim Small, VisualResearch, Inc.

Virginia Department of Health Professions

APPROVED

Observers Sara Heisler, VHHA

Call to Order

Acting Chair Mr. Catron **Time** 10:03 a.m.

Quorum Established

Public Comment

Comment None provided

Approval of Minutes

Presenter Mr. Catron

Discussion

The August 18, 2016 Full Board meeting minutes were approved with two amendments: remove "Acting" from Mr. Catron's signature line on page 5; and change Ms. Russell to Ms. Hahn on page 4 under Board of Physical Therapy. All members in favor, none opposed.

Directors Report

Presenter Dr. Brown

Discussion

Dr. Brown provided an update on the agency's General Assembly activity to date. DHP has only two bills this session and they are very technical in nature: **HB 1541(BON; powers and duties)** - authorizing the Board to deny or withdraw approval from *training* programs for failure to meet prescribed standards and **SB 922 (DPOR and DHP; licensure, certification, registration, and permitting)** - making it clear that health regulatory boards have authority to take action on permits also. Also discussed were **SB1020** - Peer recovery specialists and qualified mental health professionals; registration, and VDHs needle exchange bill HB 2317 - relating to harm reduction programs; public health emergency; dispensing and distributing needles and syringes.

Legislative and Regulatory Report

Presenter Ms. Yeatts

Discussion

Ms. Yeatts advised the Board of updates to the laws and regulations that affect DHP currently in the General Assembly. HB1566 concerning active supervision of regulatory boards includes evaluation of the need for regulation of professions. The measure does not refer, specifically, to the Board's long-standing statutory authority to evaluate and advise on the need for regulation or deregulation of health professions. However, if funds are appropriated in the 2017 state budget, it would require additional review by a new analyst position within the legislative branch.

Virginia Department of
Health Professions

APPROVED

Executive Directors Report

Presenter Dr. Carter

Agency Performance

Dr. Carter reviewed the agencies performance measures in relation to clearance rate, age of pending caseload and time to disposition. Kathy Siddall, Director of Business Planning and Research provided an overview for the Board of the agency's strategic plan goals and objectives for 2017-2018.

Board Budget

Dr. Carter stated that the Board is working under budget.

Healthcare Workforce Data Center

Dr. Carter provided an update on the Data Center. Handouts included: Series 1 Brief: State & National Employment; Series 2 Brief: Regional and Sectoral Employment and Series 3 Brief: Income and Compensation. A new addition to the Center is the Healthcare Occupational Roadmap. It is a digital tool designed to aid school counselors on entry level healthcare careers.

Communications

Dr. Carter discussed the Prescription Monitoring Program's (PMP) new Education Toolkit. Mr. Orr elaborated on its purpose and functionality. Mr. Orr also noted that the PMP has received a $3.1 million grant from PurduePharma to help integrate use of its data in doctors' and pharmacists' regular work flow.

Also discussed was the press release from the Governor's office announcing VaAware, a new website funded by the Board of Medicine and developed by DHP staff that provides resources for prevention, treatment and recovery from opioid addiction. VaAware is a collaboration among four Virginia agencies, the Department of Health, Department of Behavioral Health and Developmental Services, Department of Criminal Justice Services, and Department of Health Professions.

VLDS

Dr. Carter provided information regarding DHP's involvement with the Virginia Longitudinal Data System. An Interagency Data Sharing agreement has been signed and DHPs workforce survey data has been added. The data is double de-identified making it very secure. Researchers interested in accessing DHPs workforce data may do so my submitting a request to VLDS.

Stakeholder Group to Determine Demand

Dr. Carter asked the board members for participants in a stakeholder planning group to aid in determining how the Board may proceed with identifying healthcare workforce demand in Virginia. Dr. Stewart, Dr. Clayton-Jeter, and Mr. Figueroa agreed to assist.

APPROVED

Certified Anesthesiologist Assistant Study

Dr. Carter reviewed the proposed workplan and asked the Board to move forward with the study.

Motion

A motion was made to approve the workplan and move forward with the study. The motion was properly seconded by Ms. Verdun. All members were in favor, none opposed.

Sanction Reference Points (SRP) & Disciplinary Caseload Overview

Presenter Mr. Kauder

Mr. Kauder with VisualResearch provided a PowerPoint presentation to educate new board members on the purpose of SRPs, its guiding principles, and how it was developed and to provide a status report on the program for all.

Lunch Break

Presenter Mr. Catron

Mr. Catron announced a lunch break at 12:12 p.m. The meeting reconvened at 12:41 p.m.

Interstate Compacts, Portability, and Telehealth in the Behavioral Sciences Boards

Presenter Ms. Hoyle

Ms. Hoyle provided a PowerPoint presentation on how the Behavioral Sciences Boards are utilizing interstate compacts, portability, and telehealth.

Board Reports

Presenter Mr. Catron

Board of Pharmacy

Mr. Logan reported that the Board of Pharmacy has developed a workgroup to review USP Chapter 800 - Hazardous Drugs—Handling in Healthcare Settings.

Board of Physical Therapy

Dr. Jones reported that the Licensure Compact Committee members decided against recommending pursuit of the Compact during the 2018 legislative session to the full board. He also stated that the Board of Physical Therapy held a public hearing to receive comment on the proposed regulations regarding the practice of Dry Needling.

Board of Social Work

Ms. Haynes stated that the Board of Social Work has amended two regulations: 1) Psychosocial interventions in the definition of "clinical social work services" and, 2) revise the requirements for reactivation and reinstatement.

Virginia Department of Health Professions

APPROVED

Board of Psychology

Dr. Stewart stated that The Board of Psychology is moving forward with collaboration in the Psychology Interjurisdictional Compact (PSYPACT). He also stated that the Board is reviewing credentialing and performing a regulations review match up.

Elections: Board Chair

Presenter Mr. Catron

Chair Nominations: Helene Clayton-Jeter, OD

With no other nominations made for position of Board Chair, Dr. Clayton-Jeter was unanimously elected Chair. All members in favor, none opposed.

Vice Chair Nominations: Allen R. Jones, Jr., DPT, PT

With no other nominations made for position of Vice Chair, Dr. Jones, Jr., was unanimously elected Vice Chair. All members in favor, none opposed.

New Business

Presenter Mr. Catron

There was no new business to discuss.

Adjourned

Adjourned 1:16 p.m.

Chair Robert Catron

Signature: _____ Date: _____/_____/_____

Board Executive Director Elizabeth A. Carter, Ph.D.

Signature: _____ Date: _____/_____/_____

Virginia Department of Health Professions

APPROVED

Board of Health Professions Regulatory Research Committee Meeting

April 3, 2017
10:00 a.m. - Board Room 2
9960 Mayland Dr, Henrico, VA 23233

In Attendance	Yvonne Haynes, LCSW, Board of Social Work
	James Wells, RPH, Citizen Member
Absent	Barbara Allison-Bryan, MD, Board of Medicine
	Martha S. Perry, MS, Citizen Member
	Jacquelyn M. Tyler, RN, Citizen Member
DHP Staff	Elizabeth A. Carter, Ph.D., Executive Director BHP
	Yetty Shobo, Ph.D., Deputy Executive Director
	Laura L. Jackson, Operations Manager BHP
	Jay Douglas, Executive Director Board of Nursing
Observers	W. Scott Johnson, Medical Society of Virginia
Speakers	Katie Payne, Virginia Society of Anesthesiologists
	Ralston King, Medical Society of Virginia
Emergency Egress	Dr. Carter

Call to Order

Chair Mr. Wells **Time** 10:06 a.m.

Quorum No Quorum

Public Comment

Comment Katie Payne, Virginia Society of Anesthesiologists

Discussion

Ms. Payne is with the Virginia Society of Anesthesiologists and stated that she is available to assist with information the board may need to complete the study.

Mr. King stated that he is with the Medical Society of Virginia and is currently working with the Virginia Society of Anesthesiologists.

Virginia Department of
Health Professions

APPROVED

Review of Certified Anesthesiologist Assistants

Presenter Dr. Carter

Review of Research to Date

Dr. Carter reviewed the meeting packet and provided a handout referencing the Virginia LMI occupational profile on Anesthesiologists and HRSA and FutureDocs.

Chairman Wells stated that this study will apply seven criteria for evaluating the need for regulation of this profession. The scope of practice determined by the 18 regulating states reflects that the Certified Anesthesiologist Assistants (CAA) perform activities under supervision of an Anesthesiologist. He indicated that it will be important to consider the existing practice restrictions among the 18 states, ranking from the most to least restrictive.

Ms. Haynes stated that the Committee will need insight into supply and demand issues in Virginia and the role that oversite by anesthesiologists may entail.

Adjourned

Adjourned 10:49 a.m.

Chair James Wells, RPh.

Signature: _____ Date: ____/____/____

Board Executive Director Elizabeth A. Carter, Ph.D.

Signature: _____ Date: ____/____/____

Virginia Department of Health Professions

DRAFT

Board of Health Professions Regulatory Research Committee Meeting

May 9, 2017
9:00 a.m. - Board Room 4
9960 Mayland Dr, Henrico, VA 23233

In Attendance	Barbara Allison-Bryan, MD, Board of Medicine
	Yvonne Haynes, LCSW, Board of Social Work
	Jacquelyn M. Tyler, RN, Citizen Member
	James Wells, RPH, Citizen Member
Absent	Martha S. Perry, MS, Citizen Member
DHP Staff	Elizabeth A. Carter, Ph.D., Executive Director BHP
	Laura L. Jackson, Operations Manager BHP
Observers	Susan Heisler, Virginia Hospital and Healthcare Association (VHHA)
	Julie Galloway, Medical Society of Virginia (MSV)
Speakers	Katie Payne, Virginia Society of Anesthesiologists (VSA)
	Michele Satterlund, VANA
Emergency Egress	Dr. Carter

Call to Order

Chair Mr. Wells **Time** 9:06 a.m.

Quorum Quorum

Public Comment

Discussion

Ms. Payne is with the Virginia Society of Anesthesiologists and stated that she is available to assist with information the board may need to complete the study.

Ms. Satterlund is with VANA and stated she is may be utilized as a resource on information regarding CRNAs.

Review of Certified Anesthesiologist Assistants

Presenter Dr. Carter

Review of Research to Date

Dr. Carter reviewed the Certified Anesthesiologist Assistant study materials to date.

Ms. Haynes stated that based on material received it appears that there is a low to moderate supply/demand for this profession.

Dr. Allison-Bryan asked Ms. Payne if there are currently CAAs practicing in Virginia. Ms. Payne stated that there are 16 CAAs who live in Virginia but work in surrounding states. Dr. Allison-Bryan stated that if there are people practicing in Virginia then they need to be regulated and that competition may be higher with the addition of CAAs. Ms. Payne stated that there are a couple of schools who are interested in opening CAA training programs in Virginia and that larger hospital systems in Virginia and across the United States would utilize them.

Ms. Satterlund stated that a moderate number of CAAs should not affect the current supply of providers. She stated that getting CRNA regulations changed would be more beneficial than adding a new profession of CAAs. Ms. Satterlund noted that the Masters to Doctoral CRNA adds one year of critical care to the curriculum, whereas CAA requires ~~is~~ a Bachelors ~~college~~ degree plus three years of training.

Ms. Payne stated that Delegate Orrock's letter's reference to a shortage of providers should be considered a blanket statement relating to concerns over healthcare provider supplies in general and is not taken as a precise assessment of anesthesia care provider availability here in Virginia.

Ms. Satterlund stated she does not believe that there is currently a shortage of CRNAs based on 2015 Virginia Nurse Anesthetist Association pipeline data.

Mr. Wells noted that reciprocity can allow CAAs to move from state to state.

New Business

Presenter Mr. Wells

A public hearing will be held June 27, 2017 to allow public comment on the Certified Anesthesiologist Study.

Adjourned

Adjourned 9:58 a.m.

Chair James Wells, R.Ph.

Signature: _____ Date: ____/____/____

Board Executive Director Elizabeth A. Carter, Ph.D.

Signature: _____ Date: ____/____/____

Virginia Department of Health Professions

DRAFT

Board of Health Professions Full Board Meeting

May 9, 2017
11:00 a.m. - Board Room 4
9960 Mayland Dr, Henrico, VA 23233

In Attendance	Barbara Allison-Bryan, MD, Board of Medicine
	Helene D. Clayton-Jeter, OD, Board of Optometry
	Kevin Doyle, Ed.D., LPC, LSATP, Board of Counseling
	Yvonne Haynes, LCSW, Board of Social Work
	Mark Johnson, DVM, Board of Veterinary Medicine
	Allen R. Jones, Jr., DPT, PT
	Ryan Logan, Board of Pharmacy
	Trula E. Minton, MS, RN, Board of Nursing
	Martha S. Perry, MS, Citizen Member
	Herb Stewart, PhD, Board of Psychology
	Jacquelyn M. Tyler, RN, Citizen Member
	Laura P. Verdun, MA, CCC-SLP, Board of Audiology & Speech-Language Pathology
	James Wells, RPH, Citizen Member
Absent	Robert J. Catron, Citizen Member
	Marvin Figueroa, Citizen Member
	Derrick Kendall, NHA, Board of Long-Term Care Administrators
	James D. Watkins, DDS, Board of Dentistry
	Junius Williams, Jr, MA, Board of Funeral Directors and Embalmers
DHP Staff	Lisa Hahn, MPA, Chief Deputy DHP
	Elizabeth A. Carter, Ph.D., Executive Director BHP
	Kathy Siddall, Business Planning & Research Director DHP
	Elaine Yeatts, Senior Policy Analyst DHP
	Peggy Wood, HPMP Program Manager
	Yetty Shobo, Ph.D., Deputy Executive Director, BHP
	Diane Powers, Communications Director DHP
	Matt Treacy, Communications Associate DHP
	Laura L. Jackson, Operations Manager BHP
Observers	Sara Heisler, VHHA
	Julie Galloway, MSV

Virginia Department of Health Professions

DRAFT

Call to Order

Chair item: Dr. Clayton-Jeter **Time** 11:00 a.m.

Quorum Established

Public Comment

Comment None provided

Approval of Minutes

Presenter Dr. Clayton-Jeter

Discussion

The February 23, 2017 Full Board meeting minutes were approved. All members in favor, none opposed.

Directors Report

Presenter Ms. Hahn

Discussion

Ms. Hahn provided a handout notating charts and graphs depicting different aspects of the opioid epidemic. She noted that a lot of work has been put into education and establishing guidelines that have had an impact on the epidemic. In addition to the opioid epidemic, Hepatitis C has reached the emergency crisis level. The Virginia Department of Health (VDH) has established a safe syringe exchange program to help reduce the transfer of Hepatitis C.

The Virginia Department of Health Professions is working in conjunction with the Department of Behavioral Health and Developmental Services, the Department of Health in support of the Department of Medical Assistance Services' (DMAS) Addiction and Recovery Treatment (ARTS) Benefit program in response to the opioid epidemic. The program went ~~goes~~ into effect April 1, 2017.

Legislative and Regulatory Report

Presenter Ms. Yeatts

Discussion

Ms. Yeatts provided a handout and advised the Board of updates to the laws and regulations that affect DHP.

Health Practitioners Monitoring Program (HPMP)

Presenter Ms. Wood

Ms. Wood provided a PowerPoint presentation on the role of the Health Practitioners Monitoring Program within DHP. She stated that she has made several program presentations at the state and local level and provides flyers and brochures upon request.

Communications

Presenter Ms. Powers

Ms. Powers provided an overview of the Communications Departments May projects which include: assisting all boards and programs, creating traditional and new media, a flyer for Veterinary Medicine on fentanyl and pets, creating a library of video shorts, and researching and redesigning DHPs logo as digital media.

Ms. Powers asked the Board if they would be interested in joining the focus group for the logo project. Several members expressed interest in serving on the focus group for the project.

Strategic Planning

Presenter Ms. Siddall

Ms. Siddall provided an overview of the Department's performance measures and stated that the agency looked very good for this past quarter. She also reviewed the 2016-2018 DHP Strategic Plan and discussed its references to agency goals and measures and proposed biennial budget.

Lunch Break

Presenter Dr. Clayton-Jeter

Dr. Clayton-Jeter announced a lunch break at 12:17 p.m. The meeting reconvened at 12:40 p.m.

Executive Directors Report

Presenter Dr. Carter

Board Budget

Dr. Carter stated that the Board is working well within budget.

Demand Model

Dr. Carter would like to convene a workgroup to plan for convening a session of stakeholders with interest in assessing healthcare workforce demand in comparison with supply. Dr. Carter would like to invite a national expert from the Cecil G. Sheps Center at University of North Carolina-Chapel Hill or other well-known expert in healthcare workforce supply and demand modeling to inform the group on the latest developments relevant to the states. The scheduling will be determined later this year.

Healthcare Workforce Data Center – Dr. Shobo

Dr. Shobo provided an overview of the 11 workforce survey reports resulting from the December licensure renewals. There are several workforce reports awaiting review by their respective boards and will be posted to the DHP webpage once approved. The January/February economic briefs have been posted to the website.

Regulatory Research Committee

Presenter Mr. Wells

Mr. Wells advised the board on the progress being made on the Certified Anesthesiologist Assistant (CAA) study. He stated that the draft of the report is thorough and ready for the public hearing scheduled for June 27, 2017.

Board Reports

Presenter Dr. Clayton-Jeter

Board of Physical Therapy

Dr. Jones advised that the Board of Physical Therapy has created at Regulatory Advisory Panel (RAP) to assist them with recommendations for response to public comment and/or recommendations for revisions to the regulations specifically related to dry needling.

Board of Social Work

Ms. Haynes reported positive movement for mid-level licensure and noted that there was full public support to move forward with mid-level licensure as a regulatory approach instead of by legislative means.

Board of Nursing

Ms. Minton reported that the Board of Nursing adopted the Proposed Amendments to 18VAC90-19-50 (Name Badge Regulation) under a Fast-Track Action in response to a petition for rulemaking requesting an amendment to allow use of first name and last initial on a name tag for nurses in all settings.

The board has added a new citizen member position bringing the board member total to 14.

Board of Counseling

Ms. Yeatts provided comment on behalf of Dr. Doyle that SB 1020 (HB2095) allows for the registration of peer recovery specialists and qualified mental health professions by the Board of Counseling.

Regulations Governing the Practice of Professional Counseling requirement for CACREP accreditation for educational programs will begin a 60-day comment period next week.

Board of Medicine

Dr. Allison-Bryan reported that the Board of Medicine has opted to not participate in the Physician's Compact. When telemedicine and the compact were mapped, it was clear that telemedicine was available all across Virginia, proving that telemedicine in Virginian is working.

January 6, 2017 the Regulatory Advisory Panel met to created and discuss Draft Regulations for Pain Management and Draft Regulations for the Use of Buprenorphine in Office-Based Treatment of Opioid Addiction. These products were then forwarded to Ms. Yeatts. Dr. Allison-Bryan was happy to report that these were approved signed March 15, 2017.

Board of Psychology

Dr. Stewart stated that The Board of Psychology is moving forward with collaboration in the Psychology Interjurisdictional Compact (PSYPACT). Two states, Arizona and Utah, have already joined with five more states in the process of joining. The first seven states that join the compact establish the rules.

He also stated that the Board is reviewing credentialing and performing a regulations review match up with ASBPB as there are gaps and areas that need be added and articulated.

New Business

Presenter Dr. Clayton-Jeter

Dr. Clayton-Jeter asked for participants to form a DHP Logo Committee. Dr. Clayton-Jeter, Dr. Allison-Bryan, and Dr. Stewart all expressed interest. Ms. Hahn commented that she would love for BHP to be the focus group. Volunteers are asked to contact Ms. Powers.

Motion

A motion was made to have the Board of Health Professions create a DHP Logo Committee. The motion was carried and properly seconded by Mr. Logan. All members were in favor, none opposed.

Adjourned

Adjourned 1:23 p.m.

Chair Dr. Clayton-Jeter

Signature: _____ Date: ____/____/____

Board Executive Director Elizabeth A. Carter, Ph.D.

Signature: _____ Date: ____/____/____

DRAFT

VIRGINIA BOARD OF NURSING
COMMITTEE OF THE JOINT BOARDS OF NURSING AND MEDICINE
BUSINESS MEETING MINUTES
April 12, 2017

TIME AND PLACE: The meeting of the Committee of the Joint Boards of Nursing and Medicine was convened at 9:30 A.M., April 12, 2017 in Board Room 4, Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 201, Henrico, Virginia.

MEMBERS PRESENT:
Louise Hershkowitz, CRNA. MSHA; Chair
Marie Gerardo, MS, RN, ANP-BC
Kenneth Walker, MD

MEMBERS ABSENT:
Lori D. Conklin, MD
Rebecca Poston, PhD, RN, CPNP
Wayne Reynolds, DO

ADVISORY COMMITTEE MEMBERS PRESENT:
Joseph F. Borzelleca, Jr., MD, MPH
Kevin E. Brigle, RN, NP
Mark Coles, RN, BA, MSN, NP-C
Wendy Dotson, CNM, MSN
David A. Ellington, MD
Cathy A. Harrison, DNAP, CRNA
Sarah E. Hobgood, MD
Stuart F. Mackler, MD

STAFF PRESENT:
Jay P. Douglas, MSM, RN, CSAC, FRE; Executive Director; Board of Nursing
Stephanie Willinger, Deputy Executive Director; Board of Nursing
Darlene Graham, Senior Discipline Specialist; Board of Nursing

OTHERS PRESENT:
Erin Barrett, Assistant Attorney General; Board Counsel
David Brown, DC; Director; Department of Health Professions
Elaine Yeatts, Senior Policy Analyst, Department of Health Professions
William L. Harp, MD, Executive Director; Board of Medicine

IN THE AUDIENCE:
W. Scott Johnson, Medical Society of Virginia (MSV)
Richard Grossman, Virginia Council of Nurse Practitioners (VCNP)
Lynn Poole, FNP-BC
Mary Duggan, American Association of Nurse Practitioners (AANP) State Representative
Sarah Heisler, Virginia Hospital and Healthcare Association (VHHA)

INTRODUCTIONS: Committee members, Advisory Committee members and staff members introduced themselves.

ESTABLISHMENT OF A QUORUM:
Ms. Hershkowitz noted that there was not enough Committee members to establish a quorum. She added that the following items are deferred at the next meeting for action:

- Adoption of February 8, 2017 Business meeting and Formal Hearings minutes
- Appointment of Joint Boards Advisory Committee Member, Dr. Thokozeni Lipato
- Ms. Barrett's discussion of establishing a standard for expert witnesses will go directly to Board of Medicine and Board of Nursing with a recommendation from the Committee of the Joint Boards of Nursing and Medicine.

PUBLIC COMMENT: There was no one present that wished to address the Board.

DIALOGUE WITH AGENCY DIRECTOR: **Opioid Crisis** – Dr. Brown reported the followings:

- Virginia has a 30% increase from 2015 in deaths due to heroin and fentanyl overdoses.
- 80% heroin users reported starting journey with prescription.
- 2017 General Assembly many opioid related bills such as:
  - Requiring prescribers to obtain information from Prescription Monitoring Program (PMP) if anticipating prescribing of opioids more than seven consecutive days
  - Mandating electronic prescription of opioids by 2020 to help eliminate prescription fraud (technology issues require delay)
  - Authorizing the registration of Peer Recovery Specialist
  - Facilitating Naloxone distribution and training by the Department of Behavioral Health and Development Services (DBHDS)
  - Convening workgroups by Secretary to educate health care practitioners;
  - Limiting Buprenorphine for pain management

Dr. Walker noted that the BOM has approved regulations on opioid and buprenorphine prescribing and the BOM has established a task force.

Dr. Harp said that the basis for pain management regulations was from CDC Guidelines.

Dr. Brown stated that prescribers need to review regulations and best practice techniques for dealing with overprescribing through pain management. Dr. Ellington questioned who determines "best practices" for licensed specialists and recommended that when regulations are distributed, it would be helpful to explain the background. Ms. Douglas stated that all nurse practitioners will be notified of new regulations via e-mail once they are effective Both Dr. Harp and Dr. Brown stated that regulations/guidelines are in place and forthcoming along with education for health care providers and establishing guidelines for training health care providers in the safe prescribing and appropriate use of opioids. Dr. Harp stated he has begun to receive telephone calls regarding concerns of referrals to pain management specialist.

Dr. Hobgood stated that her experience is that the pain management regulations for physicians (identical to nurse practitioner regulations) have been beneficial so far.

Dr. Walker stated that he was aware that in some practices the strategy is to "hand off" pain management to nurse practitioners and physician assistants.

OLD BUSINESS:

Nurse Practitioners Regulations on Pain Management and Prescribing of Buprenorphine:
Ms. Yeatts reviewed the regulations that have been adopted by BOM and BON. She indicated that no additional changes were made after the March BON meeting as anticipated. She added that the regulations are now in the Governor's office for approval.

Expert Witness:
Ms. Barrett stated there will be no action on this item due to lack of a quorum and will be deferred to the next meeting.

Final Report on 2017 General Assembly Legislation:
Ms. Yeatts reported of Bills affecting nurse practitioners to include:

- HB 2119 (**Laser hair removal, limits practice**)
- HB 2301 (**Nurses, licensed practical; administration of vaccinations**) – the "*immediate and direct*" requirement of supervision of LPNs by RNs for PPD and vaccine administration was.

Update on Board Counsel review of Statutory limitations related to proposal of eliminating prescriptive authority license:
Ms. Douglas stated that a full report will be presented at the next meeting, Ms. Mitchell, Board Counsel, is currently reviewing the matters.

CARA Waiver from SAMHSA:
Ms. Herhkowitz stated that this is provided as information only.

NEW BUSINESS:

Report of the March 9, 2017 "*Addiction Disease Management*" training provided by Virginia Department of Health (VDH):
Ms. Hershkowitz provided a summary of the training and stated that it was beneficial. She added that her written report was sent to Ms. Douglas via e-mail on April 11, 2017.

Report of National Council State Board of Nursing (NCSBN) Advance Practice Registered Nurses (APRN) Roundtable on April 4, 2017:
Ms. Hershkowitz provided a brief summary of the meeting.

Written report submitted.

Board of Nursing Executive Director Report:
Ms. Douglas reported the followings:

March 13-15, 2017 NCSBN Mid-Year Meeting - attention and focus on the opioid epidemic/crisis and more research and collaboration with the U.S. Public Health Service. The U.S. Surgeon General is engaged in a public awareness campaign regarding the opioid crisis in the U.S., "Turn the Tide RX" and more information is available on their website.

NURSYS Update - working to implement data on advance practice licensee's in our data system, to include information regarding national certifications issued to licensee's by recognized credentialing agencies.

APRN **Compact** - 3 states have adopted the consensus model and passed legislation: Iowa, North Dakota, West Virginia.

Veteran's Affair New Rule - NCSBN is doing work with Veteran's Affairs Administration regarding expanding the scope of practice of APRNs and Board's access to information necessary for investigations.

2018 Proposed Meeting Dates - Ms. Hershkowitz noted the schedule of meeting dates for 2018.

Ms. Hershkowitz appointed BON members to serve as Joint Boards Committee members for purpose of consideration of Agency Subordinate recommendations.

Ms. Jeanne Holmes, BON Citizen Member, and Dr. Dustin Ross, BON Board Member, joined the meeting at 11:30 A.M.

RECOMMENDATIONS FOR CONSIDERATION

CLOSED MEETING: Ms. Gerardo moved that the Committee of the Joint Boards of Nursing and Medicine and the Board of Nursing convene a closed meeting pursuant to Section 2.2-3711(A)(27) of the *Code of Virginia* at 11:35 A.M. for the purpose of deliberation to consider Agency Subordinate recommendations. Additionally, Ms. Gerardo moved that Ms. Holmes, Dr. Ross, Ms. Douglas, Ms. Willinger, Ms. Graham, and Ms. Barrett attend the closed meeting because their presence in the closed meeting is deemed necessary and their presence will aid the Board in its deliberations. The motion was seconded and carried unanimously.

RECONVENTION: The Board reconvened in open session at 11:37 P.M.

Ms. Gerardo moved that the Committee of the Joint Boards of Nursing and Medicine and the Board of Nursing certify that it heard, discussed or considered only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business

matters as were identified in the motion by which the closed meeting was convened. The motion was seconded and carried unanimously.

Ann Cibuzar McTernan, LNP 0024-075991

Mr. Gerardo moved to accept the Agency Subordinate recommendation to indefinitely suspend the license of Ann Cibuzar McTernan to practice as a nurse practitioner in the Commonwealth of Virginia. The motion was seconded and carried unanimously.

Dr. Ross left the meeting at 11:12 A.M.

Traci M. Colley, LNP 0024-165103

Ms. Gerardo moved to modify the Agency Subordinate recommendation as follow:

- To reprimand Traci M. Colley;
- To indefinitely suspend her license to practice as a nurse practitioner in the Commonwealth of Virginia;
- Said suspension is stayed upon proof of Ms. Colley's re-entry into a Contract with the Virginia Health Practitioners' Monitoring Program (HPMP) and comply with terms and conditions of the HPMP for the period specified by the HPMP;
- To require Ms. Colley to provide to the Board proof of current professional certification in nurse anesthesia from a certifying agency designated in 18VAC90-30-90 or to complete at least 40 hours of continuing education in the area of nurse anesthesia approved by one of the certifying entities designated in 18VAC90-30-90 prior to her suspension being stayed or prior to reinstatement.

The motion was seconded and carried unanimously.

Ms. Hershkowitz reminded available Board Members that assistance was needed with probable cause review following the meeting.

ADJOURNMENT: As there was no additional business, the meeting was adjourned at 11:14 A.M.

Jay P. Douglas, MSM, RN, CSAC, FRE
Executive Director

Agenda Item: **Regulatory Actions - Chart of Regulatory Actions**

Staff Note: Attached is a chart with the status of regulations for the Board as of June 8, 2017

Board **Board of Medicine**

Chapter		Action / Stage Information
[18 VAC 85 - 20]	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic	Licensure by endorsement [Action 4716] NOIRA - *Register Date: 1/23/17* *Adoption of proposed regulations: 6/22/17*
[18 VAC 85 - 21]	Regulations Governing Prescribing of Opioids and Buprenorphine	Initial regulations [Action 4760] Emergency/NOIRA - *Register Date: 4/3/17* *Emergency effective: 3/15/17* *Adoption of proposed regulations and re-adoption of emergency regulations – 6/22/17*
[18 VAC 85 - 50]	Regulations Governing the Practice of Physician Assistants	Elimination of required submission of certain documents [Action 4629] Fast-Track - *Register Date: 5/15/17* *Effective: 6/29/17*
[18 VAC 85 - 80]	Regulations for Licensure of Occupational Therapists	NBCOT certification as option for CE [Action 4461] Proposed - *At Secretary's Office* *To be modified and re-proposed*
[18 VAC 85 - 170]	Regulations Governing the Practice of Genetic Counselors	Initial regulations for licensure [Action 4254] Final - *Register Date: 5/15/17* *Effective: 6/14/17*

Agenda Item: Legislative proposals

Staff Note:

The Advisory Board on Genetic Counseling noted this issue:

Years ago, the examination for genetic counselors was given by the American Board of Medical Genetics (ABMG). In 1993, the ABMG became part of the American Board of Medical Specialties and could no longer certify genetic counselors. To continue to be able to certify genetic counselors, a new organization, the American Board of Genetic Counseling (ABGC) was formed. All who had passed the ABMG examination were grandfathered into the ABGC.
In 2013, the ABGC split into 2 organizations—1) ABGC to administer exams, and 2) the Accreditation Council for Genetic Counseling (ACGC) to approve programs. The law and regulations require that an applicant have a master's degree from an ACGC-accredited school, but many polysomnographic technologists graduated before the ACGC was established

The Advisory Board on Polysomnographic Technology noted an issue with persons receiving on-the-job training & in educational programs with no exemption from the practice act. Additionally, it takes a few months for certification to be granted after taking the examination in order to qualify for licensure.

To address these issues, the Advisory Boards have recommended introduction of legislation to amend the Code of Virginia.

Included in agenda package:

Draft legislative proposals

Action: Adoption of draft legislative proposals as presented or as amended by Board

§ 54.1-2957.19. Genetic counseling; regulation of the practice; license required; licensure; temporary license.

A. The Board shall adopt regulations governing the practice of genetic counseling, upon consultation with the Advisory Board on Genetic Counseling. The regulations shall (i) set forth the requirements for licensure to practice genetic counseling, (ii) provide for appropriate application and renewal fees, (iii) include requirements for licensure renewal and continuing education, (iv) be consistent with the American Board of Genetic Counseling's current job description for the profession and the standards of practice of the National Society of Genetic Counselors, and (v) allow for independent practice.

B. It shall be unlawful for a person to practice or hold himself out as practicing genetic counseling in the Commonwealth without a valid, unrevoked license issued by the Board. No unlicensed person may use in connection with his name or place of business the title "genetic counselor," "licensed genetic counselor," "gene counselor," "genetic consultant," or "genetic associate" or any words, letters, abbreviations, or insignia indicating or implying a person holds a genetic counseling license.

C. An applicant for licensure as a genetic counselor shall submit evidence satisfactory to the Board that the applicant (i) has earned a master's degree from a genetic counseling training program that is accredited by the Accreditation Council of Genetic Counseling, or its predecessor organizations, and (ii) holds a current, valid certificate issued by the American Board of Genetic Counseling or American Board of Medical Genetics to practice genetic counseling.

D. The Board shall waive the requirements of a master's degree and American Board of Genetic Counseling or American Board of Medical Genetics certification for license applicants who (i) apply for licensure before December 31, 2018, or within 90 days of the effective date of the regulations promulgated by the Board pursuant to subsection A, whichever is later; (ii) comply with the Board's regulations relating to the National Society of Genetic Counselors Code of Ethics; (iii) have at least 20 years of documented work experience practicing genetic counseling; (iv) submit two letters of recommendation, one from a genetic counselor and another from a physician; and (v) have completed, within the last five years, 25 hours of continuing education approved by the National Society of Genetic Counselors or the American Board of Genetic Counseling.

E. The Board may grant a temporary license to an applicant who has been granted Active Candidate Status by the American Board of Genetic Counseling and has paid the temporary license fee. Temporary licenses shall be valid for a period of up to one year. An applicant shall not be eligible for temporary license renewal upon expiration of Active Candidate Status as

defined by the American Board of Genetic Counseling. A person practicing genetic counseling under a temporary license shall be supervised by a licensed genetic counselor or physician.

§ 54.1-2957.15. Unlawful to practice as a polysomnographic technologist without a license.

A. It shall be unlawful for any person not holding a current and valid license from the Board of Medicine to practice as a polysomnographic technologist or to assume the title "licensed polysomnographic technologist," "polysomnographic technologist," or "licensed sleep tech."

B. Nothing in this section shall be construed to prohibit a health care provider licensed pursuant to this title from engaging in the full scope of practice for which he is licensed, including, but not limited to, respiratory care professionals.

C. The licensure requirement provided in this chapter shall not prohibit practice by a student enrolled in an educational program in polysomnographic technology or a person engaged in a traineeship under the direct supervision of a licensed polysomnographic technologist or doctor of medicine or osteopathic medicine. Such student or trainee shall be identified to patients as a "Student" or "Trainee" in polysomnographic technology. An exemption from the requirement for licensure shall be limited to 18 months from the start of the educational program or traineeship and shall extend to a maximum of six months from the conclusion of the educational program or traineeship.

C. For the purposes of this chapter, unless the context requires otherwise:

"Polysomnographic technology" means the process of analyzing, scoring, attended monitoring, and recording of physiologic data during sleep and wakefulness to assist in the clinical assessment and diagnosis of sleep/wake disorders and other disorders, syndromes, and dysfunctions that either are sleep related, manifest during sleep, or disrupt normal sleep/wake cycles and activities.

"Practice of polysomnographic technology" means the professional services practiced in any setting under the direction and supervision of a licensed physician involving the monitoring, testing, and treatment of individuals suffering from any sleep disorder. Other procedures include but are not limited to:

a. Application of electrodes and apparatus necessary to monitor and evaluate sleep disturbances, including application of devices that allow a physician to diagnose and treat sleep disorders, which disorders include but shall not be limited to insomnia, sleep-related breathing disorders, movement disorders, disorders of excessive somnolence, and parasomnias;

b. Under the direction of a physician, institution and evaluation of the effectiveness of therapeutic modalities and procedures including the therapeutic use of oxygen and positive

airway pressure (PAP) devices, such as continuous positive airway pressure (CPAP) and bi-level positive airway pressure of non-ventilated patients;

c. Initiation of cardiopulmonary resuscitation, maintenance of patient's airway (which does not include endotracheal intubation);

d. Transcription and implementation of physician orders pertaining to the practice of polysomnographic technology;

e. Initiation of treatment changes and testing techniques required for the implementation of polysomnographic protocols under the direction and supervision of a licensed physician; and

f. Education of patients and their families on the procedures and treatments used during polysomnographic technology or any equipment or procedure used for the treatment of any sleep disorder.

Agenda Item: Recommendations on Regulations for Genetic Counselors

Included in agenda package:

1) Copy of legislation passed by the 2017 General Assembly

2) Copy of draft amendment to Section 60 – conforming grandfathering date to legislation

Staff note:

The Advisory Board on Genetic Counseling met on 6/5/17 and recommended the amendment and a grace period for licensure.

Board Action:

1) Adoption of an amendment to 18VAC85-170-60, Regulations Governing the Practice of Genetic Counselors as an exempt action; and

2) Policy action to grant a 12-month grace period (June 13, 2018) for licensing genetic counselors, consistent with other newly licensed professions. The exception would be for applicants under the grandfathering provision, who would have until December 31, 2018 to apply for licensure.

VIRGINIA ACTS OF ASSEMBLY -- 2017 SESSION

CHAPTER 422

An Act to amend and reenact § 54.1-2957.19 of the Code of Virginia, relating to genetic counselors; licensing; grandfather clause.

[S 880]

Approved March 13, 2017

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2957.19 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-2957.19. Genetic counseling; regulation of the practice; license required; licensure; temporary license.

A. The Board shall adopt regulations governing the practice of genetic counseling, upon consultation with the Advisory Board on Genetic Counseling. The regulations shall (i) set forth the requirements for licensure to practice genetic counseling, (ii) provide for appropriate application and renewal fees, (iii) include requirements for licensure renewal and continuing education, (iv) be consistent with the American Board of Genetic Counseling's current job description for the profession and the standards of practice of the National Society of Genetic Counselors, and (v) allow for independent practice.

B. It shall be unlawful for a person to practice or hold himself out as practicing genetic counseling in the Commonwealth without a valid, unrevoked license issued by the Board. No unlicensed person may use in connection with his name or place of business the title "genetic counselor," "licensed genetic counselor," "gene counselor," "genetic consultant," or "genetic associate" or any words, letters, abbreviations, or insignia indicating or implying a person holds a genetic counseling license.

C. An applicant for licensure as a genetic counselor shall submit evidence satisfactory to the Board that the applicant (i) has earned a master's degree from a genetic counseling training program that is accredited by the Accreditation Council of Genetic Counseling and (ii) holds a current, valid certificate issued by the American Board of Genetic Counseling or American Board of Medical Genetics to practice genetic counseling.

D. The Board shall waive the requirements of a master's degree and American Board of Genetic Counseling or American Board of Medical Genetics certification for license applicants who (i) apply for licensure before ~~July 1, 2016~~ *December 31, 2018, or within 90 days of the effective date of the regulations promulgated by the Board pursuant to subsection A, whichever is later;* (ii) comply with the Board's regulations relating to the National Society of Genetic Counselors Code of Ethics; (iii) have at least 20 years of documented work experience practicing genetic counseling; (iv) submit two letters of recommendation, one from a genetic counselor and another from a physician; and (v) have completed, within the last five years, 25 hours of continuing education approved by the National Society of Genetic Counselors or the American Board of Genetic Counseling.

E. The Board may grant a temporary license to an applicant who has been granted Active Candidate Status by the American Board of Genetic Counseling and has paid the temporary license fee. Temporary licenses shall be valid for a period of up to one year. An applicant shall not be eligible for temporary license renewal upon expiration of Active Candidate Status as defined by the American Board of Genetic Counseling. A person practicing genetic counseling under a temporary license shall be supervised by a licensed genetic counselor or physician.

Exempt Action – Genetic Counselors

18VAC85-170-60. Licensure requirements.

A. An applicant for a license to practice as a genetic counselor shall provide documentation of (i) a master's degree from a genetic counseling training program that is accredited by the Accreditation Council of Genetic Counseling and (ii) a current, valid certificate issued by the ABGC or ABMG to practice genetic counseling.

B. Pursuant to § 54.1-2957.19 D of the Code of Virginia, applicants for licensure who do not meet the requirements of subsection A of this section may be issued a license provided they (i) apply for licensure before ~~July 1, 2016~~ December 31, 2018; (ii) comply with the board's regulations relating to the NSGC Code of Ethics; (iii) have at least 20 years of documented work experience practicing genetic counseling; (iv) submit two letters of recommendation, one from a genetic counselor and another from a physician; and (v) have completed, within the last five years, 25 hours of continuing education approved by the NSGC or the ABGC. For the purpose of this subsection, the board deems the provisions of Part IV (18VAC85-170-110 et seq.) of this chapter to be consistent with the NSGC Code of Ethics.

C. An applicant for a temporary license shall provide documentation of having been granted the active candidate status by the ABGC. Such license shall expire 12 months from issuance or upon expiration of active candidate status, whichever comes first.

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VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Medicine**

Chapter **Regulations Governing the Practice of Genetic Counselors [18 VAC 85 - 170]**

Action	Initial regulations for licensure
Stage	Final
Comment Period	Ends 6/14/2017

All comments for this forum

Back to List of Comments

Commenter: Josh Hetzler, Legislative Counsel at The Family Foundation 6/13/17 5:09 pm

Exceeding the scope of the law

Significant portions of what is being proposed in these regulations exceed the scope of the Board's statutory authority, particularly those parts which address the conscience rights of genetic counselors.

After SB 330 passed the General Assembly during the 2014 session, the Governor proposed an amendment (http://lis.virginia.gov/cgi-bin/legp604.exe?141+amd+SB330AG) containing some of the same items now being proposed by the Board (e.g., referral and timely notice in 18VAC85-170-150(B)(1)-(2)). Because the Senate rejected the Governor's amendment (by a 17-23 vote), anything contained in the Governor's amendment that differs from the language the General Assembly adopted is clearly outside of what the Board is permitted to consider. The Board does not have the discretion to add provisions that the Legislature specifically rejected.

The Board's job is not to "strike a balance" between what it views as "a practitioner's responsibility to his patient" on the one hand and following the law on the other. Its job is to follow the law. In furtherance of protecting the conscience rights of genetic counselors, we respectfully urge the Board to constrain itself within these parameters.

Agenda Item: Regulatory Actions – Occupational Therapy

Included in your agenda package are:

A copy of HB1484 passed by the 2017 Session of the General Assembly

A copy of amendments to Section 71 on Continuing Competency to be adopted to conform to legislation

A copy of the proposed regulation to be withdrawn or modified in conformity with legislation.

Board action:

1) To adopt changes to Section 71 as an action exempt from the APA requirements.

2) To withdraw or modify the proposed action on acceptance of NCBOT certification

VIRGINIA ACTS OF ASSEMBLY -- 2017 SESSION

CHAPTER 411

An Act to require the Board of Medicine to amend regulations governing licensure of occupational therapists to specify Type 1 continuous learning activities.

[H 1484]

Approved March 13, 2017

Be it enacted by the General Assembly of Virginia:

1. *§ 1. That the Board of Medicine shall amend regulations governing licensure of occupational therapists to provide that Type 1 continuing learning activities that shall be completed by the practitioner prior to renewal of a license shall consist of an organized program of study, classroom experience, or similar educational experience that is related to a licensee's current or anticipated roles and responsibilities in occupational therapy and approved or provided by one of the following organizations or any of its components: the Virginia Occupational Therapy Association; the American Occupational Therapy Association; the National Board for Certification in Occupational Therapy; a local, state, or federal government agency; a regionally accredited college or university; or a health care organization accredited by a national accrediting organization granted authority by the Centers for Medicare and Medicaid Services to assure compliance with Medicare conditions of participation. Such regulations shall also provide that Type 1 continuing learning activities may also include an American Medical Association Category 1 Continuing Medical Education program.*

§ 2. That the Board of Medicine shall not deem maintenance of any certification provided by the Virginia Occupational Therapy Association; the American Occupational Therapy Association; the National Board for Certification in Occupational Therapy; a local, state, or federal government agency; a regionally accredited college or university; or a health care organization accredited by a national accrediting organization granted authority by the Centers for Medicare and Medicaid Services to assure compliance with Medicare conditions of participation as sufficient to fulfill continuing learning requirements for occupational therapists.

Project 5159 - none

BOARD OF MEDICINE

CE for occupational therapy

18VAC85-80-71. Continued competency requirements for renewal of an active license.

A. In order to renew an active license biennially, a practitioner shall complete the Continued Competency Activity and Assessment Form that is provided by the board and that shall indicate completion of at least 20 contact hours of continuing learning activities as follows:

1. A minimum of 10 of the 20 hours shall be in Type 1 activities ~~offered by a sponsor or organization recognized by the profession and may include in-service training, self-study courses, continuing education courses, specialty certification, or professional workshops~~ which shall consist of an organized program of study, classroom experience, or similar educational experience that is related to a licensee's current or anticipated roles and responsibilities in occupational therapy and approved or provided by one of the following organizations or any of its components:

a. Virginia Occupational Therapy Association;

b. American Occupational Therapy Association;

c. National Board for Certification in Occupational Therapy;

d. Local, state, or federal government agency;

e. Regionally accredited college or university;

f. Health care organization accredited by a national accrediting organization granted authority by the Centers for Medicare and Medicaid Services to assure compliance with Medicare conditions of participation; or

g. An American Medical Association Category 1 Continuing Medical Education program.

2. No more than 10 of the 20 hours may be Type 2 activities, which may include consultation with another therapist, independent reading or research, preparation for a presentation, or other such experiences that promote continued learning. Up to two of the Type 2 continuing education hours may be satisfied through delivery of occupational therapy services, without compensation, to low-income individuals receiving services through a local health department or a free clinic organized in whole or primarily for the delivery of health services. One hour of continuing education may be credited for three hours of providing such volunteer services as documented by the health department or free clinic.

B. A practitioner shall be exempt from the continuing competency requirements for the first biennial renewal following the date of initial licensure in Virginia.

C. The practitioner shall retain in his records the completed form with all supporting documentation for a period of six years following the renewal of an active license.

D. The board shall periodically conduct a random audit of at least one to two percent of its active licensees to determine compliance. The practitioners selected for the audit shall provide the completed Continued Competency Activity and Assessment Form and all supporting documentation within 30 days of receiving notification of the audit.

E. Failure to comply with these requirements may subject the licensee to disciplinary action by the board.

F. The board may grant an extension of the deadline for continuing competency requirements for up to one year for good cause shown upon a written request from the licensee prior to the renewal date.

G. The board may grant an exemption for all or part of the requirements for circumstances beyond the control of the licensee, such as temporary disability, mandatory military service, or officially declared disasters.

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VIRGINIA REGULATORY TOWN HALL

Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Medicine**

Chapter **Regulations for Licensure of Occupational Therapists [18 VAC 85 - 80]**

Action: NBCOT certification as option for CE

Edit Action | Withdraw Action

General Information	
Action Summary	The Board has proposed amendments to section 71 on continued competency requirements to clarify the completion of the Continued Competency Activity and Assessment Form and to allow a licensee to fulfill the requirement by maintenance of current certification by the National Board of Certification in Occupational Therapy. An amendment will also change the title of the chapter from Regulations Governing the Licensure of Occupational Therapists to Regulations Governing the Practice of Occupational Therapy.
Chapters Affected	Only affects this chapter.
Exempt from APA	No, this action is subject to the *Administrative Process Act* and the standard executive branch review process.
RIS Project	Yes [004544]

Stages

Stages associated with this regulatory action.

Stage ID	Stage Type	Status
7363	Fast-Track	**Comment period complete, but objections were filed.**
7756	Proposed	Secretary of Health and Human Resources review in progress.

Create a new stage for this action .. Create Stage

For guidance please see the following sections of our user guide:

What type of regulatory action do I file? Flow charts of the regulatory process

Contact Information	
Name / Title:	William L. Harp, M.D. / *Executive Director*
Address:	9960 Mayland Drive Suite 300

REGULATIONS GOVERNING THE ~~LICENSURE OF OCCUPATIONAL THERAPISTS~~ PRACTICE OF OCCUPATIONAL THERAPY

18VAC85-80-71. Continued competency requirements for renewal of an active license.

A. In order to renew an active license biennially, a practitioner shall ~~complete the Continued Competency Activity and Assessment Form that is provided by the board and that shall indicate completion of~~ complete at least 20 contact hours of continuing learning activities as follows:

1. A minimum of 10 of the 20 hours shall be in Type 1 activities offered by a sponsor or organization recognized by the profession and may include in-service training, self-study courses, continuing education courses, specialty certification or professional workshops.

2. No more than 10 of the 20 hours may be Type 2 activities, which may include consultation with another therapist, independent reading or research, preparation for a presentation or other such experiences that promote continued learning.

3. The board recognizes the maintenance of current NBCOT certification as fulfilling the requirements of this subsection.

B. A practitioner shall be exempt from the continuing competency requirements for the first biennial renewal following the date of initial licensure in Virginia.

C. The practitioner shall retain ~~in his~~ records ~~the completed form~~ of continuing competency courses and activities with all supporting documentation for a period of six years following the renewal of an active license.

D. The board shall periodically conduct a random audit ~~of at least one to two percent~~ of its active licensees to determine compliance. The practitioners selected for the audit shall provide ~~the completed Continued Competency Activity and Assessment Form and~~ all supporting documentation within 30 days of receiving notification of the audit.

E. Failure to comply with these requirements may subject the licensee to disciplinary action by the board.

F. The board may grant an extension of the deadline for continuing competency requirements for up to one year for good cause shown upon a written request from the licensee prior to the renewal date.

G. The board may grant an exemption for all or part of the requirements for circumstances beyond the control of the licensee, such as temporary disability, mandatory military service, or officially declared disasters.

Agenda Item: NOIRA for supervision and direction of laser hair removal

Included in the agenda package:

A copy of HB2119

Staff note:

Since the statutory language requires laser hair removal by a *properly trained person under the direction and supervision of a licensed doctor of medicine or osteopathic medicine or a physician assistant,* regulations for doctors of medicine and osteopathy, physician assistants and nurse practitioners will need to be amended to define "direction and supervision" in this context and provide guidance about the practitioner responsibility relative to a "properly trained person."

Action:

Adoption of a NOIRA to implement HB2119 in 18VAC85-20, 18VAC85-50 and 18VAC90-30.

CHAPTER 390

An Act to amend and reenact § 54.1-700 of the Code of Virginia and to amend the Code of Virginia by adding in Article 6 of Chapter 29 of Title 54.1 a section numbered 54.1-2973.1, relating to the practice of laser hair removal.

[H 2119]

Approved March 13, 2017

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-700 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding in Article 6 of Chapter 29 of Title 54.1 a section numbered 54.1-2973.1 as follows:

§ 54.1-700. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Barber" means any person who shaves, shapes or trims the beard; cuts, singes, shampoos or dyes the hair or applies lotions thereto; applies, treats or massages the face, neck or scalp with oils, creams, lotions, cosmetics, antiseptics, powders, clays or other preparations in connection with shaving, cutting or trimming the hair or beard, and practices barbering for compensation and when such services are not performed for the treatment of disease.

"Barbering" means any one or any combination of the following acts, when done on the human body for compensation and not for the treatment of disease, shaving, shaping and trimming the beard; cutting, singeing, shampooing or dyeing the hair or applying lotions thereto; applications, treatment or massages of the face, neck or scalp with oils, creams, lotions, cosmetics, antiseptics, powders, clays, or other preparations in connection with shaving, cutting or trimming the hair or a beard. The term "barbering" shall not apply to the acts described hereinabove when performed by any person in his home if such service is not offered to the public.

"Barber instructor" means any person who has been certified by the Board as having completed an approved curriculum and who meets the competency standards of the Board as an instructor of barbering.

"Barbershop" means any establishment or place of business within which the practice of barbering is engaged in or carried on by one or more barbers.

"Board" means the Board for Barbers and Cosmetology.

"Body-piercer" means any person who for remuneration penetrates the skin of a person to make a hole, mark, or scar, generally permanent in nature.

"Body-piercing" means the act of penetrating the skin of a person to make a hole, mark, or scar, generally permanent in nature.

"Body-piercing salon" means any place in which a fee is charged for the act of penetrating the skin of a person to make a hole, mark, or scar, generally permanent in nature.

"Body-piercing school" means a place or establishment licensed by the Board to accept and train students in body-piercing.

"Cosmetologist" means any person who administers cosmetic treatments; manicures or pedicures the nails of any person; arranges, dresses, curls, waves, cleanses, cuts, shapes, singes, waxes, tweezes, shaves, bleaches, colors, relaxes, straightens, or performs similar work, upon human hair, or a wig or hairpiece, by any means, including hands or mechanical or electrical apparatus or appliances unless such acts as adjusting, combing, or brushing prestyled wigs or hairpieces do not alter the prestyled nature of the wig or hairpiece, and practices cosmetology for compensation.

"Cosmetology" includes, but is not limited to, the following practices: administering cosmetic treatments; manicuring or pedicuring the nails of any person; arranging, dressing, curling, waving, cleansing, cutting, shaping, singeing, waxing, tweezing, shaving, bleaching, coloring, relaxing, straightening, or similar work, upon human hair, or a wig or hairpiece, by any means, including hands or mechanical or electrical apparatus or appliances, but shall not include hair braiding or such acts as adjusting, combing, or brushing prestyled wigs or hairpieces when such acts do not alter the prestyled nature of the wig or hairpiece.

"Cosmetology instructor" means a person who has been certified by the Board as having completed an approved curriculum and who meets the competency standards of the Board as an instructor of cosmetology.

"Cosmetology salon" means any commercial establishment, residence, vehicle or other establishment. place or event wherein cosmetology is offered or practiced on a regular basis for compensation and may include the training of apprentices under regulations of the Board.

"Esthetician" means a person who engages in the practice of esthetics for compensation.

"Esthetics" includes, but is not limited to, the following practices of administering cosmetic treatments to enhance or improve the appearance of the skin: cleansing, toning, performing effleurage or other related movements, stimulating, exfoliating, or performing any other similar procedure on the skin of the human body or scalp by means of cosmetic preparations, treatments, *or* any nonlaser device, *whether by* electrical, mechanical, or manual *means*, for care of the skin; applying make-up or eyelashes to any person, tinting or perming eyelashes and eyebrows, and lightening hair on the body except the scalp; and removing unwanted hair from the body of any person by the use of *any nonlaser device, by* tweezing, *or by use of* chemical, or mechanical means. However, "esthetics" is not a healing art and shall not include any practice, activity, or treatment that constitutes the practice of medicine, osteopathic medicine, or chiropractic. The terms "healing arts," "practice of medicine," "practice of osteopathic medicine," and "practice of chiropractic" shall mean the same as those terms are defined in § 54.1-2900.

"Esthetics instructor" means a licensed esthetician who has been certified by the Board as having completed an approved curriculum and who meets the competency standards of the Board as an instructor of esthetics.

"Esthetics spa" means any commercial establishment, residence, vehicle, or other establishment, place, or event wherein esthetics is offered or practiced on a regular basis for compensation under regulations of the Board.

"Master esthetician" means a licensed esthetician who, in addition to the practice of esthetics, offers to the public for compensation, without the use of laser technology, lymphatic drainage, chemical exfoliation, or microdermabrasion, and who has met such additional requirements as determined by the Board to practice lymphatic drainage, chemical exfoliation with products other than Schedules II through VI controlled substances as defined in the Drug Control Act (§ 54.1-3400 et seq.), and microdermabrasion of the epidermis.

"Nail care" means manicuring or pedicuring natural nails or performing artificial nail services.

"Nail salon" means any commercial establishment, residence, vehicle or other establishment, place or event wherein nail care is offered or practiced on a regular basis for compensation and may include the training of apprentices under regulations of the Board.

"Nail school" means a place or establishment licensed by the board to accept and train students in nail care.

"Nail technician" means any person who for compensation manicures or pedicures natural nails, or who performs artificial nail services for compensation, or any combination thereof.

"Nail technician instructor" means a licensed nail technician who has been certified by the Board as having completed an approved curriculum and who meets the competency standards of the Board as an instructor of nail care.

"Physical (wax) depilatory" means the wax depilatory product or substance used to remove superfluous hair.

"School of cosmetology" means a place or establishment licensed by the Board to accept and train students and which offers a cosmetology curriculum approved by the Board.

"School of esthetics" means a place or establishment licensed by the Board to accept and train students and which offers an esthetics curriculum approved by the Board.

"Tattoo parlor" means any place in which tattooing is offered or practiced.

"Tattoo school" means a place or establishment licensed by the Board to accept and train students in tattooing.

"Tattooer" means any person who for remuneration practices tattooing.

"Tattooing" means the placing of designs, letters, scrolls, figures, symbols or any other marks upon or under the skin of any person with ink or any other substance, resulting in the permanent coloration of the skin, including permanent make-up or permanent jewelry, by the aid of needles or any other instrument designed to touch or puncture the skin.

"Wax technician" means any person licensed by the Board who removes hair from the hair follicle using a physical (wax) depilatory or by tweezing.

"Wax technician instructor" means a licensed wax technician who has been certified by the Board as having completed an approved curriculum and who meets the competency standards of the Board as an instructor of waxing.

"Waxing" means the temporary removal of superfluous hair from the hair follicle on any area of the human body through the use of a physical (wax) depilatory or by tweezing.

"Waxing salon" means any commercial establishment, residence, vehicle or other establishment, place or event wherein waxing is offered or practiced on a regular basis for compensation and may include the training of apprentices under regulations of the Board.

"Waxing school" means a place or establishment licensed by the Board to accept and train students in waxing.

§ 54.1-2973.1. Practice of laser hair removal.

The practice of laser hair removal shall be performed by a properly trained person licensed to practice medicine or osteopathic medicine or a physician assistant as authorized pursuant to § 54.1-2952 or a nurse practitioner as authorized pursuant to § 54.1-2957 or by a properly trained

person under the direction and supervision of a licensed doctor of medicine or osteopathic medicine or a physician assistant as authorized pursuant to § 54.1-2952 or a nurse practitioner as authorized pursuant to § 54.1-2957 who may delegate such practice in accordance with subdivision A 6 of § 54.1-2901.

Agenda Item: Agenda Item: Draft regulations for Licensure by Endorsement

Included in the agenda package:

Copy of Notice of Intended Regulatory Action (NOIRA) background document

Copy of draft regulations for licensure by endorsement as recommended by the Legislative Committee

Staff note:

There was a comment period on the NOIRA from 1/23/17 to 2/22/17 – no comment was received

Action:

Adoption of proposed amendments as presented or as amended by the Board.

Form: TH-01
11/14

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC85-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Doctors of Medicine, Osteopathic Medicine, Podiatry, or Chiropractic
Action title	Licensure by endorsement
Date this document prepared	11/2/16

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

The Board intends to propose regulations for licensure by endorsement for physicians who hold licenses in other states and who meet certain requirements established in regulation. The goal of the planned action is establishment of an expedited process for licensure of qualified physicians who want to practice in Virginia, either in person or by telemedicine.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and(2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific

provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:

...

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...

The Code section relating to authority to issue licenses by endorsement is:

§ 54.1-103. Additional training of regulated persons; reciprocity; endorsement.
A. The regulatory boards within the Department of Professional and Occupational Regulation and the Department of Health Professions may promulgate regulations specifying additional training or conditions for individuals seeking certification or licensure, or for the renewal of certificates or licenses.
B. The regulatory boards may enter into agreements with other jurisdictions for the recognition of certificates and licenses issued by other jurisdictions.
C. The regulatory boards are authorized to promulgate regulations recognizing licenses or certificates issued by other states, the District of Columbia, or any territory or possession of the United States as full or partial fulfillment of qualifications for licensure or certification in the Commonwealth.

Purpose

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.

The Board has reviewed elements of licensure by endorsement that would provide assurance of competency to practice but also discussed potential disqualifiers including disciplinary actions by another state board, malpractice claims, and/or certain criminal convictions. While the Board may be able to license physicians who have had discipline, malpractice claims, or criminal convictions, it may determine that such an applicant requires a full review and would not qualify for an expedited license by endorsement. The intent is to facilitate licensure for physicians who have a demonstrated history of competent, safe practice in order to protect the health and safety of citizens of the Commonwealth who may become their patients.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

The Credentials Committee reviewed some elements of licensure by endorsement, which may include requirements such as: 1) Current, unrestricted license to practice in another U. S. jurisdiction and in good standing in each jurisdiction in which a license is currently held or has been held; 2) Continuous, clinical practice in another U. S. jurisdiction or in federal civil or military service for a period of time immediately preceding application for licensure in Virginia; 3) Current certification by the American Board of Medical Specialties or the Bureau of Osteopathic Specialists or is a diplomate of the American Board of Podiatric Surgery; and 4) Current report from the U.S. Department of Health and Human Services National Practitioner Data Bank (NPDB). Neither the Committee nor the full board has determined which requirements will be included in the proposal, but intends to facilitate licensure for physicians who have an unrestricted license and strong evidence of competency to practice.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no viable alternatives to the selection of the least burdensome and intrusive regulation, since the intent of this action is to expedite licensure for some applicants.

Public participation

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Richmond, VA 23233 or **elaine.yeatts@dhp.virginia.gov** or by fax to (804) 527-4434. Written comments must include the name and address of the

commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

The Credentials Committee of the Board, consisting of six licensed physicians and three citizen members will serve as the Regulatory Advisory Panel to develop proposed regulations resulting from the NOIRA and any comment on the NOIRA.

Project 4970 - NOIRA

BOARD OF MEDICINE

Licensure by endorsement

18VAC85-20-141. Licensure by endorsement.

To be licensed by endorsement, an applicant shall:

1. Hold at least one current, unrestricted license in a U. S. jurisdiction or Canada for the five years immediately preceding application to the board;

2. Have been engaged in active practice, defined as an average of 20 hours per week or 640 hours per year, for five years after post-graduate training and immediately preceding application;

3. Verify that all licenses held in another U. S. jurisdiction or Canada are in good standing, defined as not currently under investigation and if lapsed, eligible for renewal or reinstatement;

4. Hold current certification by one of the following:

a. American Board of Medical Specialties;

b. Bureau of Osteopathic Specialists;

c. American Board of Podiatric Surgery;

d. Fellowship of Royal College of Physicians of Canada

e. Fellowship of the Royal College of Surgeons of Canada; or

f. College of Family Physicians of Canada;

5. Submit a current report from the U. S. Department of Health and Human Services Data Bank (NPDB); and

6. Have no grounds for denial based on provisions of § 54.1-2915 of the Code of Virginia or regulations of the board.

Agenda Item: Guidance document for Licensed Midwives

Included in your agenda package:

- Copy of draft guidance document as recommended by the Advisory Board

Staff note:

At its June 9, 2017 meeting, the Advisory Board on Midwifery discussed an issue that was of concern to midwives who are licensed by the Board of Medicine and practice in Virginia. A number of licensed midwives report that their orders for laboratory tests, ultrasounds, and biophysical profiles have been declined by laboratories and hospitals. The Advisory Board asked for clarification through the development of a guidance document that would inform all parties regarding the authority of licensed midwives to order testing.

Action:

Motion to adopt guidance document as proposed or as amended by the Board

Guidance document: 85-28 Adopted:

Virginia Board of Medicine

Authority of Licensed Midwives to Order Tests

Code of Virginia 54.1-2957.9 indicates that the scope of practice for licensed midwives in Virginia is to "be consistent with the North American Registry of Midwives' current job description for the profession and the National Association of Certified Professional Midwives' standards of practice."

The *North American Registry of Midwives (NARM) 2016 Job Analysis Survey Comprehensive Report* Exam Content Outline for the NARM Written Examination, recommended by the NARM Job Analysis Committee and approved by the NARM Board of Directors contains the following:

On page 20

- Obtains or refers for urine culture
- Obtains or refers for vaginal culture
- Obtains or refers for blood screening tests

On page 24-25

Assess and evaluate a post-date pregnancy by monitoring/screening:
Consult or refer for:

- Ultrasound
- Non-stress test
- Biophysical profile

Agenda Item: Guidance document – Telemedicine

Included in the agenda package:

Amended Guidance Document 85-12 (Medicine) and 90-64 (Nurse Practitioners)

Staff note:

With recent amendments to the Code on prescribing by telemedicine, these guidance documents must be amended. The two documents are identical, with the exception of the preamble on the document for nurse practitioners.

Action:

Adoption of the revised guidance documents, 85-12 and 90-64

Virginia Board of Medicine

Telemedicine

Section One: Preamble.

The Virginia Board of Medicine ("Board") recognizes that using telemedicine services in the delivery of medical services offers potential benefits in the provision of medical care. The appropriate application of these services can enhance medical care by facilitating communication between practitioners, other health care providers, and their patients, prescribing medication, medication management, obtaining laboratory results, scheduling appointments, monitoring chronic conditions, providing health care information, and clarifying medical advice. With the exception of prescribing controlled substances, the Virginia General Assembly has not established statutory parameters regarding the provision and delivery of telemedicine services. Therefore, practitioners must apply existing laws and regulations to the provision of telemedicine services. The Board issues this guidance document to assist practitioners with the application of current laws to telemedicine service practices.

These guidelines should not be construed to alter the scope of practice of any health care provider or authorize the delivery of health care services in a setting, or in a manner, not authorized by law. In fact, these guidelines support a consistent standard of care and scope of practice notwithstanding the delivery tool or business method used to enable practitioner-to-patient communications. ~~For clarity,~~ For the purpose of prescribing controlled substances, a practitioner using telemedicine services in the provision of medical services to a patient (whether existing or new) must take appropriate steps to establish the practitioner-patient relationship as defined in Virginia Code § 54.1-3303. ~~and~~ A practitioner should conduct all appropriate evaluations and history of the patient consistent with traditional standards of care for the particular patient presentation. As such, some situations and patient presentations are appropriate for the utilization of telemedicine services as a component of, or in lieu of, in-person provision of medical care, while others are not. The practitioner is responsible for making this determination, and in doing so must adhere to applicable laws and standards of care.

The Board has developed these guidelines to educate licensees as to the appropriate use of telemedicine services in the practice of medicine. The Board is committed to ensuring patient access to the convenience and benefits afforded by telemedicine services, while promoting the responsible provision of health care services.

It is the expectation of the Board that practitioners who provide medical care, electronically or otherwise, maintain the highest degree of professionalism and should:

- Place the welfare of patients first;
- Maintain acceptable and appropriate standards of practice;
- Adhere to recognized ethical codes governing the applicable profession;
- Adhere to applicable laws and regulations;

- In the case of physicians, properly supervise non-physician clinicians when required to do so by statute; and
- Protect patient confidentiality.

Section Two: Establishing the Practitioner-Patient Relationship.

The practitioner-patient relationship is fundamental to the provision of acceptable medical care. It is the expectation of the Board that practitioners recognize the obligations, responsibilities, and patient rights associated with establishing and maintaining a practitioner-patient relationship. Where an existing practitioner-patient relationship is not present,[1] a practitioner must take appropriate steps to establish a practitioner-patient relationship consistent with the guidelines identified in this document, with Virginia law, and with any other applicable law.[2] While each circumstance is unique, such practitioner-patient relationships may be established using telemedicine services provided the standard of care is met.

~~Specifically, Virginia Code § 54.1-3303(A) provides the requirements to establish a practitioner-patient relationship. *See* Va. Code § 54.1-3303(A).~~

A practitioner is discouraged from rendering medical advice and/or care using telemedicine services without (1) fully verifying and authenticating the location and, to the extent possible, confirming the identity of the requesting patient; (2) disclosing and validating the practitioner's identity and applicable credential(s); and (3) obtaining appropriate consents from requesting patients after disclosures regarding the delivery models and treatment methods or limitations, including any special informed consents regarding the use of telemedicine services. An appropriate practitioner-patient relationship has not been established when the identity of the practitioner may be unknown to the patient.

Section Three: Guidelines for the Appropriate Use of Telemedicine Services.
The Board has adopted the following guidelines for practitioners utilizing telemedicine services in the delivery of patient care, regardless of an existing practitioner-patient relationship prior to an encounter.

Licensure:

The practice of medicine occurs where the patient is located at the time telemedicine services are used, and insurers may issue reimbursements based on where the practitioner is located. Therefore, a practitioner must be licensed by, or under the jurisdiction of, the regulatory board of the state where the patient is located and the state where the practitioner is located. Practitioners who treat or prescribe through online service sites must possess appropriate licensure in all jurisdictions where patients receive care. To ensure appropriate insurance coverage, practitioners must make certain that they are compliant with federal and state laws and policies regarding reimbursements.

[1] This guidance document is not intended to address existing patient-practitioner relationships established through in-person visits.
[2] The practitioner must adhere not only to Virginia law defining a practitioner-patient relationship, but the law in any state where a patient is receiving services that defines the practitioner-patient relationship.

Evaluation and Treatment of the Patient:

A documented medical evaluation and collection of relevant clinical history commensurate with the presentation of the patient to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided must be obtained prior to providing treatment, which treatment includes the issuance of prescriptions, electronically or otherwise. Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional, in-person encounters. Treatment, including issuing a prescription based solely on an online questionnaire, does not constitute an acceptable standard of care.

Informed Consent:

Evidence documenting appropriate patient informed consent for the use of telemedicine services must be obtained and maintained. Appropriate informed consent should, as a baseline, include the following:

- Identification of the patient, the practitioner, and the practitioner's credentials;
- Types of activities permitted using telemedicine services (e.g. prescription refills, appointment scheduling, patient education, etc.);
- Agreement by the patient that it is the role of the practitioner to determine whether or not the condition being diagnosed and/or treated is appropriate for a telemedicine encounter;
- Details on security measures taken with the use of telemedicine services, such as encrypting date of service, password protected screen savers, encrypting data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy notwithstanding such measures;
- Hold harmless clause for information lost due to technical failures; and
- Requirement for express patient consent to forward patient-identifiable information to a third party.

Medical Records:

The medical record should include, if applicable, copies of all patient-related electronic communications, including patient-practitioner communication, prescriptions, laboratory and test results, evaluations and consultations, records of past care, and instructions obtained or produced in connection with the utilization of telemedicine services. Informed consents obtained in connection with an encounter involving telemedicine services should also be filed in the medical record. The patient record established during the use of telemedicine services must be accessible to both the practitioner and the patient, and consistent with all established laws and regulations governing patient healthcare records.

Privacy and Security of Patient Records and Exchange of Information:

Written policies and procedures should be maintained for documentation, maintenance, and transmission of the records of encounters using telemedicine services. Such policies and procedures should address (1) privacy, (2) health-care personnel (in addition to the practitioner

addressee) who will process messages, (3) hours of operation, (4) types of transactions that will be permitted electronically, (5) required patient information to be included in the communication, such as patient name, identification number and type of transaction, (6) archival and retrieval, and (7) quality oversight mechanisms. Policies and procedures should be periodically evaluated for currency and be maintained in an accessible and readily available manner for review.

Section Four: Prescribing:

Prescribing controlled substances requires the establishment of a bona fide practitioner-patient relationship in accordance with § 54.1-3303 (A) of the Code of Virginia. Prescribing ~~medications~~ controlled substances, in-person or via telemedicine services, is at the professional discretion of the prescribing practitioner. The indication, appropriateness, and safety considerations for each prescription provided via telemedicine services must be evaluated by the practitioner in accordance with applicable law and current standards of practice and consequently carries the same professional accountability as prescriptions delivered during an in-person encounter. Where such measures are upheld, and the appropriate clinical consideration is carried out and documented, the practitioner may exercise their judgment and prescribe ~~medications~~ controlled substances as part of telemedicine encounters in accordance with applicable state and federal law.

Prescriptions must comply with the requirements set out in Virginia Code §§ 54.1-3408.01 and 54.1-3303(A). Prescribing controlled substances in Schedule II through V via telemedicine also requires compliance with federal rules for the practice of telemedicine. ~~Additionally,~~ Practitioners issuing prescriptions as part of telemedicine services should include direct contact for the prescriber or the prescriber's agent on the prescription. This direct contact information ensures ease of access by pharmacists to clarify prescription orders, and further facilitates the prescriber-patient-pharmacist relationship.

For the purpose of prescribing Schedule VI controlled substances, "telemedicine services" is defined as it is in § 38.2-3418.16 of the Code of Virginia. Under that definition, *"telemedicine services," as it pertains to the delivery of health care services, means the use of electronic technology or media, including interactive audio or video, for the purpose of diagnosing or treating a patient or consulting with other health care providers regarding a patient's diagnosis or treatment. "Telemedicine services" does not include an audio-only telephone, electronic mail message, facsimile transmission, or online questionnaire.*

Section Five: Guidance Document Limitations.

Nothing in this document shall be construed to limit the authority of the Board to investigate, discipline, or regulate its licensees pursuant to applicable Virginia statutes and regulations. Additionally, nothing in this document shall be construed to limit the Board's ability to review the delivery or use of telemedicine services by its licensees for adherence to the standard of care and compliance with the requirements set forth in the laws and regulations of the Commonwealth of Virginia. Furthermore, this document does not limit the Board's ability to determine that certain situations fail to meet the standard of care or standards set forth in laws and regulations despite technical adherence to the guidance produced herein.

Statutory references:

§ 54.1-3303. Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32. The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship.

For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice. In addition, a bona fide practitioner-patient relationship means that the practitioner shall (i) ensure that a medical or drug history is obtained; (ii) provide information to the patient about the benefits and risks of the drug being prescribed; (iii) perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription; and (iv) initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. A practitioner who performs or has performed an appropriate examination of the patient required pursuant to clause (iii), either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically, for the purpose of establishing a bona fide practitioner-patient relationship, may prescribe Schedule II through VI controlled substances to the patient, provided that the prescribing of such Schedule II through V controlled substance is in compliance with federal requirements for the practice of telemedicine.

For the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine services as defined in § 38.2-3418.16, a prescriber may establish a bona fide practitioner-patient relationship by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; and (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations. Nothing in this paragraph shall permit a prescriber to establish a bona fide practitioner-patient relationship for the purpose of prescribing a Schedule VI controlled substance when the standard of care dictates that an in-person physical examination is necessary for diagnosis. Nothing in this

paragraph shall apply to: (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.

Any practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than medicinally or for therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.

§ 54.1-3408.01. Requirements for prescriptions.

A. The written prescription referred to in § 54.1-3408 shall be written with ink or individually typed or printed. The prescription shall contain the name, address, and telephone number of the prescriber. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, electronically printed, typewritten, rubber stamped, or printed by hand.

The written prescription shall contain the first and last name of the patient for whom the drug is prescribed. The address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription. If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription. Each written prescription shall be dated as of, and signed by the prescriber on, the day when issued. The prescription may be prepared by an agent for the prescriber's signature.

This section shall not prohibit a prescriber from using preprinted prescriptions for drugs classified in Schedule VI if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

No written prescription order form shall include more than one prescription. However, this provision shall not apply (i) to prescriptions written as chart orders for patients in hospitals and long-term-care facilities, patients receiving home infusion services or hospice patients, or (ii) to a prescription ordered through a pharmacy operated by or for the Department of Corrections or the Department of Juvenile Justice, the central pharmacy of the Department of Health, or the central outpatient pharmacy operated by the Department of Behavioral Health and Developmental Services; or (iii) to prescriptions written for patients residing in adult and juvenile detention centers, local or regional jails, or work release centers operated by the Department of Corrections.

B. Prescribers' orders, whether written as chart orders or prescriptions, for Schedules II, III, IV, and V controlled drugs to be administered to (i) patients or residents of long-term care facilities served by a Virginia pharmacy from a remote location or (ii) patients receiving parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion therapy and served by a home infusion pharmacy from a remote location, may be transmitted to that remote pharmacy by an electronic communications device over telephone lines which send the exact image to the receiver in hard copy form, and such facsimile copy shall be treated as a valid original prescription order. If the order is for a radiopharmaceutical, a physician authorized by state or federal law to possess and administer medical radioactive materials may authorize a nuclear medicine technologist to transmit a prescriber's verbal or written orders for radiopharmaceuticals.

C. The oral prescription referred to in § 54.1-3408 shall be transmitted to the pharmacy of the patient's choice by the prescriber or his authorized agent. For the purposes of this section, an authorized agent of the prescriber shall be an employee of the prescriber who is under his immediate and personal supervision, or if not an employee, an individual who holds a valid license allowing the administration or dispensing of drugs and who is specifically directed by the prescriber.

Guidance document: 90-64

Revised:
Board of Medicine, June 22, 2017
Board of Nursing,

Virginia Board of Medicine
Virginia Board of Nursing

Telemedicine for Nurse Practitioners

Introduction:

The Board of Nursing concurs with the Guidance Document adopted by the Board of Medicine for the use of telemedicine in the delivery of medical services for practice by nurse practitioners, as recommended by the Committee of the Joint Boards of Nursing and Medicine.

Section One: Preamble.

The Virginia Board of Medicine ("Board") recognizes that using telemedicine services in the delivery of medical services offers potential benefits in the provision of medical care. The appropriate application of these services can enhance medical care by facilitating communication between practitioners, other health care providers, and their patients, prescribing medication, medication management, obtaining laboratory results, scheduling appointments, monitoring chronic conditions, providing health care information, and clarifying medical advice. With the exception of prescribing controlled substances, the Virginia General Assembly has not established statutory parameters regarding the provision and delivery of telemedicine services. Therefore, practitioners must apply existing laws and regulations to the provision of telemedicine services. The Board issues this guidance document to assist practitioners with the application of current laws to telemedicine service practices.

These guidelines should not be construed to alter the scope of practice of any health care provider or authorize the delivery of health care services in a setting, or in a manner, not authorized by law. In fact, these guidelines support a consistent standard of care and scope of practice notwithstanding the delivery tool or business method used to enable practitioner-to-patient communications. ~~For clarity,~~ For the purpose of prescribing controlled substances, a practitioner using telemedicine services in the provision of medical services to a patient (whether existing or new) must take appropriate steps to establish the practitioner-patient relationship as defined in Virginia Code § 54.1-3303. ~~and~~ A practitioner should conduct all appropriate evaluations and history of the patient consistent with traditional standards of care for the particular patient presentation. As such, some situations and patient presentations are appropriate for the utilization of telemedicine services as a component of, or in lieu of, in-person provision of medical care, while others are not. The practitioner is responsible for making this determination, and in doing so must adhere to applicable laws and standards of care.

The Board has developed these guidelines to educate licensees as to the appropriate use of telemedicine services in the practice of medicine. The Board is committed to ensuring patient access to the convenience and benefits afforded by telemedicine services, while promoting the responsible provision of health care services.

It is the expectation of the Board that practitioners who provide medical care, electronically or otherwise, maintain the highest degree of professionalism and should:

- Place the welfare of patients first;
- Maintain acceptable and appropriate standards of practice;
- Adhere to recognized ethical codes governing the applicable profession;
- Adhere to applicable laws and regulations;
- In the case of physicians, properly supervise non-physician clinicians when required to do so by statute; and
- Protect patient confidentiality.

Section Two: Establishing the Practitioner-Patient Relationship.

The practitioner-patient relationship is fundamental to the provision of acceptable medical care. It is the expectation of the Board that practitioners recognize the obligations, responsibilities, and patient rights associated with establishing and maintaining a practitioner-patient relationship.

Where an existing practitioner-patient relationship is not present,[1] a practitioner must take appropriate steps to establish a practitioner-patient relationship consistent with the guidelines identified in this document, with Virginia law, and with any other applicable law.[2] While each circumstance is unique, such practitioner-patient relationships may be established using telemedicine services provided the standard of care is met.

~~Specifically, Virginia Code § 54.1-3303(A) provides the requirements to establish a practitioner-patient relationship. *See* Va. Code § 54.1-3303(A).~~

A practitioner is discouraged from rendering medical advice and/or care using telemedicine services without (1) fully verifying and authenticating the location and, to the extent possible, confirming the identity of the requesting patient; (2) disclosing and validating the practitioner's identity and applicable credential(s); and (3) obtaining appropriate consents from requesting patients after disclosures regarding the delivery models and treatment methods or limitations, including any special informed consents regarding the use of telemedicine services. An appropriate practitioner-patient relationship has not been established when the identity of the practitioner may be unknown to the patient.

Section Three: Guidelines for the Appropriate Use of Telemedicine Services.

The Board has adopted the following guidelines for practitioners utilizing telemedicine services in the delivery of patient care, regardless of an existing practitioner-patient relationship prior to an encounter.

Licensure:

[1] This guidance document is not intended to address existing patient-practitioner relationships established through in-person visits.

[2] The practitioner must adhere not only to Virginia law defining a practitioner-patient relationship, but the law in any state where a patient is receiving services that defines the practitioner-patient relationship.

The practice of medicine occurs where the patient is located at the time telemedicine services are used, and insurers may issue reimbursements based on where the practitioner is located. Therefore, a practitioner must be licensed by, or under the jurisdiction of, the regulatory board of the state where the patient is located and the state where the practitioner is located. Practitioners who treat or prescribe through online service sites must possess appropriate licensure in all jurisdictions where patients receive care. To ensure appropriate insurance coverage, practitioners must make certain that they are compliant with federal and state laws and policies regarding reimbursements.

Evaluation and Treatment of the Patient:

A documented medical evaluation and collection of relevant clinical history commensurate with the presentation of the patient to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided must be obtained prior to providing treatment, which treatment includes the issuance of prescriptions, electronically or otherwise. Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional, in-person encounters. Treatment, including issuing a prescription based solely on an online questionnaire, does not constitute an acceptable standard of care. (See section on prescribing)

Informed Consent:

Evidence documenting appropriate patient informed consent for the use of telemedicine services must be obtained and maintained. Appropriate informed consent should, as a baseline, include the following:

- Identification of the patient, the practitioner, and the practitioner's credentials;
- Types of activities permitted using telemedicine services (e.g. prescription refills, appointment scheduling, patient education, etc.);
- Agreement by the patient that it is the role of the practitioner to determine whether or not the condition being diagnosed and/or treated is appropriate for a telemedicine encounter;
- Details on security measures taken with the use of telemedicine services, such as encrypting date of service, password protected screen savers, encrypting data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy notwithstanding such measures;
- Hold harmless clause for information lost due to technical failures; and
- Requirement for express patient consent to forward patient-identifiable information to a third party.

Medical Records:

The medical record should include, if applicable, copies of all patient-related electronic communications, including patient-practitioner communication, prescriptions, laboratory and test results, evaluations and consultations, records of past care, and instructions obtained or produced in connection with the utilization of telemedicine services. Informed consents obtained in

connection with an encounter involving telemedicine services should also be filed in the medical record. The patient record established during the use of telemedicine services must be accessible to both the practitioner and the patient, and consistent with all established laws and regulations governing patient healthcare records.

Privacy and Security of Patient Records and Exchange of Information:

Written policies and procedures should be maintained for documentation, maintenance, and transmission of the records of encounters using telemedicine services. Such policies and procedures should address (1) privacy, (2) health-care personnel (in addition to the practitioner addressee) who will process messages, (3) hours of operation, (4) types of transactions that will be permitted electronically, (5) required patient information to be included in the communication, such as patient name, identification number and type of transaction, (6) archival and retrieval, and (7) quality oversight mechanisms. Policies and procedures should be periodically evaluated for currency and be maintained in an accessible and readily available manner for review.

Section Four: Prescribing.

Prescribing controlled substances requires the establishment of a bona fide practitioner-patient relationship in accordance with § 54.1-3303 (A) of the Code of Virginia. Prescribing ~~medications~~ controlled substances, in-person or via telemedicine services, is at the professional discretion of the prescribing practitioner. The indication, appropriateness, and safety considerations for each prescription provided via telemedicine services must be evaluated by the practitioner in accordance with applicable law and current standards of practice and consequently carries the same professional accountability as prescriptions delivered during an in-person encounter. Where such measures are upheld, and the appropriate clinical consideration is carried out and documented, the practitioner may exercise their judgment and prescribe ~~medications~~ controlled substances as part of telemedicine encounters in accordance with applicable state and federal law.

Prescriptions must comply with the requirements set out in Virginia Code §§ 54.1-3408.01 and 54.1-3303(A). Prescribing controlled substances in Schedule II through V via telemedicine also requires compliance with federal rules for the practice of telemedicine. ~~Additionally,~~ Practitioners issuing prescriptions as part of telemedicine services should include direct contact for the prescriber or the prescriber's agent on the prescription. This direct contact information ensures ease of access by pharmacists to clarify prescription orders, and further facilitates the prescriber-patient-pharmacist relationship.

For the purpose of prescribing Schedule VI controlled substances, "telemedicine services" is defined as it is in § 38.2-3418.16 of the Code of Virginia. Under that definition, *"telemedicine services," as it pertains to the delivery of health care services, means the use of electronic technology or media, including interactive audio or video, for the purpose of diagnosing or treating a patient or consulting with other health care providers regarding a patient's diagnosis or treatment. "Telemedicine services" does not include an audio-only telephone, electronic mail message, facsimile transmission, or online questionnaire.*

Section Five: Guidance Document Limitations.

Nothing in this document shall be construed to limit the authority of the Board to investigate, discipline, or regulate its licensees pursuant to applicable Virginia statutes and regulations. Additionally, nothing in this document shall be construed to limit the Board's ability to review the delivery or use of telemedicine services by its licensees for adherence to the standard of care and compliance with the requirements set forth in the laws and regulations of the Commonwealth of Virginia. Furthermore, this document does not limit the Board's ability to determine that certain situations fail to meet the standard of care or standards set forth in laws and regulations despite technical adherence to the guidance produced herein.

Statutory references:

§ 54.1-3303. Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32. The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship.

For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice. In addition, a bona fide practitioner-patient relationship means that the practitioner shall (i) ensure that a medical or drug history is obtained; (ii) provide information to the patient about the benefits and risks of the drug being prescribed; (iii) perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription; and (iv) initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. A practitioner who performs or has performed an appropriate examination of the patient required pursuant to clause (iii), either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically, for the purpose of establishing a bona fide practitioner-patient relationship, may prescribe Schedule II through VI controlled substances to the patient, provided that the prescribing of such Schedule II through V controlled substance is in compliance with federal requirements for the practice of telemedicine.

For the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine services as defined in § 38.2-3418.16, a prescriber may establish a bona fide practitioner-patient relationship by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated

medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; and (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations. Nothing in this paragraph shall permit a prescriber to establish a bona fide practitioner-patient relationship for the purpose of prescribing a Schedule VI controlled substance when the standard of care dictates that an in-person physical examination is necessary for diagnosis. Nothing in this paragraph shall apply to: (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.

Any practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than medicinally or for therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.

§ 54.1-3408.01. Requirements for prescriptions.

A. The written prescription referred to in § 54.1-3408 shall be written with ink or individually typed or printed. The prescription shall contain the name, address, and telephone number of the prescriber. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, electronically printed, typewritten, rubber stamped, or printed by hand.

The written prescription shall contain the first and last name of the patient for whom the drug is prescribed. The address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription. If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription. Each written prescription shall be dated as of, and signed by the prescriber on, the day when issued. The prescription may be prepared by an agent for the prescriber's signature.

This section shall not prohibit a prescriber from using preprinted prescriptions for drugs classified in Schedule VI if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

No written prescription order form shall include more than one prescription. However, this provision shall not apply (i) to prescriptions written as chart orders for patients in hospitals and long-term-care facilities, patients receiving home infusion services or hospice patients, or (ii) to a prescription ordered through a pharmacy operated by or for the Department of Corrections or the Department of Juvenile Justice, the central pharmacy of the Department of Health, or the central outpatient pharmacy operated by the Department of Behavioral Health and Developmental Services; or (iii) to prescriptions written for

patients residing in adult and juvenile detention centers, local or regional jails, or work release centers operated by the Department of Corrections.

B. Prescribers' orders, whether written as chart orders or prescriptions, for Schedules II, III, IV, and V controlled drugs to be administered to (i) patients or residents of long-term care facilities served by a Virginia pharmacy from a remote location or (ii) patients receiving parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion therapy and served by a home infusion pharmacy from a remote location, may be transmitted to that remote pharmacy by an electronic communications device over telephone lines which send the exact image to the receiver in hard copy form, and such facsimile copy shall be treated as a valid original prescription order. If the order is for a radiopharmaceutical, a physician authorized by state or federal law to possess and administer medical radioactive materials may authorize a nuclear medicine technologist to transmit a prescriber's verbal or written orders for radiopharmaceuticals.

C. The oral prescription referred to in § 54.1-3408 shall be transmitted to the pharmacy of the patient's choice by the prescriber or his authorized agent. For the purposes of this section, an authorized agent of the prescriber shall be an employee of the prescriber who is under his immediate and personal supervision, or if not an employee, an individual who holds a valid license allowing the administration or dispensing of drugs and who is specifically directed by the prescriber.

Agenda Item: Regulations Governing Prescribing of Opioids and Buprenorphine

Included in the agenda package:

Copies of public comment received during the 30-day comment period on the Notice of Intended Regulatory Action

Copy of re-adopted emergency regulations as recommended by the Legislative Committee of the Board of Medicine

Copy of regulations as recommended by the Regulatory Advisory Panel

Staff note:

Emergency regulations for MDs, DOs, DPMs and PAs became effective on March 15, 2017

To address concerns/comments expressed by practitioners and the public, a Regulatory Advisory Panel (RAP) was convened on May 15, 2017 to receive oral comment and consider written/electronic comment. Minutes of that meeting are included in your agenda package.

The Legislative Committee met on May 19, 2017 to consider the recommendations of the RAP; amendments were modified as presented in your agenda package.

Action:

Re-adoption of emergency regulations in Chapter 21; and

Adoption of proposed regulations to replace emergency regulations.

Virginia.gov Agencies | Governor

Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Medicine**

Chapter **Regulations Governing Prescribing of Opioids and Buprenorphine [18 VAC 85 - 21]**

Action	Initial regulations
Stage	Emergency/NOIRA
Comment Period	Ends 5/3/2017

All good comments for this forum Show Only Flagged

Back to List of Comments

Commenter: Kyle Miles 4/4/17 9:22 am

Buprenorphine regulations are hurting people with a documented allergy.

These new regulations are hurting people that have a documented hypersensitivity/allergy on record. They are already being turned away from treatment because the doctors hands are tied. According to the legislative site the bill was never signed. When I called the Governors office on march 16th I was told the bill hadn't been signed. It was put into effect anyway. I can understand regulations on medications but to turn patients away because they cannot have the combination drug is wrong. These patients have been trying to get their lives together, and as far as I know most doctors won't write buprenorphine mono unless they have a reason too in the first place. I urge you all to amend the regulations and allow people with a hypersensitivity/allergy to also be allowed to get a prescription at the very least. I believe OTP cinics should also be allowed to dispense it in take homes, because patients that go to these clinics have earned their take homes just like a methadone patient did. They went for months on end to earn their couple of take homes and after around 9 months they earn a week. Switching what medications an OTP can dispense increases cost to the patient and the clinic. The patients that do have a documented allergy on file should be allowed to continue to get a prescription. It isn't their fault they cannot have the combination drug. I'm sure if they could they would rather do that than lose treatment all together. The 2 closest clinics in my area are both around 50 miles away one way. One of them is in Virginia, and this town has no doctors in it so a lot of the people that are struggling with opiate dependency are now back on the streets. I am from Virginia originally and live right on its boarder now. In this war on addiction kicking people out of treatment because of something they cannot control doesn't do anything but hurt the communities around us.

Commenter: Dg 4/4/17 10:36 am

HB 2163, SB 1178

Did anyone research and think about the side affects of naloxone. There are people allergic to it and just simply can't take it or if they dont have insurance they can't afford it. They are running people back to the streets and the drug cartels are going to have heroin everywhere now. Why put

laws on the things that's helping. I have 3 children 2 teenagers and 1 that's 12, it scares the crap out of me and all the government is doing is making it worse.

Commenter: Jade 4/4/17 10:43 am

Buprenorphine laws

I don't?live in VA, but I have been taking buprenorphine for a few years now. It has saved my life along with countless others. We are all well aware of the fact that these drugs can and will be abused, but I am also very aware of the fact that whether it's plain buprenorphine or bup/ naloxone, those who are abusing these meds will not be deterred by the naloxone. The only thing this law is doing is hurting people who have serious allergies as well as those who can't afford the ridiculously high price of anything but buprenorphine (which from my experience can be around $100 less than buprenorphine/naloxone). If a doctor forced someone to take a certain brand of insulin that that patient was allergic to, that doctor could be sued for malpractice if said patient ended up having serious issues due to that allergy. Addiction treatment, just like all medical treatments, should be considered on a patient to patient basis. The government needs to stop trying to lump everyone into a single category, because we are all different and what works for one may not work for another and it saddens me to know that instead of thinking of us as different people trying to heal our ailments, we are all still considered just as bad as the guy shooting heroin on the street.

Commenter: Cathleen A Burns 4/4/17 11:58 am

HB2163

I am very concerned about this bill and the adverse affects on those individuals struggling with opiate addiction and allergic to naloxone. I personally am aware of one young one who has been successful with subutex who now has to start a new medication with a low dose of naloxone who after the first day is experiencing severe nausea and depression and has hives on her neck. She is a freshman at VCU and has done well on subutex over the past 7 months. After 2 years of multiple rehabs, IOP's, different medication management programs including suboxone which she is allergic to and has had ER visit for respiratory distress after starting suboxone. My understanding is that the SAMSHA recommendations include subutex for individuals who have medically been determined to have an allergy for naloaxone. I am perplexed why the Commonwealth of VA would go against those recommendations and outlaw any treatment for anyone with an opiate addiction that been successful and then mandate taking a medicine that one is allergic too as the only alternative for medication assisted treatment. Seems like a huge liability issue with the very real possibility of death either by overdose of an opiate after relapse because she can not tolerate the naloxone or a life threatening reaction to naloxone. This is a no brainer and breaks my heart after coming so far personally in this fight for this young girl's life. This law will fail her and most likely will be a death sentence for my loved one....I do not want to loose her and I am angry that this law is taking away the one treatment that has worked for her after so many failed attempts. I do not understand why goverment has to interfer with medicine especially when in this case the medical profession has done a good job in not giving up on this one precious being. I realize the subutex can be abused however why for those who it is working and have an allergy to naloxone and is not abusing this medication, why should the only available treatment that worked be taken away. I think the Commonwealth of VA is punishing and perhaps will cause death for this young girl who is working very hard to beat this addiction. You are setting her up to die in my judgement. My background is in nursing and I am an LPC in Fairfax. Prfessionally and personally I oppose this bill and know first hand there will be fatal outcomes.

Commenter: Pamela sickal 4/4/17 5:24 pm

Hb 2163

I am writing today about hb2163 bill. I have been sober since 2013. When I first went to get help for my addiction I was prescribed suboxone. After my first dose I broke out in hives, had severe itching, and a migraine. It was then I learned I was allergic to the naloxone in suboxone. I was then switched to a subutex. It was life changing. I got my life back. Since then I have become a mother, a fiancée, a full time worker, and a good person. When I went to my doctors appointment this month I was switched back to suboxone because of this bill, despite my documented allergy. I'm not even sure how this can be legal. So now I have to suffer fromantic hives, itching and migraines everyday.

Commenter: A concerned mother 4/4/17 5:32 pm

Hb 2163

I am very concerned for my daughters health. She has been sober for years and this bill jeopardizes her sobriety, she is allergic to suboxone but yet she's forced to take it so she doesn't relapse. She is so scared that she will all because of the government had dictation over her medical care. Would you make someone with an infection take a antibiotic that they are allergic to? I didn't think so, so why make all these patients take a medication that could potentionally be life threatening? Please reconsider this bill or put in a clause for the patients who have a documented drug allergy. I'm begging you for my daughters life/sobriety.

Commenter: Amanda Robertson 4/4/17 6:41 pm

Bill

I feel this bill is a little ridiculous. People are going to abuse any drug, no one will stop them. Their are so many people who are allergic to the nalaxone, I know when I had to make the switch back it was very hard and I was sick for a very long time, and still am. I think passing this bill will cause the ones who really cannot handle the nalaxone to stop taking their medication and end up relapsing because they simply could not handle the affects they get from just the nalaxone. I feel this bill is putting those people at risk and is just going to cause more problems. Its already hard enough to get the medicine we need. And this is making it harder. I hope that you consider our petition. And help save lives.

Commenter: Carrie R 4/4/17 6:41 pm

Naloxone can be harmful to some!

I am highly allergic to naloxone and while I agree in emergency forms it's a miracle medication, to some it could also be deadly. When on SUBOXONE I had a lot of "illnesses" passing out, legs going numb, hives, throat feeling as if it was swelling along with MAJOR weight loss I was being tested for cancers and thyroid issues as I had these severe lumps in the back of my neck due to the naloxone also being only 98 lbs and when starting out in late 2013 I was 175. I was switched and my life, depression and health suddenly changed drastically for the better! 16 months on buprenorphine I am completely back to normal with NO strange symptoms, until the switch back tommro which I will be back to losing extreme amounts of weight in which I plan to document daily. I got pregnant when I made the switch however also HAD to stay on (I was tapering off because of how sick I was on suboxone, at 1 mg) I agree that laws DO need to be in place but the allergy tests

cannot be faked if one is truly allergic as many others and myself are. Many people I know may relapse because of this people that have lived normal lives on MAT doing the program right up until this was in place. If you're allergic to peanuts, you cannot have them. It's the same thing with this. I know some do abuse this life saving medication but I can promise it's a lot less than the ones actually doing right by it! Please reconsider the allergy test exception because there IS people who cannot take it but want to do right in life. I am tapering again now off the MAT program but wanted to at least taper comfortably and safely without hospitalizations and health issues as I am a mom to 2 small children!

Commenter: Amanda P 4/4/17 7:08 pm

Buprenorphine without naloxone should be still prescribed to individuals who have been on years

I have been on Subutex for multiple years and now, I am no longer able to get prescribed it in Va. The only alternate offered give me terrible side effects which are equivalent to withdrawal. It is not tolerable and after over 10 years of sobriety, I am apprehensive about being just taken away with the minimal alternatives.

Commenter: Chelsea 4/4/17 7:24 pm

Ridiculous

i agree with amanda and some of the other comments. For some of us we have been on this for years and its not okay to do this when ACTUAL people have had long sobriety runs while taking this medication and are unable to take the other options. If this works for people and has been keeping them sober for YEARS how can you guys do this. Do you understand what is gonna happen or what you guys have done to those this medication has been a life saver for?? This is not right.

Commenter: R. Kinsey 4/4/17 7:51 pm

HB 2163

Let me start off by saying that Buprenorphine has saved my life. I was on heroin for 7 years and lost everything that meant anything to me, including myself. I went to prison, lied to, and stole from every person in my life. I was in and out of rehabs for years, Nothing worked to keep me clean and keep me as a functioning human being. It wasn't until I discovered Buprenorphine that I was able to get my life on track and start on a positive path to living a clean, sober, happy, productive life for my son and I. I honestly believe it is a miracle medication, and without it I would be dead today. However, I do have Naloxone sensitivity and I am not able to take Suboxone, only Subutex. Severe panic attacks, nightmares, and migraine headaches are just a few of the debilitating side effects I have when taking Naloxone. I have to mention that I have a severe panic disorder, and this being one of the main reasons I began using heroin and other opiate substances, to try and self medicate to not feel the panic attacks. This is just my story of why I can't take Suboxone versus Subutex. There are many other people, like me, with many other legitimate health issues against Naloxone that still do need the Buprenorphine. I do realize that some people abuse the Subutex because it does not contain the Naloxone, but the Buprenorphine is most certainly still an opiate blocker in itself as well, and there will always be some people that abuse things and make it harder for people like myself. I hope that you can understand not everyone is going to do that and there truly are some people that have legitimate reasons for needing the Subutex in place of Suboxone.

Commenter: Sara Y 4/4/17 9:14 pm

Naloxone Dangerous for Some

I fully appreciate and understand the current opiate crisis our country, and specifically our state, is experiencing. However, these new regulations are putting many stable patients at a great risk for severe illness, or worse. I sincerely hope that this may be revised to include exceptions where medically indicated for those who are unable to safely take Suboxone/Naloxone due to debilitating side effects. These drugs were created to help sick patients, not make patients more sick..

Commenter: Bobbi Woolum 4/5/17 2:27 am

Please do not stop any form of medication assisted treatment!!!

All forms of medication assisted treatment are the proven most effective treatment for opiate addicts. Restricting anyone from any one form of medication makes no sense. Suboxone and Subutex or generic buprenorphine work exactly the same way and many patients on buprenorphine alone are able to live without chronic headaches and other additional side effects. It is also the least expensive form of medication and not allowing patients to begin or continue this medication is immediately life-threatening. So many people will return to relapse and drug use without the medication that has proven to be effective for them. It is also the least expensive of pharmaceutical treatments so anybody who is paying cash is dependent on a medication they can afford. There is absolutely no reason to demand these patients be switched to a medication with naloxone that is three or four times more expensive when the new loxone has been proven to be inactive. I don't know what occurred to encourage this change but it is not the right way to go. Take some time to get to know the patients who all their lives two these life-saving medications. Or those lives worth compromising for the change that has been set in place? I think all of us can agree that they are not. I would be curious to know why these changes have been set in place and I'm 100% positive that some very simple Research into the matter would show that it is unnecessary and also detrimental. If anyone takes the time to read this I very much appreciate it.

Commenter: Bobbi Woolum 4/5/17 2:38 am

Naloxone not effective

The research clearly shows that naloxone is not effective in any route of administration when combined with buprenorphine. Even those who choose to use their medication intravenously will Almost Never become ill with withdrawal symptoms. Buprenorphine itself has a much stronger binding affinity to opiate receptors and last several times as long as naloxone meaning that the buprenorphine we'll find stronger and longer to receptors then the naloxone ever could. It is truly useless in the presence of buprenorphine. So there is no reason two insist that that formulation is best. All it is is way more expensive. The buprenorphine alone will block a patient from being able to use other full Agonist opiates and achieve a high. Then the lock Zone does absolutely nothing and is a waste of time money and resources. This is very simple science that can be confirmed on any reputable website or other source. It is widely misunderstood but it is the scientific truth. Please don't make those in recovery suffer because of false information. Thank you

Commenter: Ashley Powell 4/5/17 5:49 am

I have been on subutex for four to five years only thing that has worked for me I've tried dverythin

Commenter: Nicole Shank, SWA 4/5/17 8:24 am

Not Prescribing Subutex Even With Documented Allergy

I am in Ohio AMD currently pregnant and on subutex. What I've found is that some people are actually allergic to the nalaxone in Suboxone and can become very sick when it is taken. We do not prohibit a person with allergies to an antibiotic from receiving the next best option so why is it fair to do with Subutex? The government is stepping in where they should be monitoring prescription distribution and the policies required for the doctors prescribing Subutex. Everything is abused if it has any desirable traits. To make people trying to better their lives from a past addiction to lose any chance at receiving their medication is unfair and unjust. We are being treated differently because we are addicts. Most opiate addictions stem from doctors over prescribing narcotic pain meds. It's time to move forward in the battle against heroin addiction and passing this bill is pushing hundreds or thousands of recovering addicts back into addiction because without their medicine they are very sick, just like a diabetic without insulin or a cancer patient with no access to pain relief or chemotherapy. You're playing with people's lives when people are dying left and right due to opiate addiction. Please reconsider this decision. Thank you.

Commenter: Miranda 4/5/17 2:54 pm

Subutex allergies

Subutex should allowed to be given, not taken away. Some people are allergic to the naloxone, or cannot afford Suboxone. Anything that can help our addicts get clean legally and responsibly should be allowed. If abuse or illegal selling is a worry, then reduce the prescription length, and keep the practice of counting pills. Or do something like they do with suboxone strips--put each pill in an individual packet and have them counted at the doctors office--used ones and unused ones!

Commenter: Michael Dowdy 4/5/17 8:01 pm

Subutex

Please reconsider adding a clause to this bill to include people with a hypersensitivity to naloxone if it isn't included what is a person to do the only option is methadone a far more dangerous drug

Commenter: Lori Miller 4/5/17 11:19 pm

HB 2163

HB 2163 will do harm to those that can not afford suboxone and to those that have a legit hypersensitivity to naloxone. This is not a one size fits all situation. Some people who can not take suboxone are unable to get to a methadone clinic everyday or can not afford it. Suboxone and methadone are both abused and sold on the streets, and in my opinion methadone is so much worse than plain buprenorphine/subutex. This law wouldn't be a bad idea if it included that people with a legit reaction to naloxone, documented and seen by a doctor could still receive mono-buprenorphine/subutex. And also allow people to still continue getting take homes from the clinics. I feel like something needs to be changed in this law cause people are going to resort back to illicit street drugs because they are either allergic to or can not afford suboxone or even get to a methadone clinic every day. Over doses are going to go back up. In my opinion addicts are going

to use no matter what, but it would be safer for them to take a life saving drug than to take heroin. Please rethink this bill.

Commenter: Denise 4/6/17 6:38 am

Bup

Seems a lack of knowledge is going on stop being so ignorant and focus on helping people.

Commenter: Ashley Jones 4/6/17 9:42 am

Hb 2163 dangerous

I am a patient who has been on buprenorphine mono (subutex) for 3 years. I am asking that you please overturn this bill as it endangers the sobriety and lives of people like me. I have a bad reaction to naloxone, so being forced to take suboxone has been a nightmare, but i have no other option because of the governments decision to only allow pregnant women to have it. I cannot allow myself to go back to the lifestyle i was living before I was put on this medication. I have been very successful in recovery, I have been able to hold a full time job, i volunteer in my community as a soccer coach, and i volunteer my time in a classroom working with kindergartners every Tuesday. I have 2 children who need their mom to be 100%, and without this nedication, I am not able to provide that. Put more strict rules down, call for mandatory pill counts, whatever is necessary, but please allow those of us who have done so well on this medication, to continue living fulfilling lives. This will turn so many back to the streets, and so many lives will be lost to the nasty throws of addiction because those people wont be able to get the treatment they need. Please help us who are trying to help ourselves and overturn this bill.

Commenter: Nicole Holmes 4/6/17 6:47 pm

Allergy to Naloxone

I myself also have an allergy to Naloxone, and would like for you to please reconsider allowing ppl with allergies to stay on this medication. It really scares people to think their only option to stay clean is going to be taken away from them. So please reconsider this.

Commenter: Ashley Tucker 4/6/17 7:13 pm

New law will cost more lives!

I'm not sure why this has been done since my doctor said there's not alot of propping mixing subutex with opiates and dying but there are people selling it. If that's the reason well it's still gonna be on the street and I would have to assume the street value probably doubled making it more enticing for people to sell. It's not fair for so many of us to suffer for the mistakes of a few. Why not make it up to the doctor and make the guidelines that he would have to have explanations to back up his reasoning. I have a strict doctor who doesn't give subutex unless it's necessary. I have a severe migraine disorder with over a decade of medical records. My neurologist as well as my subutex doctor agree I can't take suboxone. Unfortunately my migraines are so severe that I wouldn't be able to work and finish college and raise children if I were on suboxone so I'm being weaned off of subutex and I'm definitely not ready. I have a chronic pain disorder which is how I ended up on pain meds to begin with. The subutex helps with my pain as well as keeps me off the opiates. I'm gonna try but I'm very concerned that I will be back on pills. We are begging

you,please fix this. Too Manu people will go back to pills and heroin and now there tolerance is gonna be messed up and we could end up dead. This will cost more lives than it saves.

Commenter: Sarah W 4/6/17 9:24 pm

Take it back! Please.

Please undo this new regulation. I am on subutex and it has saved my life. I was pregnant and breastfeeding and I'm allergic to naloxone. I really really loved my pharmacy and the people who work there. Please take this back!

Commenter: Chrissy Winslow 4/7/17 12:37 am

Treatment for Herion/MAT

Medicated assisted therapy is PROVEN TO SAVE LIVES! WHY WOULD YOU EVEN NOT WANT TO HELP SAVE THE LIFE of someone addicted to opioids?

Commenter: Lacey Patterson 4/7/17 3:53 pm

HB 2163

HB2163 will hurt people more than help, it will cost lives. Please take it back, don't do this. Addicts deserve to be rehabilitated, they deserve all the resources they can get, they are not scum or worthless so please don't treat them as such. Some people are allergic to naloxone and honestly it doesn't matter whether a drug has naloxone in it or not, if the person wants to abuse it they will. I was on suboxone treatment for several months and it worked wonders, but I wasn't ready to stop using and my partner was using and I wasn't willing to get away from him so I started back up. Now I'm on methadone because it's cheaper and works even better for me. Please don't make it even harder for people who have it hard already and feel so much guilt and remorse. Don't be inhumane.

Commenter: Dg 4/7/17 4:20 pm

18VAC85-21-150. Treatment with buprenorphine for addiction. Hb2163 sb1178

I think the governor and all of the other dumbasses in Richmond that just voted yes to these bills to get their heads out of each others asses and listen to the practicing Doctors about this instead of listening to the media that has glorified naloxone in the past and realize that there is a such thing as an allergy to this stuff. I have been successful only on buprenorphine monotherapy, I have tried it all and this is the only way I can have a productive life. Please give us our lives back. It's not right to take it away from the ones that have allergies or are hypersensitive to naloxone. Terry McAulliffe get you head out of your ass!!!

Commenter: Dg 4/7/17 4:34 pm

Hb2163 sb1178

Another thing you are setting us up for the biggest heroin epidemic there ever was, because the addicts are out here and u are restricting addiction doctors and pain management doctor where else are they going to go besides the heroin that is most likely laced with something that will kill them. Just wait and see all you dumbasses in Richmond with a blind eye, or should I say with a brown eye, GET YOUR HEADS OUT OF EACH OTHERS ASSES, RICHMOND!!!

Commenter: CONNECTICUT NAMA 4/8/17 9:36 am

benzodiazepines / methadone and or naltrexone

I will make this short. I hate to see tgesecregs changed because of people who abuse these meds or don't follow protocols. I have been on methadone and clonopin for 22 years. I am in perfect health, have never had an overdose or and medical problems related to these meds. Please contact me if you would like more info.

Commenter: Paul, CT NAMA 4/8/17 9:57 am

New drug rules

I don't understand the DEA, FDA, gov't etc. All these new rules and recomrecommendations for prescribing solves NOTHING. All it will do is push people on pain management to start doing illegal activities such as purchasing pills on the street and when that gets too expensive they will go to heroin and there will be more deaths.why do you think overdoses have increased over the past 5-8 years? Because that is when doctors started to get scared of the DE A and FDA and started cutting people who have legitimate chronic pain diseases such as M.S. or different types of Neuropathy. Before I started methadone I lived in a bed except to use the bathroom and showered 2 or 3 times a week. Since methadone I am as normal as can be with my disease. I only use the bed to sleep 6 or 7 hours a night. But I'm getting off topic. Trillions of dollars have been spent since Nixon started the war on drugs and where has it gotten us? NOWHERE. As long as there are humans walking on this planet there will be a desire, need, want for drugs and that will never change. Someone get in touch with me. I have studied this for 19 years now. I am extremely educated and can offer some good ideas. Thank you.

Commenter: Greg casey 4/8/17 10:34 am

Reconsider this bill

Commenter: Andrew Marshall 4/8/17 11:03 am

Reconsider exemptions for this law

I have been in a subutex outpatient program for about a year now. I have tried other rehab programs in the past, including methadone, but subutex is by far the best. Methadone is extremely hard on your body and the withdraws actually motivate you to keep taking it instead of trying to lower your dose and get clean. Subutex, on the other hand hasn't had any negative impact on my body and I have easily decreased my dose from 24mg per day down to 6mg per day in a matter of three months. I am unable to take suboxone because I have an allergy to naloxone that is a

legitimate threat to my wellbeing. My response to naloxone is rapid heart rate, wheezing, dizzy, faint, throat swelling, and without the doctor who recognized the reaction, I may not be here today. I can't believe that this bill was rushed through without any consideration for the people who were benefiting from its use, or people who couldn't take suboxone as an alternative.

There definitely needs to be provisions to this awful law which consider those patients who are allergic to suboxone.

Commenter: Safepointsinnorcali@gmail.com 4/8/17 12:27 pm

Not a good idea

My opinion. Don't do it.

Commenter: Kyle Miles 4/8/17 3:04 pm

Buprenorphine laws. Patients with an allergic reaction have no true alternative

People that are truly allergic are losing treatment totally. Doctors that know their patient is allergy/hypersensitivity they will not write you suboxone or generiic buprenorphine/naloxone PERIOD. I know because someone close to just went throught it. The doctor told them to seek treatment in another state, that they would not right them because of the tongue swelling, and throat swelling. This patient has a true hypersensitivity/allergy and the doctor was so scared of the reaction he wouldn't try to give him the combination tablet because of the tongue swelling. What is a patient to do then, when the doctor cares for the patient but cant treatment. He won't take a chance on writing the Suboxone or the Generic. These patients deserve treatment with this medication too, and methadone isn't a option. He shouldnt have been punished for something he cannot control. What is he supposed to do now?

Commenter: Tim W 4/8/17 4:19 pm

allow naloxone allergy exception

My fiance is highly allergic to naloxone and tapering off but now suffering from allergy while tapering. She is swelling up, vomiting, cannot move, pain has doubled and very sick. We have two small children and she cannot have these reactions, that's just NOT fair because some abuse it! Drugs will always be a thing, but if the addict wants help thats the only way it will stop. Not allowing the allergy acception is discrimination. These people are living ordinary lives and this is messing with their sobriety. Some with allergies being so bad they're forced out of treatment! Shes been clean for 4 years and now being punished for others who arent truly ready to be clean and do right! Naloxone is poison to these peoples bodies who are allergic! Generally out of 100 patients only 5-10 is allergic! Its also more common for abusers to sell suboxone for their drug of choice than it is subutex!

Commenter: Kimberly W. 4/8/17 5:55 pm

Subutex

This is the most ridiculous thing the government can take away from people in the recovery stage..all you are going to do is force some really sincere people that want to get clean hit the streets. Maybe have more overdoses. There is a lot of people that just can not take suboxen due

to the huge allergy to naloxen. I have a very close person to me and if something happens to her, the board of medicine will be hearing from me...i vote to keep subutex for the indviduals that cant take suboxen.

Commenter: Barbara Vargas 4/9/17 12:08 am

Please leave things as they are.

Commenter: Kelly Miles 4/9/17 11:54 pm

My son lost treatment because his doctor is scared for his life to switch him.

Why should my son lose treatment after he has done nothing but follow the rules. His doctor won't even write it unless he cannot have suboxone. Is it fair suboxone patients get to keep on getting treatment, but people like my son that allergies, hypersensitivity whatever you want to call it have tongue swelling, throat swelling, and Hives documented just lose treatment. My son was getting his life together, and doing well on buprenorphine treatment, and he has no alternative. He cannot go to a methadone clinic everyday, and everyone knows methadone is a far more powerful drug. Please reconsider this bill before people lose their kids to the streets.

Commenter: Sharon Thomas 4/10/17 11:06 am

HB2163 disregards SAMSHA recommendations

SAMSHA recommends use of Buprenorpine mono product when there is an allergy or other adverse medical reaction to products containing Naloxone. My 19 year old daughter has only had success on Subutex. Naloxone resulted in hives, rash, nausea, depression and a respiratory reaction requiring ER intervention. This mandate not only ignores established guidelines, it is punitive in nature in that patients who have followed protocol and have demonstrated success are being denied proven effective treatment. Any drug can be abused: this mandate is not going to assist or deter active addicts who are not invested in recovery. It will put the fragile recovery of many others at risk and denies physicians the right to use sound clinical judgement in continuing Bupe only protocols with patients who have demonstrated success and have documented sensitvity to Naloxone. A well intended law with potentially fatal outcomes.

Commenter: Amanda Key 4/11/17 11:59 am

Allow patient's with a documented allergy to continue to be prescribed Subutex.

My husband is allergic to nalaxone when he first started taking suboxone he woke up in the middle of the night with a severe reaction. He broke out in hives, and he swelled up. Why is it because his body doesn't agree with a medication is he being punished? You want to help addicts. All you are doing is hurting them. People are losing there doctor. God forbid something happens to someone you will have one help of a lawsuit. This is a joke and the sad thing is you are playing with so many people's lives. What if it was your brother, mother, father, sister? Would you have thought more about what you are doing to addicts?

Commenter: Liz 4/11/17 5:44 pm

Please do not take subtex away due to people having allergies to Suboxone

Commenter: Kristy boyce 4/11/17 11:14 pm

Are you a doctor? Do you know what's best for the addict?

first I've been clean for 5 1/2 years! I've been taking subutex because I'm allergic to the naloxone. I had to leave my doctor of 5 1/2 years to go to another states so I won't relapse! As my treatment is none of the governments business in the first place!!! I understand people abuse this medication but in all HONESTY YOU WHAT MEDICATION ISNT ABUSED! Are you going to pass bills for all medication?!?!?!?! Did you go to school as long as my doctors did? Do you know the first thing about and addict???? I don't think you do! NO ADDICT GOES THROUGH CHANGE WELL! I pray this doesn't turn people back to the horrible herion that's going around killing people! Better yet WHY DONT YOU BAN THE OPIATES? That's the reason behind this! Opiates don't take the pain away but subutex does! You can't even die from it! The sad part is whoever reads this don't care about us addicts. Oh and no matter what you pass it's NOT GOING TO STOP THE FEW IDIOTS THAT ABSUE MEDICATION! Let our doctors do their jobs and you do yours by governing not by taking away the one medication that saves lives!

Commenter: Caitlin Laws 4/12/17 12:36 pm

I do agr

Commenter: Caitlin Laws 4/12/17 12:49 pm

Long time MAY patient

Let me first start by saying that I absolutely think there DO need to be stricter laws and regulations on subutex. But, I think that if a person can prove that they have a legitimate allergy, they should be exempt from that. I have been on suboxone for over 10 years. I know more about this medication than most doctors. I have researched it. I have become passionate about it. I have had 8 major reconstructive surgeries while on it. I have had a vaginal delivery while on it. I have had a c section while on it. I know for a fact that suboxone is often misused and abused as well. And aren't all medications? People abuse medications all the time. That is What lead most people to seek the assistance of Buperenorphine in the first place. There are some people that have legitimate naloxone allergies and sensitivities that will suffer from the fact that allergy exemptions are not allowed. Do we really want to exclude them? People with children to take care of, jobs to go to go to, lives to live, and this medication helps them do that. Yes, there do need to be some stricter regulations. Absolutely. But if a person can show that they are truly allergic to the naloxone, or truly are effected by the naloxone, then they need to be exempt. O

Commenter: Abby Coulter, MMTSA Org. 4/12/17 7:46 pm

There IS A BETTER WAY

As an MMT (methadone maintenance treatment) Patient & MAT Advocate, I am so SADDENED and honestly ANGRY about what this mandate is doing to my peers who have found Recovery thanks to Mono-Buprenorphine. I cannot IMAGINE after years of habing my life saved by my treatment only to have it RIPPED AWAY by some half baked legislation. Sure there are always reasons to regulate medications. We MMT Patients have TONS of regulations we follow in our treatment. HOWEVER NONE of those regulations strip us of our treatment. To take away a LIFE SAVING TREATMENT OPTION in the midst of the Opioid Epidemic that kills thousands every year is shameful! Its insanity and it WILL COST MORE LIVES! Im not saying 'dont' bc like I said, regulations need to exist. But government practicing medicine simply bc they have the 'Medical Board' of the state backing their play is WRONG! All we are asking is simply to ALLOW those with documented hypersensitnvity to naloxone to receive Mono-Buprenorphine. To GOVERNMENT its simply WORDS TO PAPER. To a Recovering Addict who NEEDS this TREATMENT, its their LIFE! Do whats RIGHT! Not whats the 'easy road'. We HAVE to work to save lives. NOT SHATTER them. Change this legislation. Dont sign it into effect as is. AC

Commenter: Carrie Pearson 4/13/17 8:45 pm

Proof from a government website, allergies exist!!!!

This was given to me by the FDA. Allergy exceptions are needed or people are going to relapse or die from this. This is NOT SAFE!

"SUBOXONE and SUBUTEX should not be administered to patients who have been shown to be hypersensitive to buprenorphine, and SUBOXONE should not be administered to patients who have been shown to be hypersensitive to naloxone."

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=97677ce7-9562-43d0-8b99-8d1f37c1e3c6

Commenter: Alison Taylor 4/14/17 1:01 am

allergies exist

I would never want to be forced into taking a drug I'm allergic too.

Commenter: Sandra Goshorn 4/14/17 3:37 am

Put this law on hold NOW!

I'm afraid to say that whoever is trying to pass this does not have the proper information about these addiction medications. Doctirs understand their patients and treat them accordingly and the government needs to stay out of that. You are taking people that are in recovery, and making it impossible to continue on their Ned's. A lot of people are allergic to the Nalaxone. The fact that pregnant women should not take it should he your first sign on how dangerous Nalaxone can be. There are different degrees of addiction. Some are not as serious as others but the withdrawal is still just as hard. Why force someone to take a medication that makes them more sick when another is there that does the same?? You really need to put a halt on this law, asap until you can do further research. The only thing that will come out of this, is causing thousands of people to relapse which in turn can be fatal.

Commenter: Susan J 4/14/17 11:57 am

HB2163

This is well intended law, however deeply flawed. It ignores established guidelines. It puts the recovery of citizens at risk and does not allow doctors the right to use sound clinical judgement. This law should be modified.

Commenter: Carrie Pearson 4/15/17 2:55 pm

Allergies are needed to be acknowledged!

Giving buprenorphine to pain patients and animals but not the ones allergic to suboxone.. Don't you know subutex was MADE FOR ADDICTION not for pain not for animals none of that however it helps but don't ignore the reason why it was made and it legally is FDA approved FOR ADDICTION!! You can abuse anything.. I'm wondering if the plan was to start a heroin epidemic here a bigger one because I'm not sure how taking away an addicts addiction medicine solves anything.. As the board of medicine you should know that not everyone is the same, not everyone can tolerate naloxone! Go after the pain drs overprescribing to these "pain patients" which we all know half of them don't need hard medications like that and keep in mind THATS what got the addicts to need addiction medicine to begin with.. A good amount do not start out on heroin, in fact I've never met one who did it all started with the oxys, morphine, percocets you know thepharmaceuticals!

Commenter: Allison Grey 4/15/17 3:14 pm

Naloxone allergy...shooting up suboxone

Although I understand the need for stricter laws on the drug Subutex, I am extremely upset to see that individuals with allergies to the medication WITH proof of said allergy are still required to take Suboxone. So if they are deathly allergic to Naloxone, they either come off the drug harshly (because jumping from a high dose will almost guarantee relapse) or they are stuck on suboxone? That is EXTREMELY inhumane and I ask that you please educate yourself on the drug and I encourage law makers to talk to patients on this drug or who have tapered off to find out just how tricky it.is to come off the drug. It is VERY disappointing to see addicts in recovery be treated this way. I do understand that yes, FEW people inject Subutex but I have been on suboxone for a little over six years and I have seen on forums and threads that FAR MORE people inject their SUBOXONE and fewer people who are on Subutex inject it. In your case study that you found Subutex to be more valuable vs Suboxone isn't that what you were looking for? I find that convenient. That's ONE example. It doesn't mean much to me. Because suboxone is just as injectable and I have yet to hear of any individual go into these terrible withdrawal from injecting it. I find it funny how injecting/abusing suboxone was never brought up on this bill.i find it ironic that everything addressed on the addict part of the bill fit the law makers agenda. I suggest that law makers and law enforcement and anybody else involved with making this bill rethink your agenda. Buprenorphine will be abused by few no matter if it's Suboxone or Subutex. Patients on this drug with an allergy to Naloxone are paying a huge price, whether medically or detoxing when they shouldn't have to be. A dr wouldn't prescribe somebody Allergic to Amoxicillin that specific drug, so why should this be any different?

Commenter: Megan McKinley 4/16/17 8:24 am

Subutex

Please reconsider an allergy acception for being prescribed subutex. There are some people who simply can not take suboxone. There are ways to screen people for an actual allergy. Allow it for only those who have a documented reaction. Taking away a life saving medication simply because you do not understand how it works is unfair to the people who really need it! Bio fills the receptors and blocks any other opioids from attaching/ it is not just nalaxone that blocks getting high. You could give someone who has been on subutex they're drug of choice and they will not get high. There is only potential for abuse in patients that do not want to be clean. Please don't take this medicine from those who truly need it and have not abused it, you will turn them back to active addiction!!

Commenter: Dylan Quinn 4/16/17 10:15 am

This is going to cause thousands to relapse

My name is Dylan and I've been prescribed suboxone for over a year now and it has changed my life dramatically. I have been able to remain abstinent from all other drugs during this time for the first time in my life. I truly believe there is a huge misunderstanding of the role naloxone plays when combined with buprenorphine. As you know, the name brand "Subutext" is just buprenorphine with no naloxone. But this doesn't change the way buprenorphine works at all. The naloxone in suboxone is strictly there as a deterrent to try and prevent people from using the drug intervaneously. It does not effect the way the drug works at all when taking sublingually. The problem is that many people are severely allergic to naloxone. And I'm not just talking about it may cause them to have head aches every once and a while. I mean it is life threatening and there is no way that they can have it. There has to be an exception for this new law. If not, thousands can, and will relapse. These people are not shooting , snorting, or abusing their medication. It is ludicrous to punish them bc a few people who aren't really ready to be clean are. I live in NC but am connected to a lot of suboxone/subutext users in your state via Facebook groups. These people are suffering as we speak. There has to be an allergy exception for this bizarre new law.

Thank you, Dylan

Commenter: Angela DiMattina 4/16/17 11:32 am

You can't choose to help some and not other

The fact that subutex is now only being administered to people who are pregnant and taken away from people with legitimate allergies to naloxone is ludicrous. That is essentially like telling a child with a severe peanut allergy "sorry kid but your only allowed to eat peanut butter and jelly sandwiches hope you pull through." I understand many people view addiction in a negative light because in some cases it was self inflicted but if someone is asking for help because they desperately want to get clean and turn their life around how could you be so cruel as to tell them they can only have it if they are willing to submit to seizures and other awful things because they are allergic. Every person is different as is every path to recovery but that is just inhuman to turn your back on people who are trying so hard and fighting to save their own lives.

Commenter: Dustin Walker 4/17/17 12:13 am

Less regulations = greater chance at recovery

Less access and less regulations will in fact make these drugs that treat addiction more accessible and easier access will lead to greater successfully recovery! Once an addict has decided that they need to seek help there isn't anything that anyone could do to justify addicts not being able to access these drugs that literally save people's lives! My best friend was cut off at the methadone clinic due to failing a drug test and he was put on an administrative taper and less then 10 days after they refused to dose him anymore he was shot and killed in a drug deal gone bad in January of this year! These programs and these drugs literally save people's lives, so please do not take away more people's access and send them into the streets of Richmond city to try and score their drugs just so that they can maintain and not get sick and be able to maintain their jobs and go to work every day and be a positive contributer to out city and our population! You guys are literally playing with life and death for these addicts and with great responsibility it requires great knowledge so I beg of you all to research what these drugs have done to help out members of our society! We don't need anymore Joseph Boyle's out here being murdered in your city all because yall wanted to further regulate something to pad out Dr's and other people's pockets! This is literally life or death! And if you disagree with what I am saying please look up my best friend Joseph Boyle who was shot and killed in Richmond right off of broadrock on Sneed road just a few months back!

Commenter: Koreyna Patterson 4/18/17 8:27 am

Wrong just wrong

how can you sit here and choose what someone can be on when you don't even know there history they maybe allergic or it doesn't work for them.

Commenter: Katie 4/22/17 2:53 am

This will only make things worse

As a recovering addict I can personally tell you that if I had been forced out of my treatment like this I would be dead. You are only exacerbating the drug and overdose problem by doing this. Did no one there bother to ask a professional addiction doctor or counselor about this before it was voted on? Maybe you should go to the SAMSHA webpage and do some research...

Commenter: Betty Taylor 4/22/17 8:47 pm

Carring About Thr Lives of Others

It is unfair to ruin and indanger the lives of many people because of the poor choices of a few. You are taking away peoples ability to live their everyday lives. People are still allowed to drink even though some people drink and drive. Why is this diffrent.

Commenter: Brandy Patterson 4/22/17 9:37 pm

Don't punish someone for having an allergy

I am embarrassed and ashamed that we even have to sign this ! Is this really an issue ? Wow ...

Commenter: Dondee Carver 4/22/17 10:02 pm

People need uniterupted treatment

Commenter: Jeffrey T Junig MD PhD, SuboxoneTalkZone 4/23/17 1:57 pm

Truth about buprenorphine diversion/risks

Please understand the truth about buprenorphine diversion. I work with hundreds of opioid addicts. Some injected buprenorphine or bupe/naloxone. When asked, all say the same: "you can't get high from it." Then ask, so why did you inject it? "Because 8 mg will last 5 days that way to keep me from getting sick".

Note that when they inject bupe/naloxone, they feel about the SAME.

Remove buprenorphine and fewer people will be able to afford treatment. The response will be more injecting-- of buprenorphine, or of a bupe/naloxone product. That means more hepatitis C.

Finally, look at the numbers of people who die with buprenorphine in their bloodstream. Death on buprenorphine is RARE, and only occurs in opioid-naive individuals. Buprenorphine clearly prevents death, even when taken improperly. Nationwide, about 40 people die with buprenorphine in their bloodstream. Most would have lived, if MORE buprenorphine had been present.

You are fixing a problem that doesn't exist- and worsening another problem in the process.

Commenter: Amber 4/23/17 6:30 pm

This is a total outrage

I cannot believe this is even happening. Government has NO PLACE IN HEALTHCARE! medication And treatment options are between the doctor& patient! This isn't going to help or solve anything. This will force so many people out of treatment And cause the opioid/overdoes epidemic rates to greatly multiply. The reasoning in the choice between subutex And suboxone varies so greatly that one law or blanket regulation cannot be laid upon every case! I believe it would be to great benefit to lift the the regulation And Work with the doctors And patients. Maintenance medications save lives And give people the tools they need to live productively. Please please reconsider this decision, it's a possible death sentence for so many people.

Commenter: Wesley Marin 4/24/17 6:29 am

This makes no sense.

This is craziest thing I have ever heard of! This is going to cause the overdose rate to triple! Please put this back in the hands of the patients and physicans. People that don't have a option for treatment will go back to using. This is a devasting disease that took control of my life, but with subutex I have been able to maintain a steady job for 5 years now with promotions and start a family and even buy a house. YOU ARE GOING TO LOSE A LOT OF HUMAN BEING OVER THIS . I understand other opiates but not Subutex it saves lives.

Commenter: Dr. Rod M. Rogge, DDS 4/24/17 4:56 pm

regulate pharmacy wholesalers

I hope that Virginia and other states sue enough drug wholesalers to lead to a federal law requiring tracking and reporting of large amounts of opioids. Big pharmacy companies know where the big opioid shipments are headed, and they accept no responsibility for what happens, since they make huge amounts of cash. Everyone in the chain needs to be responsible. The intent of the new regulations is good, but if you don't slow down the supply, and track sales, nothing will change. Look what making pseudophedrine OTC did to the methamphetamine mess we are in - all produced by big pharmacy greed.

Commenter: Alfred Stahlin, a random swede. 4/25/17 2:06 am

Do i need to spell it out for you, why this is wrong?

I'm sure that you already know all of this. But incase you don't, this is why this bill is stupid.

Suboxone, containing buprenorphine and naloxone, can be injected, and abused in the SAME WAY, and to the SAME DEGREE as any medication containing only buprenorphine.

Everybody knows this. The only one who has something to gain from passing a bill like this is reckitt benckiser, who produce suboxone. They have the patent. They would have a lot to gain from having a LAW remove their competition.

In my head this is all insane. Are you in reckitt benckiser's pocket, or why the h*ll would you want to pasa a bill like this?

No matter if there are allegic people or not, there is no reason for the naloxone. It's just more expensive.

I guess im lucky i'm not a US citizen so i don't have to worry about ▬ like this, but i do feel for you people over there. I'm sorry for you that a doctor cannot choose a medicin for you because lawyers and politicans opinions (that are based on nothing but misinformation)

Commenter: heather redmon 4/25/17 11:03 am

no!!!

taking away a lifesaving med is disgusting!

Commenter: Kyle Miles 4/26/17 4:09 am

Buprenorphine saves lives

This is my third comment, but I cant help it. I have seen other patients that were good patients lose treatment because they had a documented allergy on file. All this done is cut people off from the life-saving treatment they were getting. Supposedly the whole reason behind this is because someone testified that they bought one on the streets. Well if thats the truth why haven't went after Opana, Methadone, Percocets, OxyContin, Valium, Xanax, Klonopin, People are reporting they are still able to get a prescription and get them filled in Virginia but some of us are suffering. All this bill did is either create a worse black market or sent people that were in treatment back to the streets. If a person has an allergy on file there doctor would be reluctant to switch them, some people just cannot tolerate it. Buprenorphine is the safest out of all three of the drugs used for treating

addiction, and the only problem we have with it is there aren't enough doctors to stem the tides of addiction and putting up more barriers to treatment. Every one of these medications has their uses but to punish someone because suboxone makes them feel horrible or swells their throats shut is outrageous when suboxone is still available for patients that can have it. Bupe with or without Naloxone is a miracle drug, and taking one of them away because someone cannot have the other is a horrible mistake.

Commenter: Patrick Turner, Family Practice Specialists of Ricmond 4/26/17 12:35 pm

Opioid Recommendations - Comment Period

thank you all for the opportunity to submit comments regarding these regulations.

my experience has largely been positive. i am happy to see that providers are now protected to have tighter regulations on prescribing opioids.

the largest difficulty my practices faces is action upon urine drug testing that is positive for marijuana (THC). this is because we encounter patients who will intermittently use marijuana in states where it is legally obtained, and because of rapid changes in state legality, are unsure of how to act with regards to continue viewing THC as an illegal substance / drug of abuse. we have also seen cases of physician reprimand by the board of medicine for inappropriate prescribing, where urine drug testing with positive THC testing has been cited as further evidence of physician neglect. any formal guidance form the board of medicine on how to view THC in the context of management of chronic nonmalignant pain with narcotics would be incredible helpful with this common dilemma.

additionally, we are seeing limited numbers of pharmacies that are carrying naloxone, and it seems as though the intra-nasal / atomized formulation of naloxone is the only affordable option for patients when it is recommended. how is the state addressing this mandate to increase access to this important therapy?

thanks for your consideration,

Patrick Turner, MD.

Commenter: Ronald L Schubert 4/26/17 12:44 pm

Opioid prescription regulations

The bulk of my patients on chronic opiod medication are elderly with complex spinal disease with multiple compression fractures etc. They are not amenable to any more interventions. These folks feel very villified by the current regulatory invironment.

Physicians must be free to treat and diagnose and finally give comfort to the suffering when there is no definative way to cure an individual. The source of pills on the streets have largely been from a few unscrupulous physicians writing large number of prescriptions for nebulous reasons. The sources of pills are largely drying up as shown by the rising use of heroin and on line designer drugs. Please keep this in mind when drafting regulations. It could be your mother or father who

needs treatment some day!.

Respectfully submitted,

Ronald L Schubert, MD

Commenter: mark meijer md 4/26/17 1:51 pm

opiod rx

what is the probability of any random, narcotic naive, regardless of family history, patient to be genetically pre-wired to be addicted to narcotics when exposed to the first dose as some addicts are known to be? Patients discharged on narcotics 10 years ago from randomly selected hospital, how many are now addicted to narcotics through insurance diagnosis, DUI, death by overdose or excessive Rx on state data base? How many patients die from pain? ONLY with this data can we begin to determine the risk/ benefit ratio on patients with non terminal pain. Without that data (and lots more), how can we lecture physicians on the safe use of narcotics? We are not even sure narcotics give long term benefits to many patients. This makes any risk/benefit ratio even worse. Safe prescribing of any drug requires an acceptable risk/benefit ratio. Has the medical board really answered that answer. Don't lecture any doctor on safe prescribing without that information.Maybe the medical board should ask the legislators if patients have the "right" to be treated by insurance companies for pain?

Pain should not be a vital sign in all charts (as a standard of cae) until these questions are answered. Pain control should not be a "right" which every medical facility mentions when patient register to be seen. Pain control should not be a quality measure for insurance re-imbursement. Emergency dept should not be penalized for refusing to give narcotics or tranquilizers.

Look at the legislation/regulations 10-20 years ago. That is what created this mess.

I don't know why I wrote his since no one really cares anymore.

Commenter: Jason Nolet 4/26/17 4:22 pm

Long time Subutex patient concerns

Good Afternoon,

I have been a long time patient taking Subutex for my opiate dependence. This is the very first time I have commented or even signed a petition like this. I am an ex-heroin addict who after a month in detox continued to use this drug "legally" when I transition to my doctor.

My doctor initially put me on Suboxone, and I immediately noticed frequent migraines, nausea, and body discomfort. At the start I did not know what was causing me to feel so poorly and after doing a little research online I noticed other people were having similar symptoms. I then asked my doctor to please switch me over to the Naloxone free "Subutex" medication. Right away I noticed my migraines, stomachaches, and other discomforts went away.

I have been sober for over 10 years now, I have a good full-time job working with the federal government, and most importantly: stability. Now I fear that will all change because of this bill you're passing to switch me back over to a medication that makes me feel sick and does more harm than good, at least to me. Please don't punish people like myself who have followed the law and not abused this medication and who have benefited tremendously into living a life without going back on the street for drugs. There will always be people who are going to abuse drugs and find new ways to do so. I am very sorry to hear that so many are suffering right now because of these new implementations. I am very concerned and worried about what I'm going to do as I do not want to nor do I feel that methadone is a good fit for me treatment wise. My doctor just

informed me today about these new changes and even he is unsure what to do nor does he agree with it. This "uncertainty" is causing a lot of anxiety for my future. Thank you

Commenter: Mindy Thomas, Gloucester Mathews Care Clinic 4/28/17 1:43 pm

Wow, just wow

I just want to start by saying I honestly can't believe that law makers would even consider (much less make a law) restricting ANY type of recovery option. We are facing such an epidemic with the opiate crisis, we should be lifting restrictions instead of applying more! I seriously hope the practitioners will keep track of the patients who drop out of treatment due to allergies, commit crimes to get money to stop withdrawal, or end up in prison (or worse dead). There blood will be on your hands! Hope you're okay with that when you shut your eyes every night. God forbid one of your loved ones ever face this situation!

Commenter: Lorraine Murphy 4/29/17 9:18 am

Subutex vs. Suboxone

To whome this concerns,

I am an administrator for a Face Book Suboxone support group. We have over 6000 members whome all have tapered from or are on suboxone, subutex or the few other brands of buprenorphine medication. Members receive doses and a timeframe according to their needs. We have had women who became pregnant and switched to subutex, but we also have members who had to switch due to alergies to Naloxone.

The main concern doctors have with prescribing naloxone is a belief that it is a deterant for addicts who use Buprenorphine IV, when in fact any addict who has used this medication IV has done so with suboxone as well. The naloxone does not have any effect in detering addicts as the amount of naloxone in suboxone is not enough to get an addict sick, which is the desired result from adding the naloxone.

I wish you can hear the testimony from the recovering addicts in my group who have this allergy, they are now forced with having to go off of subutex when they are not ready and they are scared. I myself suffered from addictio for 30 years and found suboxone to be the one thing that enabled my recovery, I couldnt imagie having to be forced off this medication when I wasnt ready, and thanks to suboxone I can now face my life sober.

We have an opiate epidemic, with thousands of addicts losing their fight each year I cant understand why limits are being put on the one medication that is saving thousands of other lives. The members I have that have this allergy to naloxone are not kids seeking a cheap thrill, it is mothers and fathers whose recovery depends upon this medication.

We also have members who are in recovery with the use of suboxone that still suffer an addiction to the high of using a needle, this is how I know people are still using suboxone with no ill effects from the naloxone what so ever. Sometimes in addiction we dont do everything correctly right away, so breaking the the habbit of the needle takes time.

If suboxone users are still using this medication IV, why insist that subutex be only used for pregnant women? why cant a doctor who has proof of their patients alergy be able to prescribe it as well?

One day you are going to hear stories about these individuals relapsing because they had no alternative to suboxone, I hope you are preparred to take the blame for those such individuals.

Thank you,

Lorraine

Commenter: Michael Petrizzi 4/30/17 1:16 pm

Board of Medicine Opioid Regulations

Thank you for the opportunity to comment

1- It would be helpful to have a Google Drive Document that had the most up to date contact information for Pain Management Practices.

I would see if it was possible to be monitored by the Board Of Medicine, be search able by Zip Code, Insurance Company, Self Pay policies and or Medicare , Medicaid status with a real time next appointment date. It happens all to frequently that we try to give a Bridge prescription only to find the next appointment cannot be until 3 months from now or they don't take insurance.

2- I would ask that each time a patient fills a prescription for a controlled substance that they are given a copy of their PMP. I know that in the past we were not supposed to put a copy in the chart or give it to the patient. It is very time consuming to run a report the way we are supposed to FOR EVERY PATIENT NEEDING A REFILL OF A CONTROLLED SUBSTANCE. My rationale is that if it was used as a "ticket" to entry into the process of getting a refill it would be a more proactive step as compared to having the Physician need to deny the refill in the middle of a day of patient care.

ype over this text and enter your comments here. You are limited to approximately 3000 words.

Commenter: Julie Galloway, Medical Society of Virginia 5/2/17 11:00 am

MSV Comment: Regulations Governing Prescribing of Opioids and Buprenorphine 18 VAC 85-21

May 2, 2017

William L. Harp, M.D.

Executive Director

Board of Medicine

9960 Mayland Drive, Suite 300

Henrico Virginia 23233

RE: Regulations Governing Prescribing of Opioids and Buprenorphine 18 VAC 85-21

Dear Dr. Harp:

The Medical Society of Virginia (MSV) appreciates the opportunity to provide public comment on the Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21). MSV greatly appreciates the work of the Board to develop regulations that promote appropriate prescribing of opioids and buprenorphine, while maintaining physician discretion to offer treatment that best meets the medical needs of patients in extenuating circumstances.

Further, MSV supports the multi-stakeholder approach that incorporated best practices and considered the practical application in clinical settings. We look forward to continued work with the Board of Medicine, physician experts, and community stakeholders, on the implementation of

these regulations, as well as future regulations on these topics.

MSV continues to support the Board in its efforts to reduce opioid addiction in the Commonwealth and is committed to working collaboratively to address the opioid crisis.

Sincerely,

Bhushan Pandya, M.D.

President

CC:

David Brown, D.C., Director, Department of Health Professions

Elaine Yeatts, Policy Analyst, Department of Health Professions

Melina Davis-Martin, Executive Vice President, MSV

Scott Johnson, General Counsel, MSV

Lauren Bates-Rowe, Assistant Vice President of Health Policy, MSV

Ralston King, Assistant Vice President of Government Affairs, MSV

Commenter: Brenda 5/2/17 5:23 pm

SUBUTEX SAVED MY LIFE

Hello, I'm writing about the decision that was made to take my treatment away! I've been on Subutex for a little over a year now, well until a little over a month ago that is, when my doctor notified me that i would no longer receive my Subutex! I'll NEVER forget that day! I literally sat in the parking lot after my appointment for almost 2 hours crying! I felt like my life was over, because how can I continue to work and maintain a normal, productive life when I'm now SICK all the time again! I'm already sick of being SICK! I'm in fear of losing my job as I've already had to call in several days this past month due to being sick! And if i have to call into work, then my paycheck is short, hence me and my 2 teenage daughters will lose our home and everything! This bill being passed literally just took me back a million steps in recovery, because now I'm back on the streets as I've refused the suboxone treatment because i would rather be SICK than feel the side effects from Suboxone! I tried Suboxone first for awhile, but left that treatment because of how it made me feel like i was literally dying! It speeds my heart up, makes me feel like I'm struggling to breath, gives me horrible headaches, makes me sweat so bad i cannot cope as my clothes are soaked shortly after taking it, sweat literally dripping from my eyelids, made me intolerable to be around, says my kids as I'm so irritable on it, and last but certainly not least I am 38 years old, a little overweight, but still NEVER in my life, not even through 2 pregnancies have i ever had high blood pressure, but after only 30 to 45 minutes after taking Suboxone, my blood pressure shot up dramatically, and stayed up until i removed myself from that treatment! Raised it so much so, that the doctor wanted me to see another doctor about my blood pressure, which i could not afford! So, like i said I quit that treatment, and went back to the streets for a couple years, until i found my current doctor that wrote the prescription for Subutex! So after 10 plus years of being an addict, stealing, lying, in and out of jail, all the while my kids paying a huge price for my addiction, i FINALLY had a chance at LIFE again, my 2 teenage girls could even explain the 100 percent difference in me, in our life! After being put on Subutex, i immediately found employment, paid $7,000.00 in fines, got my license back, a car, a house, a LIFE again! All for this bill to be passed, and in such short time I'm already at risk of losing it ALL! I would ask for all involved to PLEASE reconsider what they've done in allowing this bill to be passed!!! MY LIFE AND FAMILY DEPEND

ON IT!! Thanks for giving me the opportunity to express my feelings and my desperate need for this bill to be reversed!!

Commenter: Virginia Hospital & Healthcare Association (R. Brent Rawlings on behalf of) 5/3/17 9:55 am

VHHA Comment on Regulations Governing the Prescribing of Opioids and Buprenorphine

May 3, 2017

William L. Harp, M.D.

Executive Director

Board of Medicine

9960 Mayland Drive, Suite 300

Henrico Virginia 23233

Re: Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21)

Dear Dr. Harp,

The Virginia Hospital & Healthcare Association (VHHA) supports the efforts of the Board of Medicine to develop these Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21) with input from stakeholders and other concerned citizens. The thoughtful approach taken to developing these regulations strikes an appropriate balance in establishing clear guidelines for health care providers without impeding the delivery of effective patient-centered care. We note that many of the guidelines are consistent with the Virginia Hospital Emergency Department Opioid Prescribing Guidelines jointly developed by VHHA and the Virginia College of Emergency Physicians in January 2016. Having these accepted practices incorporated into regulation will further promote appropriate prescribing of opioids and buprenorphine and better patient care across the Commonwealth.

There is far more that can and must be done, but these regulations are another important step in attempting to reduce the prevalence and incidence of substance abuse and opioid related deaths. VHHA and its members are committed to continuing to review and update these regulations as the medical standard and best practices evolve to ensure that Virginians are protected from harm and receive the best patient care possible.

Sincerely,

R. Brent Rawlings

Vice President and General Counsel

Commenter: S. Thomas 5/3/17 10:31 am

Already experiencing bad outcome as result of med change

It has been one month since the option of Subutex was taken off the table for my recovering daughter. Nausea, rash, depression and debilitating fatigue. In addition, the pharm compound she is now taking is a financial stress as we have to dip into her college fund to pay the out of pocket expense. My guess is that the impact of this reg has not saved one life or diverted an active addict who will find their high no matter what law is in place, but it has certainly had a negative impact on those recovering addicts who were successful and compliant with Subutex. Her qualified doctor

should be making these life altering decisions, not the state of virginia.

Commenter: Lindsey Vaughn, VAFP 5/3/17 3:15 pm

VAFP Comment: Regulations Governing Prescribing of Opioids and Buprenorphine

May 3, 2017

William L. Harp, M.D.
Executive Director
Board of Medicine
9960 Mayland Drive, Suite 300
Henrico Virginia 23233

RE: Regulations Governing Prescribing of Opioids and Buprenorphine

Dear Dr. Harp:

The Virginia Academy of Family Physicians (VAFP) appreciates the opportunity to provide public comment on the Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine. The practice of medicine is best regulated by the physicians and so the VAFP supports the Board's evidence based process to develop appropriate regulations concerning the prescribing of opioids and buprenorphine.

VAFP received a substantial number or responses from its membership in response to the Board's emergency regulations. A summary of the comments received by VAFP is included here. Please note that the summarized comments below do not necessarily reflect the views of the VAFP or its general membership.

Summary of comments received:

• Need to develop exclusions, reduced visit requirements, or reduced documentation requirements based on patient age (i.e. geriatric patients) or clinical criteria.
• Need to develop a process for withdrawing patients if a provider decides to stop prescribing opioids in response to these regulations.
• Clarification is needed as to the responsibility of Narcan prescribing; Narcan prescriptions should appear on the PMP.
• Clarification is needed as to whether or not the regulations apply to Tramadol. Many members expressed a need for confirmation that the regulations do not apply to Tramadol.
• Clarification is needed as to whether or not the regulations apply to cough syrups including codeine or hydrocodone.
• Many comments requested a definition of "opioid" be included in the regulations.
• Need clarification as to whether Narcan is required to be prescribed in conjunction with sedation medications.
• Flexibility is needed regarding the 3-month assessment requirement; individualization should be considered to allow for 3-6 month assessments with 3 month assessments reserved for patients at higher morphine equivalent doses. Frequent office visits may preclude access to primary care for other patients given limited primary care resources.
• Clarification is needed as to how patients who use opioids intermittently (i.e. opioid for back pain prescribed prn) must be managed under the regulations.
• Responsibilities should be clarified when one physician is prescribing an opioid and another physician is prescribing a benzodiazepine for the same patient.
• Clarification is needed as to how to handle a patients positive drug screen for THC if the THC was lawfully obtained.
• Many members expressed concern that the administrative requirements imposed by the regulations would have the consequence of impeding legitimate patients from accessing necessary medication as providers would be forced to see and prescribe opioids for fewer patients. Some

members reflected to VAFP that they have or will simply stop prescribing opioids entirely to avoid doubt over compliance and due to administrative burdens.

Again, thank you for the opportunity to provide comment on this matter. VAFP is committed to continuing to work with the Board of Medicine to advance public health and safety through the appropriate regulation of the prescribing of opioids and buprenorphine.

Respectfully,
Lindsey Vaughn, M.D.
President, VAFP

GENERAL QUESTIONS AND COMMENTS

MSV℠ MEDICAL SOCIETY OF VIRGINIA

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Richmond, VA 23294

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May 2, 2017

William L. Harp, M.D.
Executive Director
Board of Medicine
9960 Mayland Drive, Suite 300
Henrico Virginia 23233

RE: Regulations Governing Prescribing of Opioids and Buprenorphine 18 VAC 85-21

Dear Dr. Harp:

The Medical Society of Virginia (MSV) appreciates the opportunity to provide public comment on the Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21). MSV greatly appreciates the work of the Board to develop regulations that promote appropriate prescribing of opioids and buprenorphine, while maintaining physician discretion to offer treatment that best meets the medical needs of patients in extenuating circumstances.

Further, MSV supports the multi-stakeholder approach that incorporated best practices and considered the practical application in clinical settings. We look forward to continued work with the Board of Medicine, physician experts, and community stakeholders, on the implementation of these regulations, as well as future regulations on these topics.

MSV continues to support the Board in its efforts to reduce opioid addiction in the Commonwealth and is committed to working collaboratively to address the opioid crisis.

Sincerely,

Bhushan H. Pandya

Bhushan Pandya, M.D.
President

CC:
David Brown, D.C., Director, Department of Health Professions
Elaine Yeatts, Policy Analyst, Department of Health Professions
Melina Davis-Martin, Executive Vice President, MSV
Scott Johnson, General Counsel, MSV
Lauren Bates-Rowe, Assistant Vice President of Health Policy, MSV
Ralston King, Assistant Vice President of Government Affairs, MSV

Harp, William L. (DHP)

From: Rawlings, Brent <brawlings@vhha.com>
Sent: Wednesday, May 03, 2017 10:02 AM
To: Harp, William L. (DHP)
Subject: Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21)
Attachments: VHHA Comments - Opioid and Buprenorphine Prescribing Regulations.pdf

Dear Dr. Harp,

Please see the attached public comment on Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine submitted on behalf of the Virginia Hospital & Healthcare Association. The public comment was also submitted electronically online through the Virginia Regulatory Townhall.

Thanks for all of your work on this important matter.

Brent

R. Brent Rawlings
Vice President and General Counsel
Virginia Hospital & Healthcare Association
4200 Innslake Drive, Suite 203
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Phone: (804) 965-1228
Mobile: (804) 307-0366
brawlings@vhha.com

VIRGINIA HOSPITAL & HEALTHCARE ASSOCIATION
4200 INNSLAKE DRIVE, SUITE 203, GLEN ALLEN, VIRGINIA 23060-6772
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May 3, 2017

William L. Harp, M.D.
Executive Director
Board of Medicine
9960 Mayland Drive, Suite 300
Henrico Virginia 23233

Re: Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21)

Dear Dr. Harp,

The Virginia Hospital & Healthcare Association (VHHA) supports the efforts of the Board of Medicine to develop these Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21) with input from stakeholders and other concerned citizens. The thoughtful approach taken to developing these regulations strikes an appropriate balance in establishing clear guidelines for health care providers without impeding the delivery of effective patient-centered care. We note that many of the guidelines are consistent with the Virginia Hospital Emergency Department Opioid Prescribing Guidelines jointly developed by VHHA and the Virginia College of Emergency Physicians in January 2016. Having these accepted practices incorporated into regulation will further promote appropriate prescribing of opioids and buprenorphine and better patient care across the Commonwealth.

There is far more that can and must be done, but these regulations are another important step in attempting to reduce the prevalence and incidence of substance abuse and opioid related deaths. VHHA and its members are committed to continuing to review and update these regulations as the medical standard and best practices evolve to ensure that Virginians are protected from harm and receive the best patient care possible.

Sincerely,

R. Brent Rawlings
Vice President and General Counsel

BUPRENORPHINE QUESTIONS AND COMMENTS

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Friday, April 21, 2017 8:46 AM
To: 'Lawrence Conell'
Subject: RE: May 15th

Thanks, Larry.

I'll try to get your comments to the Panel.

Bill

From: Lawrence Conell [mailto:ljconellmd@gmail.com]
Sent: Thursday, April 20, 2017 9:35 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Cc: Morton, Colanthia D. (DHP) <CoCo.Morton@dhp.virginia.gov>
Subject: Re: May 15th

Hi Bill,
Thanks so much for trying to accommodate. I would very much like to attend but just can't see how, as have 21 patients scheduled that day, and a packed week with no place to reschedule, especially as will be leaving later in the week to go to the APA. Please keep me informed, as the change in the regulations has severely adversely effected a number of my patients.

In addition to considering allowing mono product for those with a history of adverse reaction(s) to naloxone, would ask for a time limited provision of perhaps 6 months for the occasional selected and trusted patient, to allow time to obtain insurance if they don't have it, or have lost it for some reason.

Many thanks again for considering these concerns and pursuing my input.

Larry

Thanks,

Lawrence J. Conell, M.D., DLFAPA
110 Newman Ave.
Harrisonburg, VA 22801

Phone: (540) 442-9909
Fax: (540) 442-9901
Web: www.drconell.com

On Thu, Apr 20, 2017 at 1:59 PM, Harp, William L. (DHP) <William.Harp@dhp.virginia.gov> wrote:

Larry:

Harp, William L. (DHP)

From: Board of Medicine
Sent: Tuesday, May 02, 2017 4:02 PM
To: Harp, William L. (DHP)
Subject: FW: Ban of buprenorphine, Dr Holwick endorsing letter from our clinic

From: Jann Holwick [mailto:jholwick60@gmail.com]
Sent: Sunday, April 30, 2017 9:34 AM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Ban of buprenorphine, Dr Holwick endorsing letter from our clinic

Dear Dr Harp: Re:18VAC85-21-140

The above legislation which went into effect last month has made my job, helping addicts find recovery, much more difficult. Here in southwest Virginia, we continue to deal with high rates of mortality from opioid overdoses. Heroin is cheap, and medications we offer are expensive.

One third of my patients had been taking buprenorphine monoproduct (Bup-MP), mainly for financial reasons (low income, no or little insurance) and were coping with a cost of around $3.00/pill for the 8mg pill, at a dose of 2/day ($180/month-if bought all at once, much more if bought a few at a time). A fewer number were were on Bup-MP for allergy to naloxone, or severe side effects to naloxone containing preparations (usually nausea, or migraine type headache).Elimination of the Bup-MP option for those patients has resulted in many of them trying to get off all meds prematurely, going back to street drugs, or going to other practioners who would prescribe opioids which got them into trouble in the first place (ie, methadone clinics).

This has already begun to happen, and if it becomes widespread, it will have undone the the hard won progress of many former patients, and will lead to an outcome unintended by that legislation. I have attempted to switch many to the naloxone containing products, but the cost is at the minimum (if a whole month is purchased at once) $6.00/day ($360/month) for the generic and $10.00/day ($600/month) for the Film. My uninsured/underinsured patients cannot afford these prices. Drug company reps will tell you that discount coupons are available, or that free medicine is offered for those that qualify. They will also admit that even coupons do not decrease cost anywhere near to $3.00/pill and that free med is available to only 3 patients/year and those for only one year. I expect that even those prices will go up, because of changes in market share (as per the recent issues with Epipen)

None of the above even gets to the heart of the matter, which involves the chemistry of buprenorphine (bup). Most of the fatal overdoses (ODs) in our area involve methadone and heroin-fentanyl mixtures, often associated also with alcohol or benzodiazepines (bzos). I am not aware of any fatal adult ODs due to only Bup-MP or Bup with naloxone. The reason bup is so effective, and less dangerous, is that it stimulates only 40% of available opiate receptors (and blocks the rest). So the only way to get a fatal OD on Bup-MP or Bup naloxone is to mix them with alcohol or other respiratory depressants. Taking methadone or heroin on top of either type of bup will lead to those drugs being blocked. Drug company reps will also tell you that the addition of naloxone to bup prevents diversion, or IV use, and lessens the likelihood of a fatal OD, but my patient say that the amount of naloxone is too low to result in any benefit.

Any form of bup, with or without naloxone, is used on the street primarily for prevention of withdrawal when addicts cannot get their drug of choice (either preparation costs $25-35/ 8mg pill on the street). Yes, there are those who still use either for IV purposes, but these are in the minority. The key fact here is that all

Bup products are saving addict lives, preventing other crimes (assault, robbery, breaking and entering to obtain drugs or money for drugs for those in withdrawal). And that bup with or without naloxone, by itself, even in high doses, will not shut down the respiratory center.

I would therefore propose that Bup-MP be available also to those without financial means to pay, and to those few who demonstrate and allergy/intolerance to naloxone. and would also propose that the price for naloxone containing Bup products be halved.

I hope all of this helps you understand some of the issues we face. I and my 2 colleagues practice only addiction medicine, and do not prescribe medication for addiction as a sideline to the main work as a general practitioner or psychiatrist. We are all ASAM certified, and require that our patients change their way of living, and join a support group for assistance, along with taking their meds (ie, we are not "scrip docs). And last, please understand that this letter is about our patients' lives, and not our income.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Monday, April 17, 2017 1:03 PM
To: 'Jann Holwick'
Subject: RE: Virginia State Laws re buprenorphine

Thank you, Dr. Holwick.

WLH

From: Jann Holwick [mailto:jholwick60@gmail.com]
Sent: Monday, April 17, 2017 11:23 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Virginia State Laws re buprenorphine

Kindly add exceptions nursing mothers and for those patients with potential or real hepatic disease, e.g., cirrhosis, hepatitis, liver nodules/masses, steatohepatitis, etc. Holwick, MD

Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Tuesday, April 11, 2017 5:09 PM
To: Harp, William L. (DHP)
Cc: Wood, Jennie (DHP); Brown, David (DHP)
Subject: FW: subutex

Spoke to Dr. Bulette. He explained that he had a patient bring him a letter from her cardiologist stating that the patient developed an arrhythmia in reaction to the suboxone after he switched her from subutex. He had another patient who also seemed to have a legitimate reaction. He said he had other patients who claimed to have an allergy, but he has found that most are tolerating the naloxone without problem. His concern is with the small number, who do appear to have a problem with suboxone, and wondered if there is any leeway. He also noted that the cost is double for suboxone. In response to the cardiologist's recommendation, he did write subutex for the patient and wrote a note to the pharmacist explaining the issue, and documented in his record and included the cardiologist's report in an effort to comply with 18VAC -85-21-150(C). I told him that there is no exception in the regs for intolerance or allergy and 150C is directed at the decision to use the mono product in formulations other than tablet form. He understands what the Board is trying to do, and is supportive of the Board's efforts, but believes there should be an allowance for naloxone intolerance. He plans to write a letter and it sounds like he intends to reach out to some of his former patients who have now been recovered and off subutex to speak to how proper addiction treatment helped them and saved their lives.

From: Wood, Jennie (DHP)
Sent: Tuesday, April 11, 2017 4:23 PM
To: Deschenes, Jennifer (DHP)
Subject: subutex

Dr. Bulette left a vm (he left no 1st name). "wondering if there is any leeway going from subutex to suboxone" and the Board's thoughts. He's at his office T,W, Th from 10 to 6.
757-442-2504

Jennie F. Wood
Case Manager, Discipline & Compliance
Virginia Board of Medicine
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233
804-367-4571; Fax-804-527-4429

Sheila M. Furey, MD
7711 Kenmore Circle
Richmond, VA 23225
804-717-5181 phone
804-914-1949 mobile
888-374-3883 fax

April 6, 2017

Dear Dr. Harp and Board of Medicine:

I have multiple concerns and questions on behalf of my patients regarding the new regulations for opioids and buprenorphine. I became certified to prescribe buprenorphine/naloxone over 10 years ago. I understand the intent of the regulations, however, the abrupt onset of the changes has caused significant concerns for my long term patients.

Below are some of the case vignettes of patients. What are your guidelines on how to proceed?
You stated in your letter to essentially, "do no harm," however, there does not appear to be any room for a medical decision based upon my assessment of the patient, knowledge, training, experience, and the steps I am taking to avoid misuse or diversion of the drugs.

The option of sending long term patients to a methadone clinic is unrealistic. Most of my patients are working full time and cannot leave their jobs or commute to a clinic on a daily basis. The other issue is cost. The cost of $15 per day is prohibitive to my patients who may be working full time, but do not have insurance. Additionally, the methadone clinics are not prepared to handle the influx of patients on the mono-product buprenorphine.

Patient 1. 30 year old woman 12 weeks pregnant and is on Subutex 8 mg BID. When she delivers, the protocol for the newborn is for Mom to continue to use Subutex and her breast milk is used in the weaning process. Thus, Subutex needs to be continued during lactation. The pediatricians do not want to introduce Naloxone to the new born.

Patient 2. Woman s/p delivery. Baby is now 5-6 months. Mother continues to breast feed. Her breast milk was used to wean baby while he remained at the hospital and mother continues to use breast milk at home as per the pediatrician.

Patient 3. Male in early 30s, had severe migraine headaches on combination product. He was missing work on a regular basis. I tried various interventions for the migraines without success. I moved him to mono product and he has not had a migraine headache since. He works full time and is compliant with therapy and clean. If he returns to combination product, he risks losing his job.

Patient 4: Patient on Suboxone with severe PTSD and Anxiety. Patient is prescribed benzodiazepines. There is no abuse or misuse of medications. I do urine drug screens at monthly appointments. I have been following for years. I have written for Evzio. It is unreasonable to taper benzodiazepines quickly and to what purpose if it is not helpful to the patient.

Patient 5: Patient on Suboxone film 8/2 mg daily. Co-morbid PTSD and seizure disorder.
Patient relies on Klonopin to help with seizure control in addition to high dose Neurontin.
Patient has aura prior to seizures and alerts to take Klonopin/Neurontin. The risk of DC or taper of Klonopin at this time is significant.

Patient 5: Chronic pain patient, age 40, from chronic kidney stones, passes 12-15 stones per month. He has brought the stones to my office. Additionally, he had back pain with radiation down his legs from injury approximately 15 years ago. He initially presented from his pain specialist because he wanted an alternative to his oxymorphone. I reviewed all the medical issues and he was aware that Suboxone may

not cover the pain of kidney stones. He was still willing to try. He was initially treated with Subutex during the induction. He did well. He then transitioned to Suboxone, however, this cause severe nausea and he was unable to tolerate it. He tried Suboxone for for one month and could not tolerate it anymore. He was switched back to Subutex and was stable. He was able to use Subutex part of the month and oxymorphone when he had severe kidney pain. However, in fall of 2016 kidney stone pain remained severe and had additional pain from his back. I encouraged him to have another back evaluation and he is currently post op.(February 28, 2017) lumbar back surgery, laminectomy for herniated discs. He reports significant improvement in back pain. He is no longer in constant pain with radiation down his legs from his back. He describes back pain with over exertion. However, he continues to struggle with pain from the kidney stones. He is currently prescribed Oxymorphone 10 mg (max of 8 tablets per day #240 for one month) He is compliant with medications. Subutex does not cover kidney stone pain.

This patient was told there was nothing more they could do in terms of his kidney stones by nephrology and urology. I have consulted with nephrologist at U of Pennsylvania. I had urine sent to lab specializing in chronic kidney stones. We have worked to change his diet and looked at alternative interventions for kidneys stones. I have him go to physical therapy not just for back pain but for pain from kidney stones and to teach him to relax muscles post waves of kidney stone pain. He comes to each appointment with his wife. Again, he desires to return to mono-product as soon as able to from back surgery and if he can obtain windows in which he is free from kidney stones.

Patient 6: 31 year old woman. NO insurance. Chronic Pain. Dependence s/p MVA with neck and back injury. Unable to afford Suboxone or combo product. Also, taking Xanax for panic attacks. Weaning from Xanax. With no insurance, she cannot afford alternative.

Patient 7: 38 year old male with Ehlers Danlos syndrome, rheumatoid arthritis and addiction. He had severe nausea with Suboxone and has none of those symptoms on Subutex. He is medication compliant. He works but has no health insurance. He has been prescribed Subutex 24 mg per day in divided doses. Again, this medication has provided him with stability he has not had in years.

Please respond to these and I will send additional questions as they come up. All patients on Subutex were willing to have weekly pill counts or whatever was necessary to keep the medication.

The alternative mono products are in micrograms. There is no data on how patients on milligrams will tolerate the transition to a product that is in micrograms. I understand the mechanism is different and absorption may be significantly improved but until the patients try, they will not know. However, this does not help patients who do not have insurance. Cost of mono product film is $500 plus dollars a month vs. buprenorphine tablets at $100-$200 per month depending on dose.

Respectfully,

Sheila M. Furey, MD

Harp, William L. (DHP)

From: Randall, Mellie (DBHDS)
Sent: Thursday, April 20, 2017 12:14 PM
To: Harp, William L. (DHP); Melton, Hughes (VDH); Neuhausen, Kate (DMAS)
Subject: RE: Frequently Asked Questions about the Opioid Regulations
Attachments: DBHDS to DHP re Parrino Letter Feb 17 2017.pdf

Bill – I have reviewed the comments provided by Hughes and Kate (and Donna) and don't have anything to add from a technical perspective.

As you recall, Jack Barber sent a letter to David Brown (attached) which stated the full support of DBHDS for the emergency regulations as they are now written. SAMHSA has designated DBHDS as the state agency with oversight over opioid treatment programs and the Code of Virginia designates DBHDS as the agency responsible for licensing these programs. DBHDS does not support any exemption for OTPs from these regulations at this time. I hope that the Board of Medicine will take these facts into account when considering any modification to the regulations.

Thank you for your ongoing communication about this issue.

Mellie

Mellie Randall
Substance Use Disorder Policy Director
Virginia Department of Behavioral Health and Developmental Services

P.O. Box 1797
Richmond, Virginia 23218

1220 Bank Street
Richmond, Virginia 23219

(804)371-2135


A Life of Possibilities for All Virginians

From: Harp, William L. (DHP)
Sent: Tuesday, April 18, 2017 5:17 PM
To: Melton, Hughes (VDH); Randall, Mellie (DBHDS); Neuhausen, Kate (DMAS)
Cc: Harp, William L. (DHP)
Subject: Frequently Asked Questions about the Opioid Regulations

Hughes, Mellie and Kate:

Here are some FAQ's and answers that stick closely to the emergency regulations.

I would like to get these out this week.

If you have a chance to scan them and make any comments you wish, I would be most grateful.

COMMONWEALTH of VIRGINIA

JACK BARBER, M D
INTERIM COMMISSIONER

DEPARTMENT OF
BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES
Post Office Box 1797
Richmond, Virginia 23218-1797

Telephone (804) 786-3921
Fax (804) 371-6638
www dbhds virginia gov

February 21, 2017

David Brown, DCM, Director
Department of Health Professions
9960 Mayland Drive
Richmond, Virginia

Re: Letter from Mark Parrino dated February 15, 2017

Dear Director Brown:

It has come to my attention that Mark Parrino, Executive Director of the American Association of Opiate Treatment, sent comments to the Board of Medicine for consideration at its February 16 meeting concerning proposed regulations concerning Prescribing of Buprenorphine (Part IV, 18VAC85-21-130 et seq). Mr. Parrino incorrectly asserts that "the Virginia Department of Behavioral Health and Developmental Services gave approval to OTPs to begin using the mono-formula of buprenorphine in OTPs under the rules and regulations that are in place for all methadone maintained patients." Mr. Parrino made us aware that he intended to submit these remarks on February 15, and staff were unable to respond to him in time to correct his impression.

As you know, DBHDS does not have the authority to determine what medications are used in facilities that are regulated by the federal government and otherwise licensed to dispense controlled substances and, until the current regulation is signed, it is (and was) legal for OTPs to dispense monoproduct buprenorphine for patients to take offsite. DBHDS staff took part in discussions on which these regulations are based, and I want to assure you that we are fully in support of the regulations that the Board of Medicine has adopted.

In closing, I want to assure you that DBHDS is appreciative of the close collaborative relationship with DHP, and very much appreciates the many hours of technical assistance your staff have provided, especially as we work to address the Commonwealth's significant issues with opioid abuse and addiction.

Please contact me if you have further concerns about this or other issues.

Sincerely,

Jack

Jack Barber, M.D.

c: Mark Parrino

Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Monday, April 10, 2017 3:26 PM
To: Harp, William L. (DHP)
Cc: Brown, David (DHP); Wood, Jennie (DHP); Juran, Caroline (DHP); Johnson, Sammy (DHP)
Subject: opioids and bupr call

[Caroline & Sammy—only yellow highlight might be of interest to you.]

Spoke with Dr. Greene.

His question related to co-prescribing opioids and sleep meds (ultram/soma) and the extenuating circumstances to document. He understands the need to document his medical rationale for such prescribing.

Additionally, he asked if there was an allergy exception for the mono-product. He said that he has a physician mentor in Vermont, who had suggested he write "allergy" on the prescription, but he has ceased that practice since becoming unsure as to whether there is such an exception in the regs. I told him there is no allergy exception in the regs. He noted that historically about 8-10% of his pts have claimed they have an allergy or intolerance. He said he is not sure if those numbers are accurate however, because he has since found that many who claimed to have or thought they had a problem, "lo and behold, they don't" when switched over. He does have one young lady who does insist she has nausea and is not sure how long she can tolerate the bi-product. He mentioned a compounding pharmacy that is offering a bi-product (combo tablet that goes under the tongue) with a very low dose (0.5 mg?) of naloxone and he wondered if that would be okay. I told him that the regs speak only to a prohibition on use of the mono-product, and he might want to check with the BOP on the status of the compounding pharmacy. (I saw a previous email re: a flyer that was posted in a dr's office about a compounding pharmacy with a lozenge, and I believe BOP had concerns about that flyer—not sure if this is something that should/could be addressed in the FAQs. I'm not knowledgeable on whether such compounding offers are acceptable).

Dr. Greene stated that one great side effect of the regs is the number of pts who are now interested in weaning and are in the process of doing so (I guess the price difference in the mono-product/$2 pill compared to the bi-product/ $5 pill is pushing this result).

Re: Narcan. He said that he noticed the day the regs issued he had called a local pharmacy and was given a price of $90 for narcan, and then one week later it was $325. He said he has since been in touch with a helpful pharmacist who advised that his pts get a 2mg narcan for $2-5 co-pay. Several of his pts have reported back that Humana is covering the cost of the Narcan.

From: Rothrock, Laura (DHP)
Sent: Friday, April 07, 2017 5:24 PM
To: Deschenes, Jennifer (DHP)
Cc: Morton, Colanthia D. (DHP)
Subject: RE: Returning your call

Hi Jennifer,

Apparently he hasn't seen your email because I had two voice mails from him this afternoon while I was in meetings. He said he would be in the office until 9pm if someone is able to call him. ☺

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, May 09, 2017 12:11 PM
To: Morton, Colanthia D. (DHP)
Subject: RE: buprenorphine mono product guidance

Dear Mr. Counts:

Thank you for your question.

Here is the answer found in the Frequently Asked Questions that were just sent to the waivered physicians in Virginia listed on the SAMHSA website.

6. Are buprenorphine and naloxone safe for mothers and their breastfeeding infants?

The American Society of Addiction Medicine National Practice Guideline adopted June 2015 stated, "It was shown that the amount of buprenorphine metabolites secreted in breastmilk are so low that they pose little risk to breastfeeding infants." In the May 11, 2016 issue of the ASAM Magazine, a question about breastfeeding was addressed by a Providers' Clinical Support System expert, "While buprenorphine levels transfer to breastmilk in very low levels, naloxone is even much less detectable, if at all." An August 2016 article from the Journal of Human Lactation confirmed that infant plasma levels were low or undetectable. A consultant to the Board, an OB-GYN who provides MAT, opines that naloxone-containing products prescribed to the mother can be considered safe for breastfeeding infants.

A regulatory advisory panel will be meeting on Monday the 15th.

If anything changes with this answer, it will be published on the Board of Medicine's website.

I hope this is helpful.

From: Board of Medicine
Sent: Tuesday, May 09, 2017 11:46 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: buprenorphine mono product guidance

From: Gavin Counts [mailto:highlandsrx@gmail.com]
Sent: Tuesday, May 09, 2017 10:17 AM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: buprenorphine mono product guidance

Hello, my name is Gavin. I am a pharmacist and I am emailing in regards to guidance on the appropriateness of a prescribed drug. I am trying to see if, after the new guidance was issued in march, if it is appropriate to give buprenorphine mono product to a breast feeding mother whose child is being weaned down on morphine from being born addicted. The baby was born two weeks ago and I have made an exception the last two weeks but I am concerned for my own sake if I am myself in compliance of the law as it states that breastfeeding is not a consideration. I am not here to call them out but rather get clarity for myself. Any help would be greatly appreciated

Harp, William L. (DHP)

From: CLAAD Policy <policy@claad.org>
Sent: Wednesday, May 03, 2017 4:56 PM
To: Harp, William L. (DHP)
Subject: Comment Letter Re: Regulations Governing Prescribing of Opioids and Buprenorphine [18 VAC 85 – 21]
Attachments: VA BOM Comment Letter 170501.pdf

Dear Dr. Harp and Board of Medicine Members:

Please see attached comment letter from the Center for Lawful Access and Abuse Deterrence.

Thank you for the opportunity to comment on this topic.

Sincerely,
Kate

Katherine McClaskey, J.D. Policy Advisor
Center for Lawful Access and Abuse Deterrence
202.599.8435 • www.CLAAD.org • @CLAAD_Coalition

CLAAD Center for Lawful Access and Abuse Deterrence

May 3, 2017

William L. Harp, M.D.
Executive Director
9960 Mayland Drive, Suite 300
Richmond, VA 23233
Via email: william.harp@dhp.virginia.gov

Dear Dr. Harp and Board of Medicine Members:

Thank you for the opportunity to provide input on the regulations set forth regarding the prescribing of opioids for acute or chronic pain management and for prescribing of buprenorphine for addiction treatment.

Background

The Center for Lawful Access and Abuse Deterrence (CLAAD) is a tax-exempt, not-for-profit organization that works to reduce prescription drug abuse and other substance use while advancing consumer access to high-quality care for pain, addiction, HIV, hepatitis C, and other health conditions. CLAAD's *National Prescription Drug Abuse Prevention Strategy*, now in its fourth iteration, has been vetted and endorsed by over 30 not-for-profit public health and safety organizations.

An estimated 25.3 million Americans experience persistent pain and have a legitimate need for treatment, including access to U.S. Food and Drug Administration (FDA) approved medications for pain.[1] At the same time, opioid overdose is a public health epidemic in the United States.[2] With such alarming rates of overdose, regulators and policymakers are tasked with determining the most effective methods for preventing and treating opioid use disorder (OUD), all while ensuring access to appropriate treatment for people with pain. Effective methods include encouraging the development, use, and coverage of non-pharmacologic, non-controlled, and lower scheduled treatments, as well as novel molecules, formulations, and delivery systems.

Opioid Therapy for Chronic Pain

Buprenorphine is a partial opioid-agonist that fills opioid receptors in the brain, thereby effectively treating pain without increasing opioid sensitivity and the risk of overdose.[3] When an appropriate dose is reached, buprenorphine has a "ceiling effect," which increases its safety profile by lowering the risk of respiratory depression and overdose.[4]

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[1] *Americans Are in Pain: Analysis of Data on the Prevalence and Severity of Pain from National Survey*, NATIONAL INSTITUTES OF HEALTH, (August 2015), https://nccih.nih.gov/research/results/spotlight/081515.

[2] *The U.S. Opioid Epidemic*, U.S. DEP'T OF HEALTH & HUMAN SERVS, (Apr. 8, 2016), http://www.hhs.gov/opioids/about-the-epidemic/#us-epidemic.

[3] Laura McNicholas, M.D., Ph.D. Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, (Treatment Improvement Protocol (TIP) Series, No. 40. 2 Pharmacology, (2004), https://www.ncbi.nlm.nih.gov/books/NBK64245/pdf/Bookshelf_NBK64245.pdf; The Facts about Buprenorphine for Treatment of Opioid Addiction, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, (2011), http://store.samhsa.gov/shin/content/SMA09-4442/SMA09-4442.pdf.

[4] Laura McNicholas, M.D., Ph.D., Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES

Buprenorphine is a Schedule III controlled substance, and therefore, by definition, has a lower potential for abuse than Schedule II medications, which include most opioid pain relievers currently prescribed for chronic pain.[5]

Yet, as written, the regulation for treatment of chronic pain with opioids[6] singles out buprenorphine by restricting the prescribing and administration of the medication to its FDA-approved indication, with no exceptions. However, the regulation does not impose such a requirement on all other prescription opioid medications, most of which are riskier, Schedule II medications. Rather, the regulation allows health care practitioners to prescribe opioid medications other than buprenorphine, so long as there is proper documentation and rationale in the medical record.

Restricting access to buprenorphine, a medication with lower potential for abuse than most commonly prescribed opioid pain relievers, fails to address the underlying causes of prescription drug abuse and also impedes broader efforts to reduce the opioid overdose and heroin epidemic.

Instead, we recommend regulating treatment with buprenorphine for chronic pain as you have with all other opioids in Part III of the regulations, with one exception. Specifically, we recommend excluding 18VAC85-21-70(C), which states "[b]uprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose."[7]

Such an amendment would keep the comprehensive evaluation and treatment protocols of Part III, such as performing an evaluation prior to prescribing a controlled prescription medication, the development of a treatment plan, and proper documentation in the medical record, among other things. However, the amendment would allow health care providers to otherwise prescribe or administer buprenorphine for the treatment of chronic pain when, in their professional judgment, they deem it medically necessary to do so.

Prescribing Buprenorphine for Addiction Treatment

As you are aware, a practitioner-administered buprenorphine implant has now been FDA-approved for treatment for individuals with OUD. Additionally, multiple buprenorphine mono-products with novel delivery systems, such as depot injectables, are currently in the pipeline for approval for treatment for OUD.[8]

While the regulation pertaining to treatment with buprenorphine for addiction treatment[9] is written to ensure appropriate treatment with oral buprenorphine for patients with OUD, it unintentionally prevents

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ADMINISTRATION, (Treatment Improvement Protocol (TIP) Series, No. 40. 2 Pharmacology, (2004), http://www.ncbi.nlm.nih.gov/books/NBK64236/.

[5] Medication-Assisted Treatment, Partnership for Drug Free Kids, (2017), http://drugfree.org/wp-content/uploads/2017/02/Medication-Assisted-Treatment-ebook.pdf; The Facts about Buprenorphine for Treatment of Opioid Addiction, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, (2011), http://store.samhsa.gov/shin/content/SMA09-4442/SMA09-4442.pdf.

[6] 18 V.A.C. 85-21-70(C).

[7] 18 V.A.C. 85-21-70(C).

[8] http://www.medscape.com/viewarticle/853244; John Kent, *Camurus AB: Braeburn Pharmaceuticals and Camurus Announce Positive Top-line Phase 3 Results for Long-Acting Buprenorphine for Treatment of Opioid Addiction*, Phillypurge.com, (December 12, 2016), http://www.phillypurge.com/2016/12/12/camurus-ab-braeburn-pharmaceuticals-and-camurus-announce-positive-top-line-phase-3-results-for-long-acting-buprenorphine-for-treatment-of-opioid-addiction/.

[9] 18 V.A.C. 85-21-150.

health care practitioners from using their professional training and judgement to treat patients with practitioner-administered medications that inherently enhance treatment plan adherence and reduce diversion, when they deem it medically necessary.

Medical necessity with a specific medication may be established for reasons other than those stated in the product's label based on the health care provider's clinical experience, medical judgment, and the available options for treatment. The FDA supports this position, having stated that "[g]ood medical practice and the best interests of the patient require that physicians use legally available drugs . . . and devices according to their best knowledge and judgement."[10]

Additionally, the FDA further advises that, at times, "off-label uses or treatment regimens may be important therapeutic options and may even constitute a medically recognized standard of care."[11] Practitioner-administered medications inherently ensure treatment adherence and reduce diversion unlike any oral medication. Therefore, it may be medically necessary for health care practitioners to prescribe practitioner-administered buprenorphine products for an individual not expressly addressed in the product's labeling.[12]

Therefore, we respectfully request that the Virginia Board of Medicine amend the regulation to permit health care professionals to use their medical training and judgment, along with proper documentation and rationale, when prescribing (1) buprenorphine for the treatment of pain, and (2) practitioner-administered mono buprenorphine for the treatment of opioid use disorder.

Thank you for considering our recommendation on this matter.

Sincerely,

Shruti R. Kulkarni
Outside Counsel

[10] "Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices – Information Sheet, U.S. FOOD & DRUG ADMINISTRATION, (Last updated January 25, 2016), http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm.
[11] Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, U.S. FOOD & DRUG ADMINISTRATION (December 2011), http://www.fda.gov/downloads/drugs/guidancecompliancere gulatoryinformation/guidances/ucm285145.pdf.
[12]Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, U.S. FOOD & DRUG ADMINISTRATION (December 2011), http://www.fda.gov/downloads/drugs/guidancecompliancere gulatoryinformation/guidances/ucm285145.pdf.

Addiction Treatment Forum reports on substance abuse news of interest to opioid treatment programs and patients in medication-assisted treatment.

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Buprenorphine Dispensing Problems in Virginia: Coal Country Rules

April 13, 2017

By Alison Knopf

The Virginia Board of Medicine, backed by the state, has banned the use of buprenorphine with the exception of treating pregnant patients in both office based opioid treatment (OBOT) programs and in opioid treatment programs (OTPs). OTPs may use the mono-product for on-site administration but no longer may use it for take-homes. Part of a broad set of regulations aimed at opioid prescribing in general, including for pain, this was a surprising turn of events in a state where OTPs have been dispensing take-home buprenorphine mono-product for years.

The reasoning for the decision by the Board of Medicine was that the mono-product would be diverted.

"Approximately 1,100 Virginians died of an opioid overdose in 2016, a 30% increase over 2015," said Maria Reppas, communications director for the Richmond Department of Behavioral Health and Developmental Services (DBHDS). "DBHDS has worked closely with the Board of Medicine and other state agencies, state and local organizations, and concerned citizens to address this epidemic," she added. "DBHDS supports the actions of the Board of Medicine to improve patient health and safety in the treatment of the deadly epidemic disease of opioid addiction."

In Virginia, there "continues to be concern about diversion of buprenorphine products, which contributes to opioid abuse," she said, noting that the sublingual combination product containing naloxone was developed to curtail this risk. The governor's task force therefore recommended that the Virginia Board of Medicine, in collaboration with DBHDS, convene a workgroup of physicians experienced with utilizing

buprenorphine to review standards of care from a variety of sources. The result was a guidance document, which then became the regulations.

Buprenorphine with naloxone cannot be melted down and injected, as the naloxone would render the buprenorphine inactive. However, the generic mono-product is much less expensive than the combination buprenorphine-naloxone product.

OTPs Respond

Mark Parrino

Mark Parrino, MPA, president of the American Association for the Treatment of Opioid Dependence (AATOD), wrote to William L. Harp, MD, executive director of the Virginia Board of Medicine, in February, describing the regulations governing take-home medication from OTPs. The OTPs are also conservative in providing the patient with any take-home medication. From the letter:

"Generally speaking, most patients are being medicated at the OTP five days per week," the letter continued. When take home medication is provided to the patient through the OTP, the patient must meet eight clinical standards, which have been enforced since the regulatory authority of the Food and Drug Administration that continued under the regulatory oversight of the Substance Abuse and Mental Health Services Administration (SAMHSA).

"These criteria include absence of recent drug abuse, which is determined through toxicology reports in addition to established regularity of clinic attendance, absence of serious behavioral problems, absence of known recent criminal activity, stability in the patients' home environment, length of time in comprehensive maintenance treatment, ensuring that take home medication can be safely stored within the patient's home and whether the rehabilitative benefit the patient derives from decreasing the frequency of clinic attendance outweighs potential risk. Compliance with the regulations is mandatory.

"The Virginia Department of Behavioral Health and Developmental Services gave approval to OTPs to begin using the mono-formula of buprenorphine in OTPs under the rules and regulations that are in place or all methadone maintained patients," Mr. Parrino's letter noted.

Coal Country

Mr. Parrino also noted that in Virginia, the coal mining industry is biased against treatment using methadone. Despite the fact that it would be a violation of the Americans with Disabilities Act, employers would likely terminate someone even for the therapeutic use of methadone. The same bias does not exist for buprenorphine, which is why some patients in Virginia prefer it.

There were about 600 patients in Virginia being treated in OTPs with the mono-buprenorphine product at the time the ban went into effect.

About 300 patients were being treated using the mono-buprenorphine at the four Acadia Healthcare treatment centers in Virginia. The same criteria used for take-home privileges for patients being treated with methadone were used for take-home buprenorphine, said Ed Ohlinger, Acadia Healthcare's Regional Director for Virginia and North Carolina.

The history is this: 10 years ago, the Virginia State Opioid Treatment Authority (SOTA) gave OTPs permission to give take-home buprenorphine-naloxone–at the time, the only available product was the Suboxone tablet. About 5 years ago, when the tablet was replaced with film, the price became

unaffordable for patients. But the generic mono-product was affordable, and that's what the OTPs were dispensing.

"We know the mono-product brings to treatment people who wouldn't come if the only medication available was methadone," said Mr. Ohlinger. "The coal mining industry has a zero tolerance for methadone," he said. "This is a longstanding Appalachian phenomenon."

Absorbing Costs of the Combination Product

So when the new rules were announced, Acadia switched all of its mono-buprenorphine patients in Virginia to the combination product, and—at least for now—is absorbing the added costs. "We have not increased their rates to stay in treatment, as we continue to work closely with the medical board," said Mr. Ohlinger, who was in the process of appealing the regulations to get a special exemption for OTPs. "We're incurring significantly higher medication costs at the present time. We're not passing that on until we get through an appeal and see where we go—it is what it is, and Acadia has chosen to do the right thing."

Of the 300 patients being treated by Acadia at the time of the ban, nine have transferred to treatment programs in North Carolina either because of an allergy to naloxone or because they have not done well on the combination product in the past, said Mr. Ohlinger.

Possible Appeal

But things are looking up. At the end of March, representatives of the Virginia Board of Medicine attended part of the Virginia Provider Association's 10-year anniversary conference. "We had a very frank, very open, positive 45-minute conversation where we clearly delineated for them why we are different from OBOTs [office-based opioid treatment]," said Mr. Ohlinger.

There is a problem with diverted mono-buprenorphine, as found in recent arrests and other criminal activities. "But this is mono-product that was coming out of OBOTs in North Carolina, Tennessee, and Kentucky," he said. "I know that some OBOT practices do a really good job, but we know that some don't provide any services" other than induction and prescribing of buprenorphine.

The situation is reminiscent of what happened a decade ago, when methadone diverted from pain clinics was blamed on OTPs. "This is history repeating itself," said Mr. Ohlinger.

The Board of Medicine officials "walked us through the process for filing an appeal, or through a process that could exempt us from the regulations," said Mr. Ohlinger. "They were very open-minded to our explanation about what we do."

A decision from the Board of Medicine was expected in early April.

For more information, see:

http://leg1.state.va.us/cgi-bin/legp504.exe?171+ful+HB2167ER.

https://www.dhp.virginia.gov/medicine/newsletters/OpioidPrescribingBuprenorphine03142017.pdf.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Monday, April 10, 2017 9:05 AM
To: 'Dexter Gravley'
Subject: RE: 18VAC85-21-150. Treatment with buprenorphine for addiction.

Dear Mr. Gravley:

The regulations were pursuant to the Commissioner of Health's declaration of an emergency.

As mentioned below, the issue of having an exception for naloxone intolerance was discussed, but it was not included in the emergency regulations.

Now the Board of Medicine is re-establishing the Regulatory Advisory Panel to consider this issue and several others.

I will forward your e-mail to the Secretary of Health and Human Resources.

I hope this is helpful.

Kindest regards,

WLH

From: Dexter Gravley [mailto:dgravley70@gmail.com]
Sent: Friday, April 07, 2017 9:57 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: RE: 18VAC85-21-150. Treatment with buprenorphine for addiction.

Could you please explain to me where you saw the governor's signature on HB 2163. I have looked everywhere and I see nothing of the sort. I have seen where he made recommendations but no signature. I is my opinion that the Virginia Board of Medicine stepped out of its bounds by enacting such regulations before it was signed into law. Why not put naloxone in everything then, hell let's put it in the water, make sure everyone gets a dose, it won't hurt anyone. You have put alot of innocent people out on the streets against their will. I don't want to start on the thousands of Virginians that were going to the OTP's, there should have been a little warning. I could go on and on but I'm not. After you get this I want you to sign back and think what is hb2163 going to do, I'm speechless, if someone is going to abuse buprenorphine they are going to abuse it. A doctor is supposed to use rationale and weigh the risk verses the benefits I think this puts far more people at risk and the only ones this is going to benefit is big pharma to make them BIGGER. Please forward to the governor because I can't. We won't be heard. It's all political. I hope you are not like the rest of them don't take it personal I just want to be heard this is not right. I emailed the "governor's office" like it will make it to him. We are all addicts seeking the next high, to them. I think everyone that voted yes should have to take naloxone for just 1 week, since it has no affect. Maybe I'm wrong.

On Apr 7, 2017 12:08 PM, "Harp, William L. (DHP)" <William.Harp@dhp.virginia.gov> wrote:

Dear Mr. Gravley:

Thank you for your comments.

When the Board of Medicine was developing regulations, an exception for naloxone intolerance was discussed, but at the end of the day, the Board decided not to include it. Since the regulations were signed by the Governor on March 15th and disseminated to physicians around the state, the Board has received many comments similar to yours from a number of physicians and a few patients. This morning, the Executive Committee of the Board voted to re-establish a Regulatory Advisory Panel comprised of physicians that treat opioid addiction with buprenorphine products to look at this issue.

I hope this is of some help/hope to you.

With kindest regards,

William L. Harp, MD

Executive Director

Virginia Board of Medicine

From: Dexter Gravley [mailto:dgravley70@gmail.com]
Sent: Thursday, April 06, 2017 9:48 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: 18VAC85-21-150. Treatment with buprenorphine for addiction.

I don't understand why you think everyone on buprenorphine monotherapy should pay the price for the mistakes of others. I am currently bedridden because I can't tolerate naloxone. I hurt from my head to my toes including my nuts. It feels like somebody is sticking a knife in my side and twisting it. I was doing perfectly fine for 16 months on Subutex and now because of the actions of a few idiots u think it best to put unnecessary regulations on my Dr that in your opinion doesn't know what he is doing. I have had to quit my job of 1 year because I can't leave my bed because I can't stand up because of the pain the naloxone is causing. Yes naloxone is good for some things but use some common sense about it. It's been glorified in the media for the past year so let's put it in everything is what you idiots think. Believe it or not there are people that actually can't take it and not just because they don't want to. I have been an addict for 20 years which is half my life because I'm 40 now and I have a wife and 3 teenage boys that I would like to be around for them to graduate high school, but if idiots like u keep imposing stupid regulations as these I won't be. Believe it or not we were

in a drug epidemic around 2000 I don't know where the hell all of you all were then, but the addicts have been made you need to work on not putting restrictions on things that are actually helping. The naloxone is just a political measure because buprenorphine can be abused with or without it, most people that has been on prescription meds long as I have don't get high off of anything anyway it's been 4 or 5 years since i did morphine and felt it, I just take my daily buprenorphine dose just to maintain and function no high at all. I just can't get high off of anything. All I want to do is go about my life without having to worry about what everyone else has gone and screwed up. I've been through rehab 2 times it never works I guess my brain is broken. I don't wish this on anyone but please leave the ones of us that have worked so hard to have a functionable life alone. Back to the regulations you do realize all you are doing is setting up to be the biggest illicit drug crisises (heroin) putting all of these regulations on the pain management and the addiction doctors. Please all of you get your head out of each others asses like the governor's and state health commissioner and all the senators and legislators that voted yes on hb2163. Thanks alot

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, April 11, 2017 8:56 AM
To: 'concernedforvaaddicts@gmail.com'
Subject: RE: HB 2163

Dear Ms. Walker:

Thank you for your message.

The Board has received many similar comments and will be reconvening the Regulatory Advisory Panel (RAP) to review this issue and amend the regulations if warranted.

We hope to have it pulled together in early May.

Your message will be shared with the RAP.

Kindest regards,

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

From: Board of Medicine
Sent: Tuesday, April 11, 2017 7:54 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: HB 2163

From: Ashley Walker [mailto:concernedforvaaddicts@gmail.com]
Sent: Monday, April 10, 2017 4:37 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: HB 2163

Doctor Harp,
I am urging you to reconsider adding a documented naloxone allergy to this bill. Make it stricter, make pill counts happen, more drug testing, inspecting the body of IV use. Anything but please do not take away medication from us. There are some people who CAN NOT have naloxone. And there's so people who can't possible live with these allergies everyday. I for one cant, I can't have naloxone, I can't go everyday to the doctor to get my medication, and I can't possibly be pregnant everyday. The samhsa guidelines for a naloxone allergy is to take subutex. Would you tell me if I was allergic to Penicillin to just go ahead and take it, I really don't think you would. So why tell me to take suboxone when I'm allergic to it? I'm afraid I'm running out of options here, I don't want to relapse. But if this bill doesn't change I will have no other option.

The person who takes buprenorphine feels normal, not high. However, the brain thinks it is receiving the problem opioid, so withdrawal symptoms stay away. Buprenorphine also reduces cravings. If cravings continue to be a problem, your doctor will adjust your medication or help you find other ways to reduce them.

You take buprenorphine as a pill that dissolves under the tongue. You do NOT chew or swallow it. There are two forms. **Suboxone®** contains buprenorphine plus another medication called **naloxone**. The naloxone is added to prevent abuse—it brings on withdrawal in people who abuse buprenorphine by injecting it. **Subutex®** contains only buprenorphine. This form is prescribed if you should not take naloxone for any reason, such as if you are allergic to it or are pregnant.

The pill is taken once a day. Over time, the dose interval may stay at once a day or change to every other day.

The main advantages of buprenorphine are:

- You are unlikely to overdose on buprenorphine if you take it properly.
- Buprenorphine is long acting. This means that after an initial period, your doctor may have you take the pill every other day rather than once a day.
- Doctors can prescribe buprenorphine so that you can take doses at home. **Important:** Not all doctors have approval to prescribe this medication, and not all doctors provide counseling for addiction. Also, daily check-in at a treatment center can be helpful to

combination product is injected, the naloxone produces significant attenuation of buprenorphine's effects and may precipitate acute withdrawal.[14] The combination product is designed to be less subject to diversion and injection misuse than the mono-product. For this reason, the combination product is the preferred formulation for all patients, with the exception of pregnant women[15] and those with a demonstrated allergy to naloxone.

Buprenorphine, both as a mono- and as a combination product, has long been available in sublingual tablet form. Newer formulations include a soluble buprenorphine/naloxone film for sublingual or buccal use. The films dissolve more quickly than tablets, an advantage when monitored dose ingestion is indicated.[16]

Two new formulations (Zubsolv sublingual tablets and Bunavail buccal film) provide higher bioavailability of buprenorphine than other formulations. Higher bioavailability means that more buprenorphine enters the bloodstream, allowing for lower doses. For example, one Bunavail 4.2 mg/0.7 mg buccal film provides buprenorphine exposure equivalent to one Suboxone 8 mg/2 mg sublingual tablet;[17] one Zubsolv 5.7 mg/1.4 mg sublingual tablet provides buprenorphine exposure equivalent to one

Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Wednesday, April 05, 2017 9:19 AM
To: Harp, William L. (DHP); Brown, David (DHP)
Subject: FW: Buprenorphine regulations are hurting people that cannot have the combination drug

FYI.

From: Kyle Miles [mailto:Unryl@live.com]
Sent: Tuesday, April 04, 2017 8:40 PM
To: Deschenes, Jennifer (DHP)
Subject: Re: Buprenorphine regulations are hurting people that cannot have the combination drug

Thank you for getting back to me, and I understand regulations but hurting patients for something they cannot control isn't the right way to do things. Ill comment on it via the internet, if I could comment in a public meeting I would but unfortunately Richmond is 5 hours away and I have a hard enough time getting transportation as is. Thank you so much.

From: Deschenes, Jennifer (DHP) <Jennifer.Deschenes@DHP.VIRGINIA.GOV>
Sent: Tuesday, April 4, 2017 7:48 PM
To: Unryl@live.com
Cc: Harp, William L. (DHP); Brown, David (DHP)
Subject: RE: Buprenorphine regulations are hurting people that cannot have the combination drug

Dear Mr. Myles:

Thank you for your email, explaining that you have a documented hypersensitivity/allergy to naloxone. I appreciate your concerns regarding the Board's Emergency Regulations on Buprenorphine Prescribing and the effect the regulations have had on your ability to access the buprenorphine mono-product in tablet form. The Board did consider including an exception to the limitations on prescribing the mono-product for those with a documented allergy or intolerance, but ultimately decided not to include such an exception in the Emergency Regulations. The regulations do allow for prescribing of the mono-product in FDA approved formulations other than tablet form, but I understand your concerns related to the potential costs of such alternate formulations.

The Board is hearing from patients and practitioners on this issue and will carefully consider all comments, as it moves forward on finalizing regulations in this area. I am including a link to the Regulatory Townhall: http://townhall.virginia.gov/L/viewchapter.cfm?chapterid=2929 (look under "Current Actions" and select "Emergency/NOIRA" for links to the regulations and an opportunity to comment by selecting "In Progress" under the "Comment Period" section), so that you can follow the Board's progress as it works on the regulations. You are

encouraged to make public comments on the regulations through Townhall, or by attending any public meetings the Board holds in the future on this issue. Thank you for sharing your concerns.

Virginia Regulatory Town Hall View Chapter

townhall.virginia.gov

Description: Regulations set out provisions for prescribing of opioids for acute or chronic pain management and for prescribing of buprenorphine for addiction treatment.

Kindest regards,

Jennifer L. Deschenes, JD, MS
Deputy Executive Director, Discipline
Virginia Board of Medicine

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463
Phone: 804.367.4462
Fax: 804.527.4429
Email: jennifer.deschenes@dhp.virginia.gov

From: Board of Medicine
Sent: Tuesday, April 04, 2017 10:46 AM

To: Deschenes, Jennifer (DHP)
Subject: FW: Buprenorphine regulations are hurting people that cannot have the combination drug

From: Kyle Miles [mailto:Unryl@live.com]
Sent: Monday, April 03, 2017 9:47 AM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Buprenorphine regulations are hurting people that cannot have the combination drug

Hello,

My name is Kyle, I am a patient that has a documented hypersensitivity/allergy to Naloxone. I cannot have it and have been receiving treatment with Buprenorphine. I can understand where restrictions and such need to be in place but patients with documentation need to be allowed to stay in treatment. Luckly I was seen right before these new regulations were put into effect and I thought at the least I had one more month. I don't understand why patients such as myself will lose treatment pretty much overnight. This is going to hurt some of the patients in your state, and all this does is tie the doctors hands to where he cannot treat said patient anymore. I urge you all to take these patients such as myself into consideration. Patients that have done all the counseling and followed the guidelines, have documentation, and have never failed a urine screen shouldn't lose access to a medication that has helped save their lives. If taken from the abruptly like it will have a drastic effect on their lives. Right now the only alternative I know of Is Probuphine but that treatment costs arount 5 thousand dollars. It is also a restricted program, and most insurance companies will not cover it. I know some of the restrictions have been in the making for a couple years but to outright ban people that cannot have the combination drug wasn't seen coming from anyone. If it was doctors wouldn't have remained treating patients up until the regulations, they were sure that Virginia would do what every other state has done and allow people with a documented hypersensitivity/allergy to remain in treatment. Thank you for your time and consideration, and I hope you all allow these patients to stay in treatment. We have a bad enough problem with street drugs as it is and with patients losing treatment that's where they will turn, and with since they cannot have Naloxone if they were to overdose it would probably end up in them dying.

Yours Sincerely
Kyle

Harp, William L. (DHP)

From: Kyle Miles <unryl@live.com>
Sent: Tuesday, April 11, 2017 11:57 AM
To: Harp, William L. (DHP)
Subject: RE: Lost Buprenorphine Treatment all together

Please do good people are suffering right now. Maybe some of them have found treatment already and the ones that could convert have. Maybe you all can let the pharmacies know its legal for at least a 1 week taper to be filled. Ill ask my doctor to get into contact with you all. No pharmacies will as of this moment though I mean that would at least give these people a little breathing room until you all come to a decision. I know you all mean well and there is an epidemic going on but cutting people out of treatment will only make it worse. Thank you for your time and efforts.

Get Outlook for Android

From: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Sent: Tuesday, April 11, 2017 9:52:30 AM
To: Kyle Miles
Cc: Deschenes, Jennifer (DHP); Oehl, Diane (DBHDS)
Subject: RE: Lost Buprenorphine Treatment all together

Dear Mr. Myles:

You have pointed out at least 2 important issues that the Board's regulations do not address--tapering and intolerance to naloxone.

Your comments will be presented to the Regulatory Advisory Panel.

Thanks,

WLH

From: Kyle Miles [mailto:Unryl@live.com]
Sent: Tuesday, April 11, 2017 1:38 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Re: Lost Buprenorphine Treatment all together

Dear Dr. Harp,

I never thought in a million years the board would make such a bad decision. I am not saying it's all your fault, but when this bill was first proposed and then was amended to give the board of medicine power I thought surely they know some people cannot have it like some of the other states. Restrictions and regulations to help protect the public are one thing but some things hurt people. I was all for the restrictions on prescriptions as long as the people that that cannot have naloxone for whatever reason are included. Some people do have allergies/hypersensitivities to Naloxone. While maybe 5 out of 100 patients an addiction

Harp, William L. (DHP)

From: Kyle Miles <unryl@live.com>
Sent: Wednesday, April 12, 2017 8:41 AM
To: Harp, William L. (DHP)
Subject: RE: Lost Buprenorphine Treatment all together

Can you all at least please inform these doctors and clinics that patients are allowed at least the 1 week taper prescriptipn you mentioned. The pharmacies wont fill them even if a doctor writes it. If you put out an announcement informing people the 1 more week would buy people 1 more week to try and seek treatment else where. Its not an option for me but the one more week would greatly help as i feel like crap and hopefully you all figure this out. Thank you for your time.

Get Outlook for Android

From: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Sent: Tuesday, April 11, 2017 9:52:30 AM
To: Kyle Miles
Cc: Deschenes, Jennifer (DHP); Oehl, Diane (DBHDS)
Subject: RE: Lost Buprenorphine Treatment all together

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Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, April 11, 2017 9:52 AM
To: 'Kyle Miles'
Cc: Deschenes, Jennifer (DHP); Oehl, Diane (DBHDS)
Subject: RE: Lost Buprenorphine Treatment all together

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You have pointed out at least 2 important issues that the Board's regulations do not address--tapering and intolerance to naloxone.

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From: Kyle Miles [mailto:Unryl@live.com]
Sent: Tuesday, April 11, 2017 1:38 AM
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Subject: Re: Lost Buprenorphine Treatment all together

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From: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Sent: Monday, April 10, 2017 10:14 AM
To: Kyle Miles; Oehl, Diane (DBHDS); Deschenes, Jennifer (DHP)
Subject: RE: Lost Buprenorphine Treatment all together

Dear Mr. Miles:

Thank you for your message.

It was not the Board's intention to harm any patients participating in medication-assisted treatment for opioid addiction. The Board wants all patients to get good care. The regulations do require that the treating physician use a naloxone-containing product instead of the mono-product of buprenorphine.

For those patients that do not wish to switch to a naloxone-containing product for whatever reason, the regulations appear to allow a week of mono-product for the process of tapering.

The Board of Medicine has received many comments on the issue of intolerance to naloxone and has voted to reactivate the Regulatory Advisory Panel to review the comments and consider revisions to the regulations.

I hope this is helpful to you.

With kindest regards,

William L. Harp, D

Executive Director

Virginia Board of Medicine

From: Kyle Miles [mailto:Unryl@live.com]
Sent: Sunday, April 09, 2017 12:47 AM
To: Oehl, Diane (DBHDS) <Diane.Oehl@dbhds.virginia.gov>; Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Lost Buprenorphine Treatment all together

Hello,

Hey guys, I wanted to write the both of you. I am a patient in Virginia that has a bad reaction to Naloxone. I had my doctors appointment today for the first time since the ban. I went in there only to find out I cannot be switched to suboxone because my reaction is to bad. My doctor is literally scared to administer it to me because of the tongue and throat swelling so now as of today I have to go without. I have no clue as what to do because the board of medicine tied my doctors hands. So what happens to patients like me, I guess I have to be kicked off overnight? Please guys I'm not making this up. I was getting my life together now I will be forced back into teh streets if I cant find an alternative in a couple days. The patients that were doing great, and actually cannot have it shouldn't lose treatment. I cant afford to go to NC for treatment, I have no transportation and I shouldn't have to. How is it fair Methadone and Suboxone patients get to stay in treatment but because I have something god gave me I'm all of a sudden not worth treating.

Kyle Miles

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Wednesday, April 12, 2017 8:55 AM
To: 'Pamela Sickal'
Subject: RE: Hb 2163 and naloxone allergy

Dear Ms. Sickal:

Thank you for your message.

The Board is going to revisit the issue of naloxone, hopefully in early May.

Your message will be presented to the regulatory panel that will be reviewing this matter.

However, I cannot tell you what the will of the Board will be.

With kindest regards,

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

From: Pamela Sickal [mailto:psickal09@gmail.com]
Sent: Tuesday, April 11, 2017 10:53 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Hb 2163 and naloxone allergy

Dr. Harp,
I emailed the board of medicine last week to express my concern over the newly passed house bill 2163 but I wanted to make sure my email got you personally.
My name is Pamela Sickal and I have been successful in MAT, my doctor even considers me his model patient. I go to my appointments, I go to counseling, I go to meetings, my drug screens are negative I am a stable recovering addict. When I first took suboxone, I broke out in hives, had severe itching and then debilating migraines. My doctor switched me to subutex and all of those adverse reactions went away. Since then I have been on subutex, well until I went to my last appointment and learned that my doctor couldn't legally write me my prescription. So now I have to take benadryl 30 mins before I dose so my reactions aren't so severe. But the benadryl knocks me on my feet and I feel like a zombie. I can't possibly take care of my children and work like that. I've had to call out of work this week for a debilating migraine that would not go away with OTC medications. I can't possibly go to a clinic everyday as the closest to me is over an hour away and I can't switch to methadone because I use to abuse that. I'm at a loss of options on what I can do.
Please reconsider adding naloxone allergies/sensitivity to this bill. I agree we need to stop the Drug epidemic but this bill is only going to make it worse. I saw today that the vets got permission to have buprenorphine back for animals so why can't us humans get it back. Our lives have to be just as important.
Thank you for taking the time to read this.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, April 11, 2017 8:56 AM
To: 'concernedforvaaddicts@gmail.com'
Subject: RE: HB 2163

Dear Ms. Walker:

Thank you for your message.

The Board has received many similar comments and will be reconvening the Regulatory Advisory Panel (RAP) to review this issue and amend the regulations if warranted.

We hope to have it pulled together in early May.

Your message will be shared with the RAP.

Kindest regards,

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

From: Board of Medicine
Sent: Tuesday, April 11, 2017 7:54 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: HB 2163

From: Ashley Walker [mailto:concernedforvaaddicts@gmail.com]
Sent: Monday, April 10, 2017 4:37 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: HB 2163

Doctor Harp,
I am urging you to reconsider adding a documented naloxone allergy to this bill. Make it stricter, make pill counts happen, more drug testing, inspecting the body of IV use. Anything but please do not take away medication from us. There are some people who CAN NOT have naloxone. And there's so people who can't possible live with these allergies everyday. I for one cant, I can't have naloxone, I can't go everyday to the doctor to get my medication, and I can't possibly be pregnant everyday. The samhsa guidelines for a naloxone allergy is to take subutex. Would you tell me if I was allergic to Penicillin to just go ahead and take it, I really don't think you would. So why tell me to take suboxone when I'm allergic to it? I'm afraid I'm running out of options here, I don't want to relapse. But if this bill doesn't change I will have no other option.

Harp, William L. (DHP)

From: Carrie Pearson <tjsmom7112@icloud.com>
Sent: Saturday, April 15, 2017 2:36 PM
To: Board of Medicine; Harp, William L. (DHP)
Subject: Symptoms

This is awful I am suffering VERY BAD from rashes, pulsating in my ears as well as ringing, my limbs are jerking, I feel "confused" in ways and in 9-10 days I've dropped 8 pounds. This is dangerous! Our bodies are having an allergy to naloxone regardless of how much or less we take, our bodies are giving these symptoms to warn us something isn't right and we need to "help" it. We aren't asking for much other than our allergies to be accepted and sympathized with! I have been shivering cold in 80 degree weather while taking suboxone. I've been to the hospital since this happened because well when I take naloxone that's what happens! Please don't force us out of treatment that worked because of the small few abusing it. All states with this law (which IS GOOD) have allergy exceptions! I've never been ashamed of Virginia which is my home state born and raised until now. It truly hurts me as I feel we are being discriminated against. Most of our addictions started from emotional pain from things many couldn't even imagine to endure and with subutex (even ones that CAN tolerate suboxone) we have done very well. Methadone is a harsh route we DONT want to go down, it works for some great however not everyone is the same and buprenorphine works for us! We are willing to have stricter rules as far as pill counts or random drug screens. Take the Abusers prescriptions away, not us doing well on it. This is only going to cause a HUGE heroin epidemic and sadly, death. I never knew why I felt so sick to the point myself and my dying mother believed I was dying as well until it was documented and proven that I DO have a allergy everything changed and I gained weight and completely normal again. Not everyone is the same, not everyone can take the same medications! The FDA even has proof of that (in another email I sent that information) but I am begging you please allow allergy/hypersensitive I am terrified of this allergy.. I am a momma of two, my babies need me and need me to be healthy and there for them! I've been so sick that my almost 5 year old has memorized how to call 911 and explain what is happening if I have a worse reaction.. THAT is sad and shouldn't have to happen! My son was taken to the park daily and for walks, I cannot do that being as sick and weak as I am right now from this allergy I nearly pass out after 5 minutes outside.. I have never had a dirty urine and never did wrong in my program, in fact I am basically a model patient and tapering off because I don't want on this for life however I shouldn't have to suffer in the meantime.. Why will it take weeks of suffering for us because were addicts and admitted that years ago?! Don't you know majority of pain management patients are abusing medication but just because WE admitted openly we had an issue we are to blame?! It's not fair.. I'm not saying ANY of you intentionally caused this but it defiantly wasn't fully thought through.. I am more than willing to have my fiancé drive me to Richmond even and have a meeting with you guys if you'd like! I really just want you, the board and others to understand we are normal people living life and doing normal people things finally but now we have a major set back!! This allergy CAN kill people let alone the ones having to drop out of treatment or doesn't have a doctor on call -- suicide, relapse and overdose CAN AND WILL happen.. This is addiction being dealt with here and it's a very scary but important thing to keep in mind!! All I am asking is some acknowledgement of the information I have given, it's proven by FDA.. This is killing people and pushing them to the streets, which we DONT want that!! Also please research there's been NO proven deaths on buprenorphine alone as far as overdose because it "blocks" others however methadone it has helped many but failed many too in the "euphoric feeling" so giving that as a "alternative" is almost like handing an addict a prescription of Vicodin! Methadone does get some patients high which some do need methadone as subutex/suboxone isn't strong enough but the ones on buprenorphine DONT want to even risk that!! I know of at least 5 people relapsed so this isn't the way to go.. No one can fake a allergy, it's there or it's not! I've taken pictures of mine 20 minutes after dosing.. Again my number is 571-358-7105 if someone would like to discuss ANYTHING PLEASE CALL!! I am willing at this point to do anything to prove we are normal people that deserve to be treated as such.. Yes we used and are "addicts" but we aren't in ACTIVE addiction, we don't get high or abuse it.. The ones abusing is ones not even in the program and just buying from the ridiculous ones who needs to lose treatment not us!! I feel if you sell your meds in anyway you should be cut.. Why can't that happen right? PLEASE I am begging you to allow allergy exception even just for my babies and the other babies watching their parents suffer allergy or worse dropping out of treatment. My kids are almost 5 and the other is 10 months old, I don't

want them to see their momma sick!! If you're allergic to penicillin there's another one that can help in this case subutex is needed.. Subutex was MADE FOR ADDICTION not for pain management or animals sure it helps them too but why take it away from the people it was created for??

iPhone - Carrie Pearson

Harp, William L. (DHP)

From: Board of Medicine
Sent: Monday, April 17, 2017 10:01 AM
To: Harp, William L. (DHP)
Subject: FW: Side effects of naloxone
Attachments: photo 1.JPG; ATT00001.txt; photo 2.PNG; ATT00002.txt

-----Original Message-----
From: Carrie Pearson [mailto:tjsmom7112@icloud.com]
Sent: Tuesday, April 11, 2017 7:39 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Side effects of naloxone

Here's proof from a government website and side effects of naloxone, just SOME of what we are dealing with. It also says "this medicine is not right for everyone DO NOT use if you have had a allergic reaction to naloxone" I'm trying to find all the info I can here to help others understand the suffering and what is at stake here! Sure having regulations is great but not to accept allergies? That's very unsafe with ANY medication. It's okay for pain and animals but not addicts? That's discriminating. We are people too and shouldn't suffer because of our past that we've worked so hard to change and now we have to prove ourselves after already proving hard enough starting treatment! Thank you have a good day.

https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0011328/?report=details

Micromedex Consumer Medication Information.

Published: March 1, 2017

Naloxone (By injection)

nal-OX-one

Treats narcotic overdose in an emergency situation.

Drug classes

Antidote (About this - PubMed Health)

Uses

Uses of This Medicine

Naloxone injection is used to treat an opioid emergency such as an overdose or a possible overdose of a narcotic medicine. Some signsand symptoms of an opioid emergency are breathing problems (which can range from slow or shallow breathing to no breathing), extreme sleepiness, slow heartbeat, or not being able to respond.

This medicine is available only with your doctor's prescription.

Order now (PubMed Health)

How To Use

Injectable

This medicine is given as a shot under your skin or into a muscle.

This medicine comes with patient instructions and a training device. You, your home health caregiver, and family members should read the instructions carefully. Ask your doctor if you have any questions.

Do not use the medicine if it is cloudy, discolored, or has large particles in it.

The autoinjector can be used only on time. Do not remove the red safety guard until you are ready to use it.

This medicine is available in 2 dosage strengths: 0.4 milligram (mg)/0.4 milliliter (mL) autoinjector and 2 mg/0.4mL autoinjector.

To use:

- Inject the medicine into the outer thigh, through clothing, if needed. If you are giving this medicine to a child younger than 1 year of age, pinch the thigh while you give the medicine.
- After you give the first dose to the patient, **get emergency medical help right away**.
- Closely watch the patient after the injection for signs and symptoms of an opioid emergency.
- Give a new injection every 2 to 3 minutes if symptoms return.

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light.

Drugs and Foods to Avoid

Ask your doctor or pharmacist before using any other medicine, including over-the-counter medicines, vitamins, and herbal products.

When Not To Use

Contents

What works?

Learn more about the effects of these drugs. The most reliable research is summed up for you in our featured article.

Featured article »

Things you need to know

Approved drug uses

More information about a drug

Tips about using medicines

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If you're interested in the scientific methods behind systematic reviews, we've now made it easier for you to...

read all...

This medicine is not right for everyone. Do not use it if you had an allergic reaction to naloxone.

Warnings

Tell your doctor if you are pregnant or breastfeeding, or if you have kidney disease, liver disease, or heart disease.

Keep all medicine out of the reach of children. Never share your medicine with anyone.

Possible side effects

Summary More details

Call your doctor right away if you notice any of these side effects:

Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing

Crying more than the usual (in babies)

Diarrhea, nausea, vomiting, stomach cramps

Fast, pounding, or uneven heartbeat, trouble breathing

Fever, runny nose, sneezing, sweating, yawning

Seizures, tremors, feeling restless, nervous, or irritable

If you notice other side effects that you think are caused by this medicine, tell your doctor.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

More side effects of this drug

Brand names include

Evzio, Naloxone HCl Novaplus, Narcan, PremierPro Rx naloxone HCl

There may be other brand names for this medicine.

More detailed version of this drug page

TRUVEN HEALTH ANALYTICS

Truven Health Analytics, an IBM company, Disclaimer

Recent Activity

Turn Off Clear

Naloxone (By injection) PubMed Health

Transfer of buprenorphine into breast milk and calculation of PubMed

Mast cell activation syndrome: a review. PubMed

The differential diagnosis of bigeminal rhythms. PubMed

See more...

Drugs and Foods to Avoid

Ask your doctor or pharmacist before using any other medicine, including over-the-counter medicines, vitamins, and herbal products.

When Not To Use

This medicine is not right for everyone. Do not use it if you had an allergic reaction to naloxone.

Warnings

Tell your doctor if you are pregnant or breastfeeding, or if you have kidney disease, liver disease, or heart disease.

Keep all medicine out of the reach of children. Never share your medicine with anyone.

Possible side effects

any of these side effects:

Allergic reaction: itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing

Crying more than the usual (in babies)

Diarrhea, nausea, vomiting, stomach cramps

Fast, pounding, or uneven heartbeat, trouble breathing

Fever, runny nose, sneezing, sweating, yawning

Seizures, tremors, feeling restless, nervous, or irritable

If you notice other side effects that you think are caused by this medicine, tell your doctor.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

More side effects of this drug

Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Monday, April 24, 2017 2:31 PM
To: Harp, William L. (DHP)
Subject: FW: FW: [EXTERNAL] asking for guidance regarding HB2163

FYI.

From: Shar444561@aol.com [mailto:Shar444561@aol.com]
Sent: Monday, April 24, 2017 2:25 PM
To: Deschenes, Jennifer (DHP)
Subject: Re: FW: [EXTERNAL] asking for guidance regarding HB2163

Jennifer,
Thank you so much for keeping us in mind. I have commented in the town hall discussion online and will see what I can do about attending the panel board on May 15. Was just thinking of writing you yesterday. My daughter is now on a compound with the least amount of Naloxone allowed which was developed by her doctor in conjunction with a pharmacy. Its been a few weeks and she still has nausea, extreme fatigue and the face rash has developed. In addition, the compound is not covered by insurance so she is using her college fund to pay the $300.00 out of pocket on top of paying for her clinic fees which are out of network.
The mandate has certainly made our lives more difficult and I worry about her staying power in terms of tolerating the side effects vs relapsing.
Sharon Thomas

In a message dated 4/24/2017 1:51:21 P.M. US Eastern Daylight Time, Jennifer.Deschenes@DHP.VIRGINIA.GOV writes:

Dear Ms. Thomas:

I wanted to let you know that a regulatory advisory panel of the Board will meet on May 15, 2017 at 9 AM at the Department of Health Professions in the west end of Richmond to consider possible revisions to the buprenorphine regulations (eg, the lack of an exception for illness or allergy).

The address is 9960 Mayland Drive, Henrico, VA 23233. The meeting will be in the 2nd floor conference room. You are welcome to attend the meeting and the Board will accept comments from the public at this meeting. Also, if you are unable to attend, but would still like to have your comments considered, you may send an email or letter to my attention and I will ensure that it is reviewed at the meeting on May 15. Thank you.

Kindest regards,

Jennifer

Harp, William L. (DHP)

From: Board of Medicine
Sent: Wednesday, April 26, 2017 3:14 PM
To: Harp, William L. (DHP)
Subject: FW: STOPPING DRS FROM PRESCIBING A LIFE CHANGING MEDICINE (buprenorphine)

From: Mitchell Dunlow [mailto:mitchelldunlow@gmail.com]
Sent: Tuesday, April 25, 2017 8:51 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: STOPPING DRS FROM PRESCIBING A LIFE CHANGING MEDICINE (buprenorphine)

I could not believe my ears when my DR told he could no longer prescribe me (buprenorphine) for my opiod addiction, I have been taking this medicine for 2 yrs and was down to one 8mg tablet a day.
I have been clean now for 3 yrs, and now thats all over , I do not have insurance (400 month med insutance) and I guess you people really do not care about this problem , allot of legitmet patiets was taking that med . I can not afford 700.00 month to see dr go to 2 groups a month and fill a prescipt of suboxone strips. Know I will have to go back to taking pececent, I will have to go back to that life again, because some assholes setting behind a desk just helped ruin my life and i am sure allot more have been affected fron your disission to remove this cheap and better drug for addiction..

30 day supply of bupre cost 50.00 dollars and 30 day supply of suboxone strips 8 mg cost 470.00 ,if you want to help get that greedy pharm Co to lower the price of this suboxone strips

Harp, William L. (DHP)

From: Board of Medicine
Sent: Tuesday, May 02, 2017 4:01 PM
To: Harp, William L. (DHP)
Subject: FW: What gives you the right?

From: Stephanie Godwin-Brown [mailto:stephanie.godwin.brown@gmail.com]
Sent: Thursday, April 27, 2017 9:08 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Re: What gives you the right?

I'm not sure if I will be able to make it to the 5/15/2017 meeting, but I would like you to know I have been forced to buy Subutex off the street to keep from being sick. So now, I am right back to square one. And just to let you know, all this law did was increase the street value of Subutex. They are now selling for $50 a piece in my area. There is no war on drugs. A war is a struggle between two opposing forces. Unfortunately, the side that claims to be fighting the war is actually contributing to it. I will try to make it to the meeting, if I can, but in all honesty, I don't think it will make a difference. Our government would have to actually care about the welfare of ALL people, not just the ones they deem worthy, in order to see any kind of head way. Addiction does not discriminate. It's not just affecting the poor and lower class. It affects everyone! It's just that people who have money, and power, and status can hide it better. They can also afford the price tags. I am not willing to jeopardize my sobriety, therefore, I will continue to put money into the street subutex. No one is going to make sure I'm ok, except me! If I have learned anything during my active years of addiction, it is that no one is going to fight to save my life, except me.

Thanks again,
Stephanie Brown

On Apr 12, 2017 9:40 AM, "Stephanie Godwin-Brown" <stephanie.godwin.brown@gmail.com> wrote:

I went to my doctor appointment yesterday, only to be told I can no longer receive the meds I have been on for a while because the state of VA thinks they know what is best? I was switched to a medication I have a KNOWN and DOCUMENTED allergy to because I'm not pregnant! So my physician, knowing all the symptoms and side effects I suffer from when I take Suboxone, still wrote me a prescription for it. My only other option was METHADONE! METHADONE? Are you serious? Have ANY of you people ever actually SEEN what methadone does to the body? It stores in the bone marrow and the person taking it becomes highly dependent on it. Better yet, have you ever seen anyone come off of methadone? No, because if you had, you would be ASHAMED of what you are doing! The funniest part is, instead of bringing you down off of it slowly, they gradually increase your dose until you are hooked for life. Now my physician, who knows I have severe allergic reactions to Suboxone, has to write me a medication that will make me even sicker and cause me to be on OTHER meds to control the side effects. Doctors go to school for 8+ years only for politicians to tell him they know better? Why? Because you sit in your nice houses, with all your nice things, and you have no clue what it's like to go through an addiction. Well I am in the loop! You think you are HELPING? What a JOKE! You think someone in the midst of their addiction won't find a way around this law? They will. And guess who will suffer? The unwanted babies that are going to be born to people who are good at getting

pregnant, but not good at being mothers, and the people who are actually trying to stay sober! I was on Suboxone and I stayed sick all the time! Constant migraines (that require migraine meds), swelling in my legs and feet (that requires Lasix for me to be able to walk and take care of my family), rashes on my body and sores on my tongue. There was a reason my doctor switched me to the Subutex. I now realize this is a money racket. Subutex are a third of the cost of Suboxone and they contain naloxone (narcan) which is used to being people back from overdoses! So I haven't took a pain pill or ANY OTHER drug since I was prescribed Subutex but you think I should put another medication in my body that I don't need? That makes sense! Now I have 3 choices, take the Suboxone and deal with an allergic reaction DAILY, withdrawal from the subutex, or go back to looking for opiates. Only time will tell what will happen. I know one thing, if it was up to our government, they would prefer all the addicts just die in the street. When your little scheme blows up in your face, you still won't care, because it doesn't affect you! Funny how that works? The government was the one that allowed all these drugs in, with corrupt politicians, and police officers, and all their ties to the drug mafia years ago when crack and cocaine infiltrated all the lower income cities. That was decades ago, yet I see no dent in the war on drugs. You people set up their on your high horses, preaching about things you have no clue about. If you want to stop people from doing things they shouldn't then require drug screenings at every appointment, require pill counts weekly, so things that will keep people straight. That is what a government that CARES about fixing the issues would do! What you people are doing is unconscionable. What gives you the right to tell people their MD can only write them a prescription for something that will make them sick (Suboxone) or something that will pull them so far into an addictive Hell that they want to die(Methadone)? Because that is the goal, right? Kill off all the addicts and then your war on drugs just disappears? You people have NO CLUE what you have done and it's so obvious that you do not care! Are any of you going to take responsibility for people who have a severe allergic reaction if they don't make it to the Hospital in time, after taking a Suboxone? Or should they tell their families to sue the doctors for malpractice after they are forced to prescribe them something that is less beneficial than what they were on? I have finally got my life back on track just for you people to come along and tell me I was doing TOO good? You will reap what you sow. I am an educated woman, so I know that this email will probably not even be read, and if by chance it is, I'm sure it won't affect you in any way. But? What if I was one of your children? I bet if I was, I would get the medication I need, not something I'm allergic to!

Thanks you for reading (if you did) and for pretending this will email will even matter,
Stephanie Brown

Harp, William L. (DHP)

From: Morton, Colanthia D. (DHP)
Sent: Monday, April 24, 2017 3:49 PM
To: Harp, William L. (DHP)
Subject: FW: New submission from Website Feedback

From: Ly, Mylam (VDH)
Sent: Friday, April 21, 2017 4:30 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: FW: New submission from Website Feedback

Hello,

We received the following message on our website feedback form. Would you be able to assist Tyler Moody?

Mylam Ly

Virginia Department of Health
Work: (804) 864-7263
Mobile: (804) 441-0922

From: Website Feedback
Sent: Friday, April 21, 2017 11:53 AM
To: Ly, Mylam (VDH)
Subject: New submission from Website Feedback

Type of Feedback

General Question or Comment

Name (Optional)

Tyler Moody

Email

wireghostx@gmail.com

Feedback

Dear Virgina Department of Health:

I am writing concerning House Bill 2163, in which the prescription drug Subutex is not to be prescribed without Naloxone. I was surprised that this bill passed and was signed into law. It seems it was bundled with other Bills regarding the epidemic. These other Bills make perfect sense, and will do a lot of good, but this one (HB2163) is terribly detrimental I have been on Subutex for Chronic pain , RLS & Fibromyalgia for a long time originally from Reckitt and Benckiser's trials. From the age of 16, this drug has saved my life, allowing me to accomplish quite a lot, from playing concert violin with the Richmond Philharmonic, to becoming the world's youngest professional Philatelist, to a career in Information Security deploying cutting edge security defenses.
I certainly realize we are in the midst of an opioid epidemic of epic proportion, however; this Bill does nothing to gain ground in resolving this crisis. It has a great potential to make matters much worse, especially for those like myself. Collateral ramifications to chronic pain and illness sufferers will resort in any multitude of reactions, from some having to go on addictive tolerance enhancing painkillers, to drugs on the streets or dark-markets quite possibly and probably resulting in death.
The open distribution of Naloxone for opioid addicts is certainly a great thing (I keep it with me myself & everyone should), however the drug Naloxone can have severely adverse affects on those suffering from chronic pain. House Bill 2163 is going to

have devastating affects on both chronic pain patients and their physicians.
In the past, when fighting these attempts from legislators, I've received back text book replies stating, that they are committed to fighting the opioid epidemic, or diversion crisis. Each time I cringe at the the response, as I know the full facts have not been presented in regard to representation of chronic pain sufferers, and Virginia edges ever closer to draconian laws.
As a sufferer of chronic pain, I would like the opportunity to discuss this, in depth, in front of the VA Senate or House of Delegates, before it begins to wreak havoc on those like me. This Bill must be repealed or amended. It does nothing but harm good people, and will make our epidemic worse. I absolutely do not want to end up on stronger more strictly scheduled, higher tolerance producing and more addictive painkillers
This is the first letter I am writing regarding this Bill, and I intend to contact everyone who voted on it. I can not cease to fight this matter, as it's repercussions could end my life. You are the Virginia Department of Health. Please, I implore you to look into this Bill and Amend it.

Regards,

Tyler Moody
CISO
CEHv9, MS, MCP,
Network Architect & Engineer

OPIOID QUESTIONS AND COMMENTS

1405 Early Street
Charlottesville, VA 22902-6330
March 29, 2017

Virginia Board of Medicine
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

To Whom It May Concern:

This concerns the recent requirement for opioid drug screening. I am copying my various state and federal representatives because I see this as a political matter.

I am a 77-year-old woman dealing with fibromyalgia, osteoarthritis, and psoriatic arthritis among other conditions. Using hydrocodone as well as OTC pain relievers as needed helps me to manage, despite the fact that OTC painkillers are being described more and more as probable causes of heart problems. There are days when I can barely get up in the morning; some days I can manage with acetominophen or naproxen sodium. When it's really bad I use the hydrocodone. Sometimes I take a whole pill, sometimes half. Sometimes I can go several days without it. I also have to put up with occasional mild nausea and gastric side effects (ironically, another new drug is out now to resolve the latter problem). What I find incredibly stupid is that the test looks for a positive outcome; I don't know long the opiate stays in the body but given that I don't always have to take it this means that on my test day I HAVE to take it so that it comes out positive!! Talk about enabling people!

In addition to watching prices rise and drug companies play around with tiers so they can make more money I have to put up with the hassles of calling my doctor's office when I need a new prescription, waiting for the call back, going to pick up the script, going to the pharmacy, and waiting for the medicine. It's also a trial for my doctor as well as the office staff. What'll I do when I can no longer drive? It's bad enough I can't rely on JAUNT anymore because of another stupid regulation at both local hospitals that require one to be picked up by someone one "knows" after being sedated for whatever. The last time I had to undergo this the situation was such a disaster I filed a complaint against UVA Hospital as well as the idiot doctor, so-called, who performed the incomplete procedure. I don't have anyone here except for a couple of friends/acquaintances. I was brought down here in 1995 because of a job change and then I bought a house because I was sent a nephew to take care of. He has since died and I'm stuck with the house which I can't sell because I can't afford to fix it up. I would LOVE to move back to Vermont, a more civilized state, but I find it very hard to do so and will probably end up dying here.

I dare say it's easier to buy a gun!

The cost for hydrocodone (though a generic and yet marked as a tier 3) has sextupled for me this year; I live on +/-$22K per year. Though I get some tax relief from the City I'm still not poor enough for SNAP, and despite the minute COLA rise this year I am actually getting less in social security than last year because of the price increases for Medicare A, B, and C, with a good chunk of most of my yearly expenses being medically related. Adding insult to injury I now have to pay my doctor $45 for the test though I'm going to try and recoup that from Medicare but I doubt it'll do any good. This is unneeded additional stress for me. If I'm lucky I have another ten or so years left and I'd like to live them with less stress and a little more peacefulness.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Thursday, April 06, 2017 5:50 PM
To: 'lauraburijon@yahoo.com'
Subject: RE: questions about new opiate regulations

Dear Dr. Burijon:

The regulations do not specifically speak to the intermittent administration of opioids,

The regulations address acute pain, which is usually one episode of treatment, and chronic pain which anticipates daily medication.

I cannot further interpret the regulations for you, but were there to be a complaint about your "intermittent" care, the Board would look at the regulations and the facts in the case to decide if there was a violation.

I hope this is helpful.

With kindest regards,

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

From: Board of Medicine
Sent: Thursday, March 30, 2017 5:17 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: questions about new opiate regulations

From: Laura Burijon [mailto:lauraburijon@yahoo.com]
Sent: Wednesday, March 22, 2017 2:16 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: questions about new opiate regulations

Hi there! I have 2 questions regarding the new opiate prescribing regulations:

1. How do we reasonably screen the urines of patients who only take controlled substances sporadically? Many patients receive tramadol #30 for 6 months, for example. Is there agreement for monitoring those patients?

2. What is our obligation if we are prescribing only the benzodiazepine, but another doctor is prescribing the narcotic? Would I then be expected to prescribe narcan?

I'd love some literature I can give to patients explaining the proper storage, indications, and efficacy of narcan. I've been asking my patients to bring a family member to appointments as the patient himself would clearly not be the one administering narcan. This part of the new guidelines requires more time and counseling than I expected.

Thank you for your time and consideration,

Laura Burijon MD

"Where sin abounds, Grace much more abounds." Romans 5:20

Harp, William L. (DHP)

From: Wells, Jim <jwells@valleyhealthlink.com>
Sent: Thursday, April 06, 2017 12:20 PM
To: Harp, William L. (DHP)
Subject: RE: [secure]

Absolutely does. Thank you. jim

Jim Wells, R.Ph.
Pharmacy Administrative Director
Director of Cardiopulmonary Services
Warren Memorial Hospital
1000 Shenandoah Avenue
Front Royal, VA 22630
(540) 636-0256

Pharmacy Administrative Director
Page Memorial Hospital
200 Memorial Drive
Luray, Virginia 22835
(540) 743-8029

Mobile: (540) 533-9002

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From: Harp, William L. (DHP) [mailto:William.Harp@DHP.VIRGINIA.GOV]
Sent: Thursday, April 06, 2017 12:17 PM
To: Wells, Jim
Cc: Yeatts, Elaine J. (DHP); Deschenes, Jennifer (DHP)
Subject: RE: [secure]

Dear Mr. Wells:

Thank you for your question.

Tramadol is an opioid, so it is subject to these regulations.

For your question on drug testing and chronic pain, below is what I believe to be the relevant section of the regulation (bolding and underlining added).

I hope this is helpful to you and your patient and family.

Kindest regards,

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

18VAC85-21-100. Opioid therapy for chronic pain.

A. The practitioner shall review the course of pain treatment and any new information about the etiology of the pain and the patient's state of health at least every three months.

B. Continuation of treatment with opioids shall be supported by documentation of continued benefit from such prescribing. If the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

C. Practitioners shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

D. Practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter.

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate healthcare provider, or refer the patient for evaluation for treatment if indicated.

From: Wells, Jim [mailto:jwells@valleyhealthlink.com]
Sent: Thursday, April 06, 2017 11:48 AM
To: Yeatts, Elaine J. (DHP) <Elaine.Yeatts@DHP.VIRGINIA.GOV>
Subject: [secure]

Ms. Yeatts, received a question from a patient's family.....is there any new regulation you are aware of which requires a general Physician/prescriber to urine test a patient on long term Tramadol? Is it possibly that the urine screen is one feature of "certifying the patient has a need for long term prescriptions" or is it possibly one of the elements required to write a long term prescription for a substance? Thank you. NOT EMERGENT. Jim wells

Jim Wells, R.Ph.
Pharmacy Administrative Director
Director of Cardiopulmonary Services
Warren Memorial Hospital
1000 Shenandoah Avenue
Front Royal, VA 22630
(540) 636-0256

Pharmacy Administrative Director

Page Memorial Hospital
200 Memorial Drive
Luray, Virginia 22835
(540) 743-8029

Mobile: (540) 533-9002

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Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, April 04, 2017 11:05 AM
To: 'mkuo@lmgdoctors.com'
Cc: Morton, Colanthia D. (DHP); Deschenes, Jennifer (DHP)
Subject: RE: Question regarding naloxone with the new opioid regulations

Dear Dr. Kuo:

The regulations say that naloxone is to be prescribed to patients in certain circumstances.

How far you go beyond writing the prescription and educating the patient is at your discretion.

I hope this is helpful.

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

From: Board of Medicine
Sent: Tuesday, April 04, 2017 10:36 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: Question regarding naloxone with the new opioid regulations

From: Michael Kuo, MD [mailto:mkuo@lmgdoctors.com]
Sent: Friday, March 31, 2017 9:28 AM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Question regarding naloxone with the new opioid regulations

Good morning,

I had a question about the VA Board of Medicine new opioid regulations. We are prescribing Narcan (naloxone) in specific circumstances to patients as outlined by the new regulations. I've noticed that some insurance companies are not covering the medication. How far does our office need to go to help the patient obtain the medication?

Thank you for your help!

Michael

Michael Kuo, MD
Loudoun Spine and Rehabilitation
224D Cornwall Street, NW
Suite 202
Leesburg, VA 20176
Office 703-443-8110

Harp, William L. (DHP)

From: Morton, Colanthia D. (DHP)
Sent: Wednesday, April 12, 2017 5:27 PM
To: Harp, William L. (DHP)
Subject: Voicemail message - Schleicher

1- 3/31 at 3:26pm
Richard ~~Schleicher~~ (SP?) SCHUSHER
Needs clarification on the new regs
540-986-6153

Colanthia Morton Opher
Operations Manager
Virginia Board of Medicine
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
☎ 804.367.4558
804.527.4463
coco.morton@dhp.virginia.gov

SUBUTEX FOR CHRONIC PAIN

*** NOTE NEW PHONE CONTACT***757-316-5707

From: Williams, Cindy
Sent: Tuesday, April 25, 2017 6:58 AM
To: 'medbd@dhp.virginia.gov' <medbd@dhp.virginia.gov>
Subject: clarification on BOM emergency regulations on opioid prescribing

Good morning,

I am working with our medical group on educating all providers on the emergency regulation on opioid prescribing. In rolling out the regulation, some questions have come up. If you can provide guidance, I will incorporate into future educational efforts.

1. For surgical patients that need acute pain management for more than 14 days after the immediate perioperative period, is the provider then limited to a maximum of 7 days per prescription.
2. For patients needing acute pain management (both surgical and non-surgical) past the specified maximum day supply (7 or 14 day), does the patient need to be seen in person, or can the reassessment be via a structured process via phone.

Thank you

Cindy Williams, B.S.Pharm, FASHP
Vice President/Chief Pharmacy Officer
Riverside Health System
856 J Clyde Morris Blvd, Suite C
Newport News, VA
*** NOTE NEW PHONE CONTACT***757-316-5707

Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Monday, April 10, 2017 5:30 PM
To: Harp, William L. (DHP)
Subject: FW: Questions regarding directive regarding Narcan

Please double check my answers below.

From: Teresa B. Reed [mailto:treed@selmamed.com]
Sent: Friday, April 07, 2017 2:32 PM
To: Board of Medicine
Subject: Questions regarding directive regarding Narcan

I'm from Selma Medical Associates in Winchester Va. I spoke with someone last week who recommended that any questions regarding Narcan be forwarded for an information sheet that is being created.

-If a patient is taking PRN opiates and benzo's does Narcan need to be prescribed (patient does not use prn meds consistently?

YES, see below excerpt from the Regs.

18VAC85-21-40. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

… 3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

-We have found that the Narcan being dispensed sometimes is syringes and a vial of medication other times it is an auto injector of Narcan. It depends on what the insurance company pays for. What form of Narcan do you recommend?

The Board has not taken a position on the form of Narcan that should be prescribed. The Regs simply state that "Naloxone shall be prescribed."

-What is our responsibility if the patient is self pay or their insurance will not cover the Narcan?

The Regs require that Naloxone be prescribed. It is the patient's decision as to whether he will fill the prescription.

-Should Tramadol be included even though it is a schedule 3?

Tramadol is an opioid.

-What do we do if the patient does not choose to fill the Narcan prescription not refill narcotics?

The Regs require that the Narcan be prescribed. When prescribing the Narcan, the practitioner has an opportunity to educate the patient on the dangers of taking narcotics (dangers to the patient, and to potential family members who may accidentally ingest the narcotics), and the potential life-saving benefit of having Narcan on hand in the case of an accidental overdose. The Regs do not require that the practitioner refuse to refill the patient's narcotics if the patient

elects not to fill the Narcan. Again, if the patient refuses to fill the prescription, the practitioner might want to discuss the risks and benefits of Narcan and document that such a discussion occurred in the patient's medical record, but note that the patient refused and indicate the patient's reason for refusal.

-How often should the Narcan be refilled?

There is no requirement for refills. It is expected that the Narcan would have an expiration date, and so the practitioner might wish to issue a refill on or around the date of expiration.

-Is the prescribing of Narcan for any patient on benzo's and opiates or a patient on benzo's and opiates and exceeds 120 MME/day?

Please see above excerpt from Regs. Any patient who is receiving benzos and opiates concomitantly should be prescribed Narcan. Any patient who is only receiving opioids, but in a dosage that exceeds 120MME/day, should be prescribed Narcan.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Thursday, April 13, 2017 4:16 PM
To: 'Stephen Heretick'
Subject: RE: Prescribing Narcan Outpatient

Steve:

Essentially the same language is found in both sections—ACUTE PAIN and again in CHRONIC PAIN.

Bolding and highlighting added below.

Hope this helps.

WLH

18VAC85-21-40. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

1. A prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record. This shall also apply to prescriptions of a controlled substance containing an opioid upon discharge from an emergency department.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

18VAC85-21-70. Treatment of chronic pain with opioids.

A. Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.

B. In initiating and treating with an opioid, the practitioner shall:

1. Carefully consider and document in the medical record the reasons to exceed 50 MME/day;

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Prescribe naloxone for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present; and

From: Stephen Heretick [mailto:steve@hereticklaw.com]
Sent: Thursday, April 13, 2017 4:02 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: Prescribing Narcan Outpatient

Dr. H—

A follow up question, if you can offer a little further assistance or guidance. Please see below.

It would seem to me that a side prescription for Narcan is a sound practice anytime an opiate is ordered in conjunction with a benzo, regardless of whether the pain to be addressed is acute or chronic. Frankly, it would seem to me that the danger is more pronounced in cases of chronic pain, where a patient may have less ongoing experience with the drug combination and may be more prone to over-medicate in response.

Thanks!

Steve

Stephen E. Heretick, Esquire
715 Loudoun Avenue
Portsmouth, Virginia 23707
(757) 397-9923
(757) 397-9925 (facsimile)
Steve@Hereticklaw.com

From: Obermeyer, Robert MD [mailto:robert.obermeyer@chkd.org]
Sent: Thursday, April 13, 2017 3:50 PM
To: Stephen Heretick <steve@hereticklaw.com>
Subject: Re: Prescribing Narcan Outpatient

Steve
Thank you for the rapid response!
I am sure you have been right more than once today!

There has been a debate in our practice about this because the regs didn't seem to specify that narcan was required by law if the narcotic was for acute postop pain when combined with benzo's. Some of us are reading this regulation to mean Narcan is required by law only if the narcotic is being prescribed for chronic pain and combined with benzo's.

Can you please ask Dr. Harp about this minor but important distinction?

I know the easy answer seems to be to just prescribe Narcan but there other factors that play into this - extra work, drug cost, confusion for the family, drug availability, etc.

Of course, we want all of our patients to be safe, prevent addiction, and we want to be law abiding providers.

Thank you again. I promise to let it go after this.

Bob

Robert J. Obermeyer, MD, FACS, FAAP
Pediatric Surgery
CHKD

On Apr 13, 2017, at 2:46 PM, Stephen Heretick <steve@hereticklaw.com> wrote:

> Dr. Obermeyer—
>
> It appears that, for the first time today, I was actually right. Please see the comments below from Dr. Harp. I hope this helps!
>
> As always, if I can assist you in any possible way, please don't hesitate to let me know.
>
> Steve
>
> Stephen E. Heretick, Esquire
> 715 Loudoun Avenue
> Portsmouth, Virginia 23707
> (757) 397-9923
> (757) 397-9925 (facsimile)
> Steve@Hereticklaw.com
>
> **From:** Harp, William L. (DHP) [mailto:William.Harp@DHP.VIRGINIA.GOV]
> **Sent:** Thursday, April 13, 2017 2:39 PM
> **To:** Stephen Heretick <steve@hereticklaw.com>
> **Subject:** RE: Prescribing Narcan Outpatient
>
> Steve:
>
> Well, you're right.
>
> That's what the regulations say; presence of a benzodiazepine requires a prescription for naloxone.
>
> And Board staff cannot advise anyone differently than what the regs say.
>
> However, we are keenly aware that these regs do not fit everyone's style of practice.
>
> We've had many more comments about the buprenorphine regs than the pain regs.
>
> We're going to reconvene the Regulatory Advisory Panel in May to review the regs and make revisions if deemed necessary.
>
> Hope this helps.
>
> Glad to hear your son is doing well!

WLH

From: Stephen Heretick [mailto:steve@hereticklaw.com]
Sent: Thursday, April 13, 2017 2:27 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: Prescribing Narcan Outpatient

Dr. H—

I received this inquiry from Dr. Robert Obermeyer, the surgeon who saved my son's life last year. I think the answer to his question is yes, but I wanted to run it past the pros for certainty.

Thanks!

Steve

Stephen E. Heretick, Esquire
715 Loudoun Avenue
Portsmouth, Virginia 23707
(757) 397-9923
(757) 397-9925 (facsimile)
Steve@Hereticklaw.com

From: Obermeyer, Robert MD [mailto:robert.obermeyer@chkd.org]
Sent: Thursday, April 13, 2017 1:54 PM
To: Stephen Heretick <steve@hereticklaw.com>
Subject: Fwd: Prescribing Narcan Outpatient

I hope all is well with you and your family! I hear Stephenson is doing great which makes me really happy.

I was hoping you could provide me with some guidance on whether we need to legally send our postop surgery patients home with Narcan if we give them a 2 week course of narcotics (<50MME/d) along with a prescription for Ativan (benzodiazepine) and Robaxin (muscle relaxant). This combo has worked great for pain control after Nuss chest wall reconstruction (which is painful) for over 10 years without a single overdose in over 1000 patients. Also, I don't know of any drug seeking behavior in our patients.

I sent this question to the board via the email link and I am waiting for a response.

I would really appreciate any guidance here at CHKD

My best,
Bob

Robert J. Obermeyer, MD, FACS, FAAP
Pediatric Surgery
CHKD

Begin forwarded message:

From: "Obermeyer, Robert MD" <robert.obermeyer@chkd.org>
Date: April 12, 2017 at 7:35:24 PM EDT
To: "Chicella, Michael" <Michael.Chicella@CHKD.ORG>
Cc: "Robinson, Jim" <James.Robinson@CHKD.ORG>, "Frantz, Frazier W" <Frazier.Frantz@chkd.org>
Subject: FW: Prescribing Narcan Outpatient

We typically only send patients home with a 2 week course... but since we send patients home with **Hydrocodone, Ativan, and Robaxin**
I have two questions

1) Mike: Do you think it would be safer for us to send them home with Narcan?
2) Jim: The VA law as published on the website (not the attached limited brochure) is not clear to me and I wonder if it is stating that we MUST send them home with Narcan.

Please help us with this medico-legal question.
Thank you,
Bob

From: Stout, Samantha
Sent: Wednesday, April 12, 2017 11:07 AM
To: Wiltshire, Amanda (Mandi); Soroka, Amanda P; Fike, Callan M; Kern, Stepfanie; Obermeyer, Robert MD
Subject: FW: Prescribing Narcan Outpatient

Here is an update from Mike in the PICU and his thoughts on sending kids home with narcan.

Samantha R Stout, MSN, CPNP
Pediatric Surgery and Trauma
Children's Hospital of the King's Daughters
601 Children's Ln
Norfolk, VA 23507
Phone: 757-668-9526
Email: Samantha.Stout@chkd.org

From: Chicella, Michael
Sent: Tuesday, April 11, 2017 1:06 PM
To: Stout, Samantha
Subject: RE: Prescribing Narcan Outpatient

Sorry forgot the attachments!

Mike Chicella, Pharm.D., BCPPS, FPPAG
Children's Hospital of The King's Daughters
Department of Pharmacy
Norfolk, VA

From: Chicella, Michael
Sent: Tuesday, April 11, 2017 1:05 PM
To: Stout, Samantha
Subject: RE: Prescribing Narcan Outpatient

A couple of thoughts:

1) I would think the pectus patients fall under the "acute pain" guidelines. The benzodiazepine combination only comes into play if it is for "chronic pain." I attached a copy of the letter to this.
2) You only need to prescribe naloxone if the amount of opioid exceeds 120mg of morphine (similar to 120mg of hydrocodone a day or 80mg of oxycodone a day). If you prescribe hydrocodone 10mg every 6 hours, that is only 40mg morphine equivalents and should not require naloxone. I attached a copy of the CDC calculator info to this.
3) There is a program called the REVIVE program. This includes a brochure for the patients. I have attached a copy. The guidelines lead me to believe the brochure and the education is being done by the outpatient pharmacies. Having said that, when I pick up prescriptions the pharmacist never talks to me, so I don't know how much education is being done...

Hope it helps.... Let me know if you need anything else.
Mike

Mike Chicella, Pharm.D., BCPPS, FPPAG
Children's Hospital of The King's Daughters
Department of Pharmacy
Norfolk, VA

From: Stout, Samantha
Sent: Thursday, April 06, 2017 2:10 PM
To: Chicella, Michael
Subject: Prescribing Narcan Outpatient

Michael,

We were reviewing the new laws when it comes to prescribing narcotics and we had a couple of questions regarding prescribing narcan for outpatient use that I was wondering if you could possibly help us with. The requirements now state that we are required to prescribe narcan if we send home a patient with both a benzo and a narcotic which typically only relates to our pectus patients and the occasional trauma patient if they had an ortho procedure. When it comes to writing the prescription I am reading from UptoDate that it would be 2 or 4mg intranasal, 1 spray and can be repeated every 2-3 min until medical assistance arrives.

Based on what UptoDate states it sounds like there will need to be a lot of teaching about the drug and I would assume this would be done by pharmacy, but outpatient when they fill the script? The other thing is with our pectus patients they typically have their medications filled out here at the farm fresh pharmacy. So am I right to assume they would do teaching down there? Also do you know how easily accessible this drug is to get at pharmacies?

None of us are familiar with prescribing this med either so we wanted to make sure that we're prescribing what is appropriate, providing the appropriate teaching and whether or not this drug will be easy to get when filled.

Any insight would help!
Thanks,

Samantha R Stout, MSN, CPNP
Pediatric Surgery and Trauma
Children's Hospital of the King's Daughters

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Monday, April 24, 2017 1:19 PM
To: 'robert.obermeyer@ckhd.org'
Cc: Morton, Colanthia D. (DHP)
Subject: RE: question

Dear Dr. Obermeyer:

Thank you for your question.

As the regulations currently stand, the answer to your question is YES.

#3 below does not read AND, but rather reads OR for the scenarios listed in #3.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

I hope this is helpful.

With kindest regards,

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

From: Morton, Colanthia D. (DHP)
Sent: Monday, April 24, 2017 12:51 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: question

From: Board of Medicine
Sent: Monday, April 24, 2017 12:20 PM
To: Morton, Colanthia D. (DHP) <CoCo.Morton@dhp.virginia.gov>
Subject: FW: question

From: Obermeyer, Robert MD [mailto:robert.obermeyer@chkd.org]
Sent: Wednesday, April 12, 2017 7:48 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: question

We have some patients that undergo orthopedic surgery due to trauma or elective surgery with significant pain and muscle spasms.
If I send a patient like this home from the hospital after surgery with acute pain management that includes a two week course of hydrocodone (<50 MME/day) along with Ativan (benzo) and Robxin (muscle relaxant), do I legally have to send them home with Narcan?
I know it may be safer, but I just can't seem to get a clear answer with regards to the law.

Thank you very much,
Dr. Robert J. Obermeyer
Pediatric Surgery
CHKD

Harp, William L. (DHP)

From: Morton, Colanthia D. (DHP)
Sent: Wednesday, April 12, 2017 5:04 PM
To: Harp, William L. (DHP)
Subject: Voicemail - Waxman

Otto Waxman, Stoney Creek Pharmacy
Questions about new regs
434-246-5191

SUBUTEX
OFF-LABEL FOR PAIN

Colanthia Morton Opher
Operations Manager
Virginia Board of Medicine
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
☎ 804.367.4558
804.527.4463
coco.morton@dhp.virginia.gov

Leroy Moore, Jr.
101 Jordan Drive
Hampton, VA. 23666
C: 757-508-0840, H: 757-826-7717

APR 14 2017
DHP

04/10717

Virginia Board of Medicine
Executive Director
9960 Mayland Drive, Suite 300
Henrico, VA 23233

APR 14 '17 11:47AM

Attn: Dr. William L. Harper, MD

Dear Sir:

I am a citizen living in the commonwealth of Virginia with a concern with the recent regulation on Opioids Prescribing and Bupenorphine.

I am a patient that suffers from acute chronic peripheral neuropathy feet pain, low-back pain, hand wrist extremities pains and leg pains. This pain is throbbing; shooting and burning a great deal of the time, and worsen its peak with changes in weather conditions and lying down.

I have lived and tolerated this condition for 17 years with the well managed and controls of medications. I have been treated with the Opioids. Fentanyl 50 mcg /hand Percocet 7.5-325 for breakthrough pains. During these years I have lived a very fulfilling and productive life and have a quality lifestyle. During this time I followed the pain management doctor's directions and have no apparent addiction problems.

My present pain management doctor advised me some time ago that this promulgated regulation day may come which is now a reality. My doctor pain management doctor (Jeremy Hoff, DO) has recently tried a procedure (Spinal Cord Stimulator Trial) to control the chronic pain and wean me off the Opioids. This neurostimulation system was a failure for me. ***The Fentanyl, 50 mcg/h seem to be the only medians that seem to control my pains.*** I have been prescribed doses of 25 mcg and 75 mcg, along with Morphine, Lyrcia and others in its class. Where I am with respect to doses is where I am comfortable with and want to remain at this level. I have been advised that my current dose will have to be reduced to approximately one-half of the current to be in compliance with the new MME regulations.

The purpose of this letter is to request that my current (MME) dose of Fentanyl 50 mcg/h and Percocet 7.5-325 be assign to me due to extenuating circumstances, 17 years of continuous use with pains that is tolerable. Please exempt me from the 120 MME/day rule. I don't want to be one of the persons looking for narcotics outside the medical system-on-line or the streets.

Thank you for this consideration.

Leroy Moore, Jr.
CC:
Jeremy Hoff, DO
730 Thimble shoals Blvd
Newport News, VA 23606

Harp, William L. (DHP)

From: Morton, Colanthia D. (DHP)
Sent: Monday, April 24, 2017 3:41 PM
To: Harp, William L. (DHP)
Subject: FW: 18 VAC 85-21-10 et seq. ... Error in "Prescriber Regulations Guidelines"

From: Board of Medicine
Sent: Monday, April 24, 2017 12:25 PM
To: Morton, Colanthia D. (DHP) <CoCo.Morton@dhp.virginia.gov>
Subject: FW: 18 VAC 85-21-10 et seq. ... Error in "Prescriber Regulations Guidelines"

From: Tom Small [mailto:njobvu007@gmail.com]
Sent: Sunday, April 23, 2017 7:17 AM
To: PMP (DHP) <PMP@DHP.VIRGINIA.GOV>; healthpolicy@msv.org; Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Re: 18 VAC 85-21-10 et seq. ... Error in "Prescriber Regulations Guidelines"

I received a response from Mr. Orr at Virginia's Prescription Monitoring Program indicating the subject regulations are owned by the Board of Medicine. The following update corrects a misstatement I made in the original email.

Information provided to me by an employee was incorrect. I have spoken directly to my doctor and he IS a pain management specialist, resolving my particular situation.

While this new information resolves my immediate issue, it does not address the discrepancy between the "Regulations" and "Guidelines". I look forward to hearing from the Board of Mecicine on this matter.

Respectfully,
Tom Small
A Severe Chronic Pain Sufferer

On Apr 19, 2017 4:38 PM, "Tom Small" <njobvu007@gmail.com> wrote:

Please note the incongruity between the REGULATIONS and the GUIDELINES. The discrepancy in the GUIDELINES makes the GUIDELINES MUCH more stringent than the REGULATIONS.

PRESCRIBER REGULATIONS GUIDELINES
New Requirements for Treating Chronic Pain
Step 3

- >120 MME/day, document reasonable justification in the medical record AND refer to or consult with a pain management specialist

REGULATIONS

Part III. Management of Chronic Pain

18VAC85-21-70 Treatment of chronic pain with opioids

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses OR refer to or consult with a pain management specialist.

I think you must agree there is a HUGE difference between these two statements.

I have had to use opioid pain medications for over a decade for severe cervical, thoracic and lumbar spine pain. My "pain management doctor" with Sheltering Arms "pain management clinic" is in the process of removing most of my pain medications because his medical degree is not as a pain management specialist. I have a fully documented history of physical therapy, scores of spinal injections, RFA, and trigger point injections. I even tried (unsuccessfully) to have a spinal stimulator installed. The only thing that has helped with pai management has been opioids medications. I have been told I must go to a pain management specialist to continue with opioids in excess of 120MME/day.

Honestly, I feel like a criminal. Nobody wishes my pain could be managed without opiods more than me but history has proven that currently it is the only method that enables me to play with me grand-children, baby sit when needed, travel toTexas to see my daughter and other grandchild. This ability to somewhat function in my life is being taken awy.

Apparently, my doctor is reading the AND and not the OR.

Respectfully,

A Chronic Severe Pain Sufferer

Harp, William L. (DHP)

From: Richard Wood <rick@solusinc.com>
Sent: Wednesday, April 26, 2017 11:08 AM
To: Board of Medicine; Harp, William L. (DHP)
Cc: Rick Wood; idnas44@cox.net
Subject: Emergency Regulations 18VAC85-21-10 through 18VAC85-21-170
Attachments: Sandra VA Board LtrApril 24.docx; Sandra VA Board LtrApril 24.pdf

Dr. Harp and Members of the Virginia Board of Medicine;

We request the Virginia Board of Medicine amend the subject regulations to further clarify and define appropriate extenuating circumstances related to the use of opioids and benzodiazepines by patients with severe chronic illnesses and health histories that require the use of both opioids and benzodiazepines to treat their chronic illnesses, improve their a quality of life, and increase their life expectancy.

Attached are word and pdf docs of a signed letter we have mailed to the Virginia Board of Medicine regarding the subject regulation. Please feel free to rwach out to us if you have any questions or would like additonal information.

Regards

Sandra and Richard Wood
754 Suffolk Lane
Virginia Beach, VA
23452
757-486-3570
richard.wood@solusinc.com
idnas44@cox.net

Sandra and Richard Wood
754 Suffolk Lane
Virginia Beach, VA 23452

April 26, 2017

Virginia Board of Medicine
Executive Director; William L. Harp, M.D.
9960 Maryland Drive
Suite 300
Richmond, VA 23233

Subject: Emergency Regulations 18VAC85-21-10 through 18VAC85-21-170

Dr. Harp and Members of the Virginia Board of Medicine;

We request the Virginia Board of Medicine amend the subject regulations to further clarify and define appropriate extenuating circumstances related to the use of opioids and benzodiazepines by patients with severe chronic illnesses and health histories that require the use of both opioids and benzodiazepines to treat their chronic illnesses, improve their a quality of life, and increase their life expectancy.

We are retired and live a quiet life in Virginia Beach, Virginia. I am affected by several chronic conditions and have been classified by the State of Virginia and the federal government as fully disabled. My husband, Richard, manages my medication to ensure its safe and proper use as directed by my treating physicians.

I am being adversely affected by the subject regulations. The negative impact is a result of actions by my treating physicians in response to the subject regulations. Their reaction may be related to the lack clarity on "appropriate extenuating circumstances" in addition it is our observation that their concern is related to their liability implied in the regulations. Below are details of my medical diagnosis, treatment history, and medication management. In closing we have provided several recommended revisions to the subject regulations.

I am a retired Virginia Beach elementary school teacher who was diagnosed with Bi-Polar and anxiety disorder in 1986, the illness progressed and in 1998 it was determined by the State of Virginia and the federal government I was 100% permanently disabled resulting in my retirement from teaching. In 2011 I was diagnosed with an auto-immune disorder that transitions in and out of remission.

When the disorder is active I am in severe pain and suffers with exhaustion. In 2012 I was diagnosed with arthritis of the spine which produces severe neck and lower back pain at random intervals. Most recently in 2015 I was diagnosed with dementia that may be the early stages of Alzheimer. The treating physicians have defined all of these illnesses as "chronic". Physicians in the appropriate field of medicine manage my treatment for each illness. All of my treating physicians are provided a full record of my illnesses and treatments. Our family doctor is at the center of my treatment regiment and directly manages the long-term care related to the chronic auto-immune and spine arthritis. Specialists in the associated fields manage my treatment for the chronic psychological illnesses.

I am prescribed Lamictal, Effexor and Xanax for the treatment of Bi-polar and Anxiety disorder. For the management of severe pain and associated symptoms related to an auto-immune illness and arthritis of the spine our family doctor prescribes Prednisone, Hydroxyzine, Norco and Cyclobenzaprine. We keep an emergency supply of these medications at home. Promethazine is also available at home to treat side effects from the other medications. An additional medication used for pain is Tylenol. I average 3 pills a week of Hydroxyzine, Norco (5/325) and Cyclobenzaprine. The need for an emergency supply is to allow immediate treatment when the pain flares. The alternative would be at least a 48-72 hour delay to; request the medication, drive to the doctors office to pick up the script, drop the Rx at the pharmacy, and pick up the Rx. This is not rationale or feasible in our case. When the need arises my I am unable to leave the house and my husband can not leave the house due to my other chronic illnesses.

The complexity of my illnesses and the proper use of medication precludes me from having direct access. To ensure all of my medications are used safely and properly my husband controls access and dispenses these in accordance with physician instructions. He takes great care is taken to ensure Xanax and Effexor are not taken within a 6-hour window in which Norco and Cyclobenzaprine were taken. Norco and Cyclobenzaprine are used only if Predisone does not control the flare-up of my auto-immune illness. Norco and Cyclobenzaprine are used only if Tylenol in combination with heat/cold compresses and analgesic ointments are ineffective in relieving my pain.

Over the years of treatment I have been diligent in working with my physicians for a replacement pain medication. I have repeatedly attempted to replace the Norco with other pain medications and treatments, such as anticonvulsant pain medications (Lyrica and Nuerontin), prescription NSAIDs (Celebrex) and I have had steroid injections. However these have not proven effective and/or have negatively affected my Bi-Polar medication.

Despite our best practices to minimize my use of pain medications my physicians are indicating they will either stop the Norco or Xanax. If either would occur I

would suffer greatly. Failing to control my pain would greatly aggravate my mental state and altering my anxiety and mood treatment regiment would aggravate my ability to manage pain. These actions would be extreme measures, especially in light of the fact of the minimal Norco dosage levels I take and the stringent procedures we follow. We believe that my situation is an extenuating circumstance and any change to my medications would negatively impact my quality of life and life expectancy. These observations are supported by published National and State data show on my quality of life and life expectancy. In contrast National and State data show no impact on my quality of life and life expectancy if I continue with my current treatment approach.

Recommended Revisions:
We urge additional clarification to the statement "extenuating circumstance" with examples and supporting evidence for real life cases such as mine. The Board should take into account the impact of mental illness and other chronic conditions that govern the lives and life expectancy of individuals. Below in *underlined italic text* are several suggested revisions.

18VAC85-21-10. Applicability.
A. This chapter shall apply to doctors of medicine, osteopathic medicine, and podiatry and to physician assistants.
B. This chapter shall not apply to:
1. The treatment of acute or chronic pain related to (i) cancer, (ii) a patient in hospice care, or (iii) a patient in palliative care; *(iv) a fully disabled patient with multiple chronic medical diagnosis where each illness has a cause of death rate 5X greater than for opioid use.*
2. The treatment of acute or chronic pain during an inpatient hospital admission or in a nursing home or an assisted living facility that uses a sole source pharmacy; or *is fully disabled and treated at home by a family member under the oversight of the prescribing physicians; or*
3. A patient enrolled in a clinical trial as authorized by state or federal law.

18VAC85-21-70. Treatment of chronic pain with opioids.
A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.
B. In initiating and treating with an opioid, the practitioner shall:
1. Carefully consider and document in the medical record the reasons to exceed 50 MME/day;
2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.
3. Prescribe naloxone for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present; and

4. Document the rationale to continue opioid therapy every three months.
C. Buprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose.
D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, 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. *Extenuating circumstances include multiple life shortening permanent chronic illnesses that require support and assistance from another person.*
E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation and treatment if indicated.

We appreciate the opportunity to assist the State in improving these regulations and welcome modifications to the subject regulations that recognize the diversity of medical challenges faced each day in an effort to improve the quality of life and extend the life of all residents.

Please feel free to contact us for additional information.

Respectfully,

Sandra Wood

Richard Wood

754 Suffolk Lane
Virginia Beach, VA 23452
(757) 486-0316
rick@solusinc.com
idnas44@cox.net

Harp, William L. (DHP)

From:	Board of Medicine
Sent:	Wednesday, April 26, 2017 3:14 PM
To:	Harp, William L. (DHP)
Subject:	FW: Narcan Prescriptions
Attachments:	NaloxoneProtocolForPharmacists.pdf

From: David Jacobson [mailto:d.jacobson3@verizon.net]
Sent: Tuesday, April 25, 2017 12:26 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Narcan Prescriptions

Pain management physician wrote a prescription for Narcan, sent it to CVS electronically and then told us about it. Physician said he's required to write the prescription now for patients taking opioids, doesn't know if we actually have to fill it. Do we have to fill it or can we treat as a standing order that's good for two years (see #3 in attachment)? Dose of opioids is low and overdose possibility minimal.

Thanks for your help.

David Jacobson for the patient and his wife Linda Vansag

Harp, William L. (DHP)

From: Yeatts, Elaine J. (DHP)
Sent: Wednesday, April 12, 2017 2:04 PM
To: Harp, William L. (DHP)
Subject: RE: constituent call- Jennifer Cornell 540-333-9390

Thanks so much

From: Harp, William L. (DHP)
Sent: Wednesday, April 12, 2017 2:04 PM
To: Yeatts, Elaine J. (DHP) <Elaine.Yeatts@DHP.VIRGINIA.GOV>
Subject: RE: constituent call- Jennifer Cornell 540-333-9390

Elaine:

I spoke with Ms. Cornell.

She provided the background that she has had 10 surgeries over the years and has other medical problems. She has taken oxycodone or some other opioid analgesic for 30 years.

At her last visit with her doctor, he told her that Gov. McAuliffe and the DEA were trying to get all patients off opioids. Her doctor said his understanding was that everyone would have to be switched to Suboxone.

I let her speak for 15 minutes or so, and then asked, "Have you read the regulations?" I suggested that she read them and take them on her next visit to her doctor so they can discuss and understand what the regulations require. They do not require everyone to stop their pain medications, and they do not require everyone to take Suboxone.

She thanked me for the call. She said she needed the regulations sent in hard copy, and they are being put in the mail as I type this.

Hope this helps,

Bill

From: Yeatts, Elaine J. (DHP)
Sent: Wednesday, April 12, 2017 12:00 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: constituent call- Jennifer Cornell 540-333-9390

Bill – can you please call her?

From: Ahern, Judith (GOV)
Sent: Wednesday, April 12, 2017 11:11 AM
To: Yeatts, Elaine J. (DHP) <Elaine.Yeatts@DHP.VIRGINIA.GOV>
Subject: constituent call- Jennifer Cornell 540-333-9390

Commonwealth of Virginia

REGULATIONS

GOVERNING PRESCRIBING OPIOIDS AND BUPRENORPHINE

AMENDMENTS RECOMMENDED BY THE REGULATORY ADVISORY PANEL

9960 Mayland Drive, Suite 300
Henrico, VA 23233-2463

(804) 367-4600 (TEL)
(804) 527-4426 (FAX)
email: medbd@dhp.virginia.gov

TABLE OF CONTENTS

Part I. General Provisions.

18VAC85-21-10. Applicability.

A. This chapter shall apply to doctors of medicine, osteopathic medicine, and podiatry and to physician assistants.

B. This chapter shall not apply to:

1. The treatment of acute or chronic pain related to cancer, a patient in hospice care, or a patient in palliative care;

2. The treatment of acute or chronic pain during an inpatient hospital admission, or in a nursing home, ~~or~~ an assisted living facility, or a state, regional or local correctional facility that uses a sole source pharmacy; or

3. A patient enrolled in a clinical trial as authorized by state or federal law.

18VAC85-21-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Acute pain" shall mean pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances may be prescribed for no more than three months.

"Board" shall mean the Virginia Board of Medicine.

"Chronic pain" shall mean non-malignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.

"Controlled substance" shall mean drugs listed in The Drug Control Act of the Code of Virginia in Schedules II through IV.

"FDA" shall mean the U.S. Food and Drug Administration.

"MME" shall mean morphine milligram equivalent.

"Prescription Monitoring Program" shall mean the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

"SAMHSA" means the Substance Abuse and Mental Health Services Administration.

Part II. Management of Acute Pain.

18VAC85-21-30. Evaluation of the acute pain patient.

A. Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days.

B. Prior to initiating treatment with a controlled substance containing an opioid for a complaint of acute pain, the prescriber shall perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in ~~§ 54.1-2522.1 of~~ the Code of Virginia and conduct an assessment of the patient's history and risk of substance ~~abuse~~ misuse.

18VAC85-21-40. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

1. A prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record. This shall also apply to prescriptions of a controlled substance containing an opioid upon discharge from an emergency department.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

3. A prescriber shall indicate on the prescription for an opioid whether it is for acute pain or for treatment for a surgical procedure.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance ~~abuse~~ misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

C. Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, and carisoprodol, ~~and tramadol,~~ 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 if these medications are prescribed.

D. Buprenorphine is not indicated for acute pain in the outpatient setting, except when a prescriber who has obtained a SAMHSA waiver is treating pain in a patient whose primary diagnosis is the disease of addiction.

18VAC85-21-50. Medical records for acute pain.

The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan and the medication prescribed or administered to include the date, type, dosage, and quantity prescribed or administered.

Part III. Management of Chronic Pain.

18VAC85-21-60. Evaluation of the chronic pain patient.

A. Prior to initiating management of chronic pain with a controlled substance containing an opioid, a medical history and physical examination, to include a mental status examination, shall be performed and documented in the medical record, including:

1. The nature and intensity of the pain;

2. Current and past treatments for pain;

3. Underlying or coexisting diseases or conditions;

4. The effect of the pain on physical and psychological function, quality of life and activities of daily living;

5. Psychiatric, addiction and substance ~~abuse~~ misuse history of the patient and any family history of addiction or substance ~~abuse~~ misuse;

6. A urine drug screen or serum medication level;

7. A query the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia;

8. An assessment of the patient's history and risk of substance ~~abuse~~ misuse; and

9. A request for prior applicable records.

B. Prior to initiating opioid treatment for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment to include securely storing the drug and properly disposing of any unwanted or unused drugs. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective.

18VAC85-21-70. Treatment of chronic pain with opioids.

A. Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.

B. In initiating and treating with an opioid, the practitioner shall:

1. Carefully consider and document in the medical record the reasons to exceed 50 MME/day;

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Prescribe naloxone for any patient when risk factors of prior overdose, substance ~~abuse~~ misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present; ~~and~~

4. Document the rationale to continue opioid therapy every three months; and

5. Indicate on the prescription for an opioid whether it is for chronic pain.

C. Buprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose. Buprenorphine mono-product in tablet form shall not be prescribed for chronic pain.

D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, and carisoprodol~~, and tramadol~~, 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.

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate healthcare provider, or refer the patient for evaluation and treatment if indicated.

18VAC85-21-80. Treatment plan for chronic pain.

A. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including but not limited to pain relief and improved physical and psychosocial function, quality of life, and daily activities.

B. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

C. The prescriber shall document in the medical records the presence or absence of any indicators for medication misuse~~, abuse~~ or diversion and shall take appropriate action.

18VAC85-21-90. Informed consent and agreement for treatment for chronic pain.

A. The practitioner shall document in the medical record informed consent, to include risks, benefits and alternative approaches, prior to the initiation of opioids for chronic pain.

B. There shall be a written treatment agreement, signed by the patient, in the medical record that addresses the parameters of treatment, including those behaviors which will result in referral to a higher level of care, cessation of treatment, or dismissal from care.

C. The treatment agreement shall include, but not be limited to, notice that the practitioner will query and receive reports from the Prescription Monitoring Program and permission for the practitioner to:

1. Obtain urine drug screens or serum medication levels, when requested; and

2. Consult with other prescribers or dispensing pharmacists for the patient.

D. Expected outcomes shall be documented in the medical record including improvement in pain relief and function or simply in pain relief. Limitations and side effects of chronic opioid therapy shall be documented in the medical record.

18VAC85-21-100. Opioid therapy for chronic pain.

A. The practitioner shall review the course of pain treatment and any new information about the etiology of the pain and the patient's state of health at least every three months.

B. Continuation of treatment with opioids shall be supported by documentation of continued benefit from such prescribing. If the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

C. Practitioners shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

D. Practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter.

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate healthcare provider, or refer the patient for evaluation for treatment if indicated.

18VAC85-21-110. Additional consultations.

A. When necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment.

B. When a prescriber makes the diagnosis of opioid use disorder, treatment for opioid use disorder shall be initiated or the patient shall be referred for evaluation and treatment.

18VAC85-21-120. Medical records for chronic pain.

The prescriber shall keep current, accurate and complete records in an accessible manner readily available for review to include:

1. The medical history and physical examination;

2. Past medical history;

3. Applicable records from prior treatment providers and/or any documentation of attempts to obtain;

4. Diagnostic, therapeutic and laboratory results;

5. Evaluations and consultations;

6. Treatment goals;

7. Discussion of risks and benefits;

8. Informed consent and agreement for treatment;

9. Treatments;

10. Medications (including date, type, dosage and quantity prescribed and refills).

11. Patient instructions; and

12. Periodic reviews.

Part IV. Prescribing of Buprenorphine for Addiction Treatment.

18VAC85-21-130. General provisions pertaining to prescribing of buprenorphine for addiction treatment.

A. Practitioners engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a SAMHSA waiver and the appropriate Drug Enforcement Administration registration.

B. Practitioners shall abide by all federal and state laws and regulations governing the prescribing of buprenorphine for the treatment of opioid use disorder.

C. Physician assistants and nurse practitioners, who have obtained a SAMHSA waiver, shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a waivered doctor of medicine or doctor of osteopathic medicine.

D. Practitioners engaged in medication-assisted treatment shall either provide counseling in their practice or refer the patient to a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance ~~abuse~~ misuse

counseling. The practitioner shall document provision of counseling or referral in the medical record.

18VAC85-21-140. Patient assessment and treatment planning for addiction treatment.

A. A practitioner shall perform and document an assessment that includes a comprehensive medical and psychiatric history, substance ~~abuse~~ misuse history, family history and psychosocial supports, appropriate physical examination, urine drug screen, pregnancy test for women of childbearing age and ability, a check of the Prescription Monitoring Program, and, when clinically indicated, infectious disease testing for HIV, Hepatitis B, Hepatitis C and TB.

B. The treatment plan shall include the practitioner's rationale for selecting medication assisted treatment, patient education, written informed consent, how counseling will be accomplished, and a signed treatment agreement that outlines the responsibilities of the patient and the prescriber.

18VAC85-21-150. Treatment with buprenorphine for addiction.

A. Buprenorphine without naloxone (buprenorphine mono-product) shall not be prescribed except:

1. When a patient is pregnant;

2. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days; ~~or~~

3. In formulations other than tablet form for indications approved by the FDA; or

4. For patients who have a demonstrated allergy or intolerance to naloxone or who have severe financial hardship for which prescriptions for the mono-product shall not exceed 5% of the total prescriptions for buprenorphine written by the prescriber.

B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed opioid treatment programs (OTPs). With the exception of those conditions listed in subsection A, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use offsite from the program.

C. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

D. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, and carisoprodol~~, and tramadol,~~ 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 if these medications are prescribed.

E. Prior to starting medication-assisted treatment, the practitioner shall perform a check of the Prescription Monitoring Program.

F. During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on no more than 8 mg. of buprenorphine per day. The patient shall be seen by the prescriber at least once a week.

G. During the stabilization phase, the prescriber shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

H. Practitioners shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of the Prescription Monitoring Program. The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

I. Documentation of the rationale for prescribed doses exceeding 16 mg. of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 mg. of buprenorphine per day shall not be prescribed.

J. The practitioner shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance ~~abuse~~ misuse counseling.

18VAC85-21-160. Special populations in addiction treatment.

A. Pregnant women ~~shall~~ may be treated with the buprenorphine mono-product, usually 16 mg. per day or less.

B. Patients under the age of 16 years shall not be prescribed buprenorphine for addiction treatment unless such treatment is approved by the FDA.

C. The progress of patients with chronic pain shall be assessed by reduction of pain and functional objectives which can be identified, quantified and independently verified.

D. Practitioners shall evaluate patients with medical comorbidities by history, physical exam, appropriate laboratory studies, and be aware of interactions of buprenorphine with other prescribed medications.

E. Practitioners shall not undertake buprenorphine treatment with a patient who has psychiatric comorbidities and that is not stable. A patient who is determined by the prescriber to be psychiatrically unstable shall be referred for psychiatric evaluation and treatment prior to initiating medication-assisted treatment.

18VAC85-21-170. Medical records for opioid addiction treatment.

A. Records shall be timely, accurate, legible, complete and readily accessible for review.

B. The treatment agreement and informed consent shall be maintained in the medical record.

C. Confidentiality requirements of 42 CFR, Part 2 shall be followed.

D. Compliance with Board of Medicine Regulation 18VAC85-20-27, which prohibits willful or negligent breach of confidentiality or unauthorized disclosure of confidential Prescription Monitoring Program information, shall be maintained.

Commonwealth of Virginia

REGULATIONS

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REGULATIONS AS AMENDED BY THE LEGISLATIVE COMMITTEE

9960 Mayland Drive, Suite 300
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2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance ~~abuse~~ misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

C. Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, 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 if these medications are prescribed.

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2. Current and past treatments for pain;

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6. A urine drug screen or serum medication level;

7. A query the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia;

8. An assessment of the patient's history and risk of substance ~~abuse~~ misuse; and

9. A request for prior applicable records.

B. Prior to initiating opioid treatment for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment to include securely storing the drug and properly disposing of any unwanted or unused drugs. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective.

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2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Prescribe naloxone for any patient when risk factors of prior overdose, substance ~~abuse~~ misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present; ~~and~~

4. Document the rationale to continue opioid therapy every three months; and

C. ~~Buprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose.~~ Buprenorphine mono-product in tablet form shall not be prescribed for chronic pain.

D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, 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.

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B. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

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B. There shall be a written treatment agreement, signed by the patient, in the medical record that addresses the parameters of treatment, including those behaviors which will result in referral to a higher level of care, cessation of treatment, or dismissal from care.

C. The treatment agreement shall include, but not be limited to, notice that the practitioner will query and receive reports from the Prescription Monitoring Program and permission for the practitioner to:

1. Obtain urine drug screens or serum medication levels, when requested; and

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C. Practitioners shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

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D. Practitioners engaged in medication-assisted treatment shall either provide counseling in their practice or refer the patient to a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance ~~abuse~~ misuse counseling. The practitioner shall document provision of counseling or referral in the medical record.

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2. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days; ~~or~~

3. In formulations other than tablet form for indications approved by the FDA; or

4. For patients who have a demonstrated intolerance to naloxone; such prescriptions for the mono-product shall not exceed 3% of the total prescriptions for buprenorphine written by the prescriber, and the exception shall be clearly documented in the patient's medical record.

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C. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

D. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, 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 if these medications are prescribed.

E. Prior to starting medication-assisted treatment, the practitioner shall perform a check of the Prescription Monitoring Program.

F. During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on no more than 8 mg. of buprenorphine per day. The patient shall be seen by the prescriber at least once a week.

G. During the stabilization phase, the prescriber shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

H. Practitioners shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of the Prescription Monitoring Program. The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

I. Documentation of the rationale for prescribed doses exceeding 16 mg. of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 mg. of buprenorphine per day shall not be prescribed.

J. The practitioner shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance ~~abuse~~ misuse counseling.

18VAC85-21-160. Special populations in addiction treatment.

A. Pregnant women ~~shall~~ may be treated with the buprenorphine mono-product, usually 16 mg. per day or less.

B. Patients under the age of 16 years shall not be prescribed buprenorphine for addiction treatment unless such treatment is approved by the FDA.

C. The progress of patients with chronic pain shall be assessed by reduction of pain and functional objectives which can be identified, quantified and independently verified.

D. Practitioners shall evaluate patients with medical comorbidities by history, physical exam, appropriate laboratory studies, and be aware of interactions of buprenorphine with other prescribed medications.

E. Practitioners shall not undertake buprenorphine treatment with a patient who has psychiatric comorbidities and that is not stable. A patient who is determined by the prescriber to be psychiatrically unstable shall be referred for psychiatric evaluation and treatment prior to initiating medication-assisted treatment.

18VAC85-21-170. Medical records for opioid addiction treatment.

A. Records shall be timely, accurate, legible, complete and readily accessible for review.

B. The treatment agreement and informed consent shall be maintained in the medical record.

C. Confidentiality requirements of 42 CFR, Part 2 shall be followed.

D. Compliance with Board of Medicine Regulation 18VAC85-20-27, which prohibits willful or negligent breach of confidentiality or unauthorized disclosure of confidential Prescription Monitoring Program information, shall be maintained.

Agenda Item: Regulations Governing Prescribing of Opioids and Buprenorphine

Included in the agenda package:

Copy of regulations for Nurse Practitioners with changes as recommended by the Legislative Committee of the Board of Medicine

Staff note:

The re-adoption of emergency regulations will be adopted by the Board of Medicine on June 22, 2017 – both regulations for MDs, DOs, DPMs and PAs and the regulations for nurse practitioners

Regulations for nurse practitioners will then be adopted by the Board of Nursing at its meeting on July 18, 2017

Action:

Adoption of amendments on nurse practitioner regulations for prescribing of opioids and buprenorphine consistent with regulations for Medicine. (Any changes made by the Board to Chapter 21 will be incorporated into the nurse practitioner regulations).

BOARDS OF NURSING AND MEDICINE

EMERGENCY REGULATIONS FOR NURSE PRACTITIONERS

Prescribing of opioids

Part IV

Disciplinary Provisions

18VAC90-30-220. Grounds for disciplinary action against the license of a licensed nurse practitioner.

The boards may deny licensure or relicensure, revoke or suspend the license, or take other disciplinary action upon proof that the nurse practitioner:

1. Has had a license or multistate privilege to practice nursing in this Commonwealth or in another jurisdiction revoked or suspended or otherwise disciplined;

2. Has directly or indirectly represented to the public that the nurse practitioner is a physician, or is able to, or will practice independently of a physician;

3. Has exceeded the authority as a licensed nurse practitioner;

4. Has violated or cooperated in the violation of the laws or regulations governing the practice of medicine, nursing or nurse practitioners;

5. Has become unable to practice with reasonable skill and safety to patients as the result of a physical or mental illness or the excessive use of alcohol, drugs, narcotics, chemicals or any other type of material;

6. Has violated or cooperated with others in violating or attempting to violate any law or regulation, state or federal, relating to the possession, use, dispensing, administration or distribution of drugs; ~~or~~

7. Has failed to comply with continuing competency requirements as set forth in 18VAC90-30-105;

8. Has willfully or negligently breached the confidentiality between a practitioner and a patient. A breach of confidentiality that is required or permitted by applicable law or beyond the control of the practitioner shall not be considered negligent or willful; or

9. Has engaged in unauthorized use or disclosure of confidential information received from the Prescription Monitoring Program, the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

Part I

General Provisions

18VAC90-40-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"Acute pain" means pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances containing an opioid may be prescribed for no more than three months.

"Boards" means the Virginia Board of Medicine and the Virginia Board of Nursing.

"Certified nurse midwife" means an advanced practice registered nurse who is certified in the specialty of nurse midwifery and who is jointly licensed by the Boards of Medicine and Nursing as a nurse practitioner pursuant to § 54.1-2957 of the Code of Virginia.

"Chronic pain" means nonmalignant pain that goes beyond the normal course of a disease or condition for which controlled substances containing an opioid may be prescribed for a period greater than three months.

"Committee" means the Committee of the Joint Boards of Nursing and Medicine.

"FDA" means the U.S. Food and Drug Administration.

"MME" means morphine milligram equivalent.

"Nonprofit health care clinics or programs" means a clinic organized in whole or in part for the delivery of health care services without charge or when a reasonable minimum fee is charged only to cover administrative costs.

"Nurse practitioner" means an advanced practice registered nurse who has met the requirements for licensure as a nurse practitioner as stated in 18VAC90-30.

"Practice agreement" means a written or electronic agreement jointly developed by the patient care team physician and the nurse practitioner for the practice of the nurse practitioner that also describes the prescriptive authority of the nurse practitioner, if applicable. For a nurse practitioner licensed in the category of certified nurse midwife, the practice agreement is a statement jointly developed with the consulting physician.

"Prescription Monitoring Program" means the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

"SAMHSA" means the federal Substance Abuse and Mental Health Services Administration.

Part V

Management of Acute Pain

18VAC90-40-150. Evaluation of the patient for acute pain.

A. The requirements of this part shall not apply to:

1. The treatment of acute pain related to (i) cancer, (ii) a patient in hospice care, or (iii) a patient in palliative care;

2. The treatment of acute or chronic pain during an inpatient hospital admission, in a nursing home, ~~or~~ an assisted living facility that uses a sole source pharmacy; or

3. A patient enrolled in a clinical trial as authorized by state or federal law.

B. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days.

C. Prior to initiating treatment with a controlled substance containing an opioid for a complaint of acute pain, the prescriber shall perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia and conduct an assessment of the patient's history and risk of substance ~~abuse~~ misuse.

18VAC90-40-160. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

1. A prescriber providing treatment for a patient with acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record. This shall also apply to prescriptions of a controlled substance containing an opioid upon discharge from an emergency department.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance ~~abuse~~ misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine are present.

C. Due to a higher risk of fatal overdose when opioids are used with benzodiazepines, sedative hypnotics, carisoprodol, 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 if these medications are prescribed.

D. Buprenorphine is not indicated for acute pain in the outpatient setting, except when a prescriber who has obtained a SAMHSA waiver is treating pain in a patient whose primary diagnosis is the disease of addiction.

18VAC90-40-170. Medical records for acute pain.

The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan and the medication prescribed or administered to include the date, type, dosage, and quantity prescribed or administered.

Part VI

Management of Chronic Pain

18VAC90-40-180. Evaluation of the chronic pain patient.

A. The requirements of this part shall not apply to:

1. The treatment of chronic pain related to (i) cancer, (ii) a patient in hospice care, or (iii) a patient in palliative care;

2. The treatment of chronic pain during an inpatient hospital admission or in a nursing home or an assisted living facility that uses a sole source pharmacy; or

3. A patient enrolled in a clinical trial as authorized by state or federal law.

B. Prior to initiating management of chronic pain with a controlled substance containing an opioid, a medical history and physical examination, to include a mental status examination, shall be performed and documented in the medical record, including:

1. The nature and intensity of the pain;

2. Current and past treatments for pain;

3. Underlying or coexisting diseases or conditions;

4. The effect of the pain on physical and psychological function, quality of life, and activities of daily living;

5. Psychiatric, addiction and substance ~~abuse~~ misuse history of the patient and any family history of addiction or substance ~~abuse~~ misuse;

6. A urine drug screen or serum medication level;

7. A query of the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia;

8. An assessment of the patient's history and risk of substance ~~abuse~~ misuse; and

9. A request for prior applicable records.

C. Prior to initiating opioid analgesia for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment to include securely storing the drug and properly disposing of any unwanted or unused drugs. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective.

18VAC90-40-190. Treatment of chronic pain with opioids.

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.

B. In initiating opioid treatment for all patients, the practitioner shall:

1. Carefully consider and document in the medical record the reasons to exceed 50 MME/day;

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist;

3. Prescribe naloxone for any patient when risk factors of prior overdose, substance ~~abuse~~ misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present; and

4. Document the rationale to continue opioid therapy every three months.

C. ~~Buprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose.~~ Buprenorphine mono-product in tablet form shall not be prescribed for chronic pain.

D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, 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.

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation for treatment if indicated.

18VAC90-40-200. Treatment plan for chronic pain.

A. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including pain relief and improved physical and psychosocial function, quality of life, and daily activities.

B. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

C. The prescriber shall record in the medical records the presence or absence of any indicators for medication misuse~~, abuse~~, or diversion and take appropriate action.

18VAC90-40-210. Informed consent and agreement for treatment of chronic pain.

A. The practitioner shall document in the medical record informed consent, to include risks, benefits, and alternative approaches, prior to the initiation of opioids for chronic pain.

B. There shall be a written treatment agreement, signed by the patient, in the medical record that addresses the parameters of treatment, including those behaviors that will result in referral to a higher level of care, cessation of treatment, or dismissal from care.

C. The treatment agreement shall include notice that the practitioner will query and receive reports from the Prescription Monitoring Program and permission for the practitioner to:

1. Obtain urine drug screen or serum medication levels, when requested; and

2. Consult with other prescribers or dispensing pharmacists for the patient.

D. Expected outcomes shall be documented in the medical record including improvement in pain relief and function or simply in pain relief. Limitations and side effects of chronic opioid therapy shall be documented in the medical record.

18VAC90-40-220. Opioid therapy for chronic pain.

A. The practitioner shall review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health at least every three months.

B. Continuation of treatment with opioids shall be supported by documentation of continued benefit from the prescribing. If the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

C. Practitioners shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

D. The practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter.

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation for treatment if indicated.

18VAC90-40-230. Additional consultation.

A. When necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment.

B. When a practitioner makes the diagnosis of opioid use disorder, treatment for opioid use disorder shall be initiated or the patient shall be referred for evaluation and treatment.

18VAC90-40-240. Medical records.

The prescriber shall keep current, accurate, and complete records in an accessible manner and readily available for review to include:

1. The medical history and physical examination;

2. Past medical history;

3. Applicable records from prior treatment providers or any documentation of attempts to obtain those records;

4. Diagnostic, therapeutic, and laboratory results;

5. Evaluations and consultations;

6. Treatment goals;

7. Discussion of risks and benefits;

8. Informed consent and agreement for treatment;

9. Treatments;

10. Medications (including date, type, dosage and quantity prescribed, and refills);

11. Patient instructions; and

12. Periodic reviews.

Part VII

Prescribing of Buprenorphine

18VAC90-40-250. General provisions.

A. Practitioners engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a waiver from SAMHSA and the appropriate U.S. Drug Enforcement Administration registration.

B. Practitioners shall abide by all federal and state laws and regulations governing the prescribing of buprenorphine for the treatment of opioid use disorder.

C. Nurse practitioners who have obtained a SAMHSA waiver shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a SAMHSA-waivered doctor of medicine or doctor of osteopathic medicine.

D. Practitioners engaged in medication-assisted treatment shall either provide counseling in their practice or refer the patient to a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance abuse counseling. The practitioner shall document provision of counseling or referral in the medical record.

18VAC90-40-260. Patient assessment and treatment planning.

A. A practitioner shall perform and document an assessment that includes a comprehensive medical and psychiatric history, substance abuse history, family history and psychosocial supports, appropriate physical examination, urine drug screen, pregnancy test for women of childbearing age and ability, a check of the Prescription Monitoring Program, and, when clinically indicated, infectious disease testing for human immunodeficiency virus, hepatitis B, hepatitis C, and tuberculosis.

B. The treatment plan shall include the practitioner's rationale for selecting medication assisted treatment, patient education, written informed consent, how counseling will be accomplished, and a signed treatment agreement that outlines the responsibilities of the patient and the practitioner.

18VAC90-40-270. Treatment with buprenorphine.

A. Buprenorphine without naloxone (buprenorphine mono-product) shall not be prescribed except:

1. When a patient is pregnant;

2. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days; ~~or~~

3. In formulations other than tablet form for indications approved by the FDA; or

4. For patients who have a demonstrated intolerance to naloxone; such prescriptions for the mono-product shall not exceed 3% of the total prescriptions for buprenorphine written by the prescriber, and the exception shall be clearly documented in the patient's medical record.

B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed opiate treatment programs. With the exception of those conditions listed in subsection A of this section, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use off site from the program.

C. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

D. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, 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 if these medications are prescribed.

E. Prior to starting medication-assisted treatment, the practitioner shall perform a check of the Prescription Monitoring Program.

F. During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on no more than eight milligrams of buprenorphine per day. The patient shall be seen by the prescriber at least once a week.

G. During the stabilization phase, the prescriber shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

H. Practitioners shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of the Prescription Monitoring Program. The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

I. Documentation of the rationale for prescribed doses exceeding 16 milligrams of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 milligrams of buprenorphine per day shall not be prescribed.

J. The practitioner shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance abuse counseling.

18VAC90-40-280. Special populations.

A. Pregnant women ~~shall~~ may be treated with the buprenorphine mono-product, usually 16 milligrams per day or less.

B. Patients younger than the age of 16 years shall not be prescribed buprenorphine for addiction treatment unless such treatment is approved by the FDA.

C. The progress of patients with chronic pain shall be assessed by reduction of pain and functional objectives that can be identified, quantified, and independently verified.

D. Practitioners shall (i) evaluate patients with medical comorbidities by history, physical exam, and appropriate laboratory studies and (ii) be aware of interactions of buprenorphine with other prescribed medications.

E. Practitioners shall not undertake buprenorphine treatment with a patient who has psychiatric comorbidities and is not stable. A patient who is determined by the practitioner to be psychiatrically unstable shall be referred for psychiatric evaluation and treatment prior to initiating medication-assisted treatment.

18VAC90-40-290. Medical records for opioid addiction treatment.

A. Records shall be timely, accurate, legible, complete, and readily accessible for review.

B. The treatment agreement and informed consent shall be maintained in the medical record.

C. Confidentiality requirements of 42 CFR, Part 2 shall be followed.

PROPOSED

Virginia Board of Medicine
2018 Board Meeting Dates

Full Board Meetings

February 15-17, 2018	DHP/Richmond, VA	Board Rooms TBA
June 14-16, 2018	DHP/Richmond, VA	Board Rooms TBA
October 18-20, 2018	DHP/Richmond, VA	Board Rooms TBA

Times for the above meetings are 8:30 a.m. to 5:00 p.m.

Executive Committee Meetings

April 13, 2018	DHP/Richmond, VA	Board Rooms TBA
August 3, 2018	DHP/Richmond, VA	Board Rooms TBA
December 7, 2018	DHP/Richmond, VA	Board Rooms TBA

Times for the above meetings are 8:30 a.m. to 5:00 p.m.

Legislative Committee Meetings

January 19, 2018	DHP/Richmond, VA	Board Rooms TBA
May 18, 2018	DHP/Richmond, VA	Board Rooms TBA
September 7, 2018	DHP/Richmond, VA	Board Rooms TBA

Times for the above meetings are 8:30 a.m. to 1:00 p.m.

Credentials Committee Meetings

January 24, 2018	February 28, 2018	March 21, 2018
April 25, 2018	May 30, 2018	June 27, 2018
July 25, 2018	August 22, 2018	September 26, 2018
October 24, 2018	November 14, 2018	December (TBA), 2018

Times for the Credentials Committee meetings - TBA

Advisory Board on:

Behavioral Analysts			**10:00 a.m.**
January 29	June 4	October 1	
Genetic Counseling			**1:00 p.m.**
January 29	June 4	October 1	
Occupational Therapy			**10:00 a.m.**
January 30	June 5	October 2	
Respiratory Care			**1:00 p.m.**
January 30	June 5	October 2	
Acupuncture			**10:00 a.m.**
January 31	June 6	October 3	
Radiological Technology			**1:00 p.m.**
January 31	June 6	October 3	
Athletic Training			**10:00 a.m.**
February 1	June 7	October 4	
Physician Assistants			**1:00 p.m.**
February 1	June 7	October 4	
Midwifery			**10:00 a.m.**
February 2	June 8	October 5	
Polysomnographic Technology			**1:00 p.m.**
February 2	June 8	October 5	

Joint Boards of Medicine and Nursing

TBA

Agenda Item: **Report of the Nominating Committee**

Staff Note: The Committee will meet at 7:45 a.m. to develop a slate of officers for 2017-2018.

Action: Approve the slate as presented or develop an alternate slate.

Next Meeting Date of the Full Board is

October 26-28, 2017

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

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

July 21, 2017