--- FINAL APPROVED --

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

<u>FSMB Travel Authorization</u>

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