---FINAL APPROVED---

VIRGINIA BOARD OF MEDICINE
FULL BOARD MINUTES

February 15, 2018 Department of Health Professions Henrico, VA 23233

Prior to calling the meeting of the Board to order, Dr. O'Connor convened a Public Hearing to receive comment on the proposed regulations for Licensure by Endorsement. There was no comment.

CALL TO ORDER: Dr. O'Connor called the meeting of the Board to order at 8:34 a.m.

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

MEMBERS PRESENT:
Kevin O'Connor, MD, President
Ray Tuck, DC, Vice-President
Lori Conklin, MD, Secretary-Treasurer
Syed Ali, MD
Barbara Allison-Bryan, MD
David Archer, MD
Randy Clements, DPM
Alvin Edwards, PhD
David Giammittorio, MD
James Jenkins, Jr., RN
Jane Hickey, JD
Isaac Koziol, MD
Maxine Lee, MD
Jacob Miller, DO
David Taminger, MD
Svinder Toor, MD
Kenneth Walker, MD
Martha Wingfield

MEMBERS ABSENT: None

STAFF PRESENT:
David Brown, DC, Director, Department of Health Professions
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
Sherry Gibson, Administrative Assistant
Elaine Yeatts, DHP Senior Policy Analyst
Erin Barrett, JD, Assistant Attorney General

OTHERS PRESENT:
Annie Roe Rutherford, PA-C, VAPA
Robert Glasgow, PA-C, VAPA
Shiri Hickman, FSMB

David Falkenstein, PA-C, VAPA
George H. Carter, Statewide Sickle Cell Chapter of Virginia
Ryan LaMura, VHHA
Kassie Schroth, McGuire Woods
Kathy Martin, Hancock, Daniel & Johnson
Lauren Bates-Rowe, MSV
Claudette Dalton, FSMB
Dawn Morton-Rias, NCCPA

EMERGENCY EGRESS PROCEDURES

Dr. Tuck provided the emergency egress procedures for Conference Room 2.

APPROVAL OF THE OCTOBER 26, 2018 MINUTES

Dr. Edwards moved to approve the October 26, 2017, meeting minutes as presented. The motion was seconded and carried unanimously.

INTRODUCTION OF NEW BOARD MEMBERS

Dr. O'Connor introduced James Jenkins, Jr. RN as the newest member at the Board of Medicine. Mr. Jenkins provided a brief overview of his background

Dr. O'Connor then introduced Jacob Miller, DO who provided a brief overview of his background.

ADOPTION OF THE AGENDA

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

PUBLIC COMMENT ON AGENDA ITEMS

There was no public comment.

PRESENTATION: Claudette Dalton, MD, FSMB Board Member and Liaison to Virginia.

Dr. Dalton thanked the Board for its service to the Commonwealth. Dr. Dalton introduced Shiri Hickman, Director of State Policy and Legal Services for the Federation of State Medical Boards (FSMB), who provided a quick overview of FSMB. She spoke about its vision and mission and where its offices are located. Ms. Hickman invited the Board members to the Annual Meeting in Charlotte in April and also noted opportunities for Board Attorney Workshops, Monthly Roundtables, and online CME programs.

Dr. Dalton then provided an overview of new policy initiatives that will be considered at the 2018

Annual Meeting of the House of Delegates. Included were a report on Prescription Drug Monitoring Programs, a Workgroup on Regenerative and Stem Cell Therapy Practices, Guidelines for the Structure and Function of a State Medical and Osteopathic Board, and a report on Physician Wellness and Burnout. Other items that will be discussed include antitrust updates, the Good Samaritan Bill, sexual boundaries, social media issues, and the duty to report.

Dr. Dalton provided background on issues of compounding, mixing and diluting which have arisen in part from the New England compounding debacle of 2012. Compounding is broadly defined as the "formulation of any medication by admixing, mixing, diluting, pooling, reconstituting or otherwise altering a drug or bulk drug substance to create a drug." The FSMB has worked with the Pew Research Center as well as the Government Accountability Office to compile a compendium of state regulations regarding compounding.

Prior to 2013, there was no federal oversight of compounding facilities. She said that USP Chapter 797 prescribes conditions and practices to prevent harm to patients resulting from contaminated or improperly compounded sterile preparations (CSPs). The new revisions to Chapter 797 have not yet been finalized, but probably will be by the end of 2018 or early 2019.

Dr. Dalton reviewed the FSMB position statement on the duty to report. She noted it encourages physician peers, the public, hospitals, and insurers to report instances of unprofessional conduct or incompetence to state medical boards. Ms. Deschenes noted that the Board has fined licensees for failing to report. Dr. Dalton stated that the Board has an obligation to put a spotlight on the duty to report.

She then made comments about physician assistants.

There are four main organizations for physician assistants.

- American Academy of Physician Assistants (AAPA)
- Physician Assistant Education Association (PAEA)
- National Commission on Certification of Physician Assistants (NCCPA) and
- Accreditation Review Commission on Education for the Physician Assistants (ARC-PA)

After two years of education, a student physician assistant is eligible to take the Physician Assistant National Certifying Exam (PANCE). Presently, physician assistants must recertify every 10 years and are given 6 years and 6 attempts to pass the recertification exam.

Currently, 70% of physician assistants practice a specialty. There are efforts to create exams for these specialties. When this issue was opened for public comment, about 60% of initial respondents thought it was a good idea to have a specialty exam. However, those initial responses were dampened by concerns that if a PA practiced a specialty and moved to where there is no demand for that specialty, the physician assistant may not be eligible for employment.

Dr. Dalton told the Board that having a physician assistant on the Board of Medicine would enfranchise physician assistants, which an Advisory Board does not do.

Dr. Miller asked if there are physician assistants who are not affiliated with Joint Commission institutions. Dr. Dalton's response was that physician assistants affiliated with hospitals are held to a higher standard than physician assistants not affiliated with hospitals.

Dr. Lee stated that the USP requirement for the use of compounded drugs is impractical because of the 1-hour timeframe.

Dr. Dalton responded by stating that, in an emergency, USP does not even allow 1 hour. FSMB cannot demand that USP change its standards. FSMB comes from the point of view of safety, access, and cost.

Dr. Toor asked Dr. Dalton to describe how the FSMB addresses physician burnout. Under whose jurisdiction does it fall?

Dr. Dalton stated that FSMB started looking at this issue four years ago with the National Academy of Medicine.

PRESENTATION: Dawn Morton-Rias, EDD, PA-C, President and CEO of the NCCPA

Ms. Morton-Rias provided a presentation entitled *"PA Practice Patterns & Certification."* The National Commission on the Certification of Physician Assistants (NCCPA) has been certifying physician assistants since 1975. It is the only certifying body for physician assistants. The purpose of the NCCPA is to provide certification programs that assure standards of clinical knowledge, clinical reasoning, other medical skills and professional behaviors for practice as a physician assistant. NCCPA is not a membership organization. Its ultimate responsibility is protection of the public through accreditation standards that require the highest principles of integrity. The NCCPA Board of Directors consists of 11 physician assistants, 5 physicians and 2 public members.

In 2017, over 20,000 Physician Assistants completed a profession-wide survey about what constitutes core medical knowledge; the results will form the basis for future assessment programs. Physician assistants are involved at NCCPA by serving on test item-writing committees. NCCPA has hosted 22 PA team meetings to develop and validate exam questions, review exam forms, and set passing standards.

There are currently 229 physician assistant training programs in the US. There are eight programs in Virginia, four of which are fully accredited, and four of which are provisionally accredited.

Initial NCCPA certification requires graduation from an accredited PA program and passing the Physician Assistant National Certifying Examination (PANCE). In 2016, 97% of all physician assistants held current NCCPA certification. Currently, all 50 states require NCCPA certification for initial licensure. Eighteen states, including Virginia, require Physician Assistants to maintain NCCPA certification for licensure renewal. Practice in Virginia statistically mirrors national trends for practice. Currently, there are 123,000 Physician Assistants in 50 states. The

demographic background of these practitioners is changing. In the 1960's it was predominantly a field dominated by males. Now, there are more female physician assistants. Nationally and in Virginia, approximately 20% of physician assistants work in family medicine and the rest in specialty areas.

Physician assistants must complete 100 hours of continuing medical education every two years for maintenance of certification. Fifty of those hours must be Category 1. There is a recertification examination every ten years. Physician Assistants have six years and six attempts to pass the recertification exam.

Physician assistants are educated, certified and recertified as generalists. It is through continuing medical education that physician assistants become specialists. Over a career, 67% change specialties to meet workforce demands.

In a public survey conducted with the Citizens Advocacy Center, it was found that the public wants physician assistants to be tested every day, while the PAs, do not want to be tested at all. The middle ground is a combination of continuing medical education and testing that is meaningful, relevant and purposeful.

The recertification exam is designed to test core medical knowledge, e.g. generalist knowledge. Moving into 2019, the recertification process will incorporate more examinations more frequently, and provide immediate feedback to the physician assistant. .

DHP DIRECTOR'S REPORT- Elaine Yeatts

Elaine Yeatts provided the Director's report. She began by noting there is a new Governor in Virginia, Dr. Northam, who has appointed a new Secretary of Health and Human Resources, Dr. Daniel Carey, to whom DHP reports. David Brown, DC has been reappointed as Director of DHP. Dr. Brown has hired a new Chief Operations Officer, Lisa Hahn. This position will provide continuity from one administration to another. Dr. Barbara Allison-Bryan has been appointed by Governor Northam to the position of DHP Chief Deputy Director.

There is new construction in the first floor reception area where some DHP staff will be moving soon. DHP is busy at the General Assembly, with approximately 100 bills to follow. Crossover has just occurred, and about half of the bills have gone away.

REPORT OF OFFICERS AND EXECUTIVE DIRECTOR

PRESIDENT

Dr. O'Connor reported on the Joint Boards of Medicine and Nursing. He noted it was interesting to hear Elizabeth Carter, PhD, provide an update on the nurse practitioner workforce. He requested that the report be distributed to all Board of Medicine members.

VICE-PRESIDENT'S REPORT

No report.

SECRETARY-TREASURER'S REPORT

Dr. Conklin was happy to report that the Board has a positive cash balance with approximately $7.7 million.

EXECUTIVE DIRECTOR'S REPORT

Dr. Harp provided a report regarding the Revenue and Expenditures for the first half of fiscal year 2018. The Board is fortunate to have spent less than 50% of its budgeted direct expenditures at this time, except for small exceptions of overtime and organization memberships which are only paid once a year. Total direct expenditures for the first half of FY2018 represent 42.66% of the Board's total annual budget for direct expenses.

Dr. Harp noted that there are currently 433 total participants in the Virginia Health Practitioners' Monitoring Program (HPMP). Of those, 111 are either licensed by the Board of Medicine or have applied for licensure.

He continued by reviewing the Quarterly Performance Measures for patient care disciplinary case processing times. The Board's current clearance rate for FY2018 Q2 was 98%, Age of pending cases over one year old was 16%, and the percent of cases closed within 250 business days was 94%.

Finally, Dr. Harp congratulated Dr. Walker for being nominated to the FSMB Nominating Committee.

COMMITTEE and ADVISORY BOARD REPORTS

List of Committee Appointments

Executive Committee

Legislative Committee

Regulatory Advisory Panel on Laser Hair Removal

Advisory Board on Behavior Analysis

Advisory on Genetic Counseling

Advisory Board on Occupational Therapy

Advisory Board on Respiratory Therapy

Advisory Board on Acupuncture

Advisory Board on Radiologic Technology

Advisory Board on Athletic Training

Advisory Board on Physician Assistants

Advisor Board on Midwifery

Advisory Board on Polysomnographic Technology

Dr. Edwards made a motion to accept all the minutes en bloc. The motion was seconded and carried.

OTHER REPORTS

Board Counsel

Erin Barrett introduced herself to the new Board members and addressed her role as counsel. She provided an update on the status of the following cases.

Hagmann v. Virginia Board of Medicine

Clowdis v. Virginia Board of Medicine

Merchia v. Virginia Board of Medicine

Garada v. Virginia Board of Medicine

Board of Health Professions

Dr. Allison-Bryan noted that she will become DHP's new Chief Deputy Director March 1st. She said that DHP is a really big place, and the Board of Medicine is a small piece of it. There are 13 boards and 82 professions regulated in this building. Petitions for a new profession go to Board of Health Professions. There is currently one profession, Art Therapy, that has petitioned for status as a new profession. The BHP is developing a study workplan to determine if art therapists need to be regulated by the state.

Podiatry Report

Dr. Clements had no report.

Chiropractic Report

Dr. Tuck had no report.

Committee of the Joint Boards of Nursing and Medicine

Dr. O'Connor reiterated the he wants the Nurse Practitioner Workforce Manpower report distributed to all Board members.

New Business:

1. **Regulatory and Legislative Issues**
   - **Report from the 2018 General Assembly**

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

- HB 157 Right to Treat Act; requirement of Maintenance of Certification prohibited, etc.
- HB 169 Lyme disease; information disclosure requirement, sunset
- HB 226 Patients; medically or ethically inappropriate care not required
- HB 854 Polysomnographic technology; students or trainees, licensure
- HB 915 Military medical personnel program; personnel may practice under supervision of physician, etc.
- HB 1064 Medical marijuana; written certification issued by physician
- HB 1071 Health regulatory boards; electronic notice of license renewal
- HB 1378 Surgical assistants; renewal of registration
- HB 1440 Schedule I and Schedule II drugs; adds various drugs to lists
- HB 1524 Medicine, Board of; regulations related to retention of patient records, minimum time for retention
- SB 330 THC-A oil; dispensing tetrahydrocannabinol levels
- SB 505 Doctorate of medical sciences; establishes requirements for licensure and practice
- SB 511 Optometry; scope of practice
- SB 632 Controlled substances; limits on prescriptions containing opioids
- SB 832 Prescription Monitoring Program; adds controlled substances included in Schedule V and naloxone
- SB 882 Prescription refill protocol

A discussion was held regarding House Substitute Bill 793, specifically addressing Code Section 54.1-2957 *Licensure and practice of nurse practitioners*.

Dr. Walker asked if the revisions in the substitute bill would allow independent practice by nurse practitioners and was assured that it will.

Dr. Koziol stated that there are real ramifications to the lack of health care in rural areas of Virginia.

Dr. Allison-Bryan noted that only 20% of physician assistants practice primary care, and the same is true for nurse practitioners. Allowing independent practice of nurse practitioners will not solve

the problem of access to healthcare.

Dr. O'Connor said he understands the criteria allowing independent practice will go back to the Committee of the Joint Boards of Medicine and Nursing for the development of regulations.

Dr. Ali replied that this does not address access to healthcare in Southwest Virginia. Large hospitals, along with primary care practices, will be a force against physicians who are practicing primary care.

Ms. Yeatts noted that the Boards of Medicine and Nursing will report on the number of nurse practitioners who have been authorized to practice without a practice agreement by November 1, 2021. The Boards of Medicine and Nursing shall recommend any modifications to the clinical experience requirements for practice of a nurse practitioner practicing without a practice agreement by November 1, 2021.

Dr. Conklin asked what will happen if the studies show there is not a benefit to the public in accessing health care.

Ms. Yeatts responded that the purpose is not to increase access to healthcare.

Dr. Brown noted that this bill is a compromise, because nobody is happy. Most states allow independent practice of nurse practitioners without any prior supervision. The nurse practitioner community may not support this bill with the amendment from Delegate Garrett, who is a physician.

- **Chart of Regulatory Actions**

Ms. Yeatts reviewed the chart on the status of regulations for the Board as of February 15, 2018.

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

- **Guidance Document for Occupational Therapy**

Ms. Yeatts explained that the Board frequently receives questions regarding the supervisory responsibilities of an occupational therapist.

Ms. Barret recommends if the Board votes to recommend passage, the document should include regulations that are relevant to the answers, since most of the answers come straight from the regulations.

Dr. Ali moved to accept the guidance document as amended to include regulations. The motion was seconded and carried.

- **Adoption of Exempt Amendment for Fee Reduction**

Dr. Conklin moved to reduce fees for limited professorial, interns and residents for 2018 in line

with other fee reductions for renewal in 2018. The motion was seconded and carried.

- **Proposed Regulations for Performance of and Supervision and Direction of Laser Hair Removal**

Ms. Yeatts reviewed the staff note on page 109 of the agenda packet.

Dr. Archer asked if the Board is delegating more authority to less qualified individuals to practice medicine. Even though this is a simple procedure, you can burn off a lot of skin if the laser is not used appropriately. He expressed his concern that these regulations dilute the requirements to perform laser hair removal.

Ms. Yeatts replied that there is currently no regulation regarding laser hair removal. Since 2017, the Boards of Medicine and Nursing have been developing regulations. The Boards convened a Regulatory Advisory Panel (RAP) that listed competencies that need to be acquired to practice laser hair removal.

Dr. O'Connor added that, in an attempt to provide regulation for what is currently an unregulated practice, the expertise of the RAP was utilized to develop draft regulations.

Dr. Archer stated that we should only allow professionals that have some degree of training in the medical arena to provide laser hair removal.

Ms. Yeatts pointed out subsection D of the proposed regulations addresses this concern. Furthermore, section A of the proposed regulations defines proper training.

Ms. Barrett added that, in the event of a complaint or disciplinary action, the informal conference committee or the formal hearing will determine if the qualifications to perform laser hair removal or supervise laser hair removal met the regulatory requirements. The Board is entrusted to interpret the regulations as needed.

Dr. Walker moved to adopt the regulations. The motion was seconded and carried. Dr. Edwards and Dr. Archer voted in opposition to the motion.

- **Adoption of Proposed Regulations for Physician Assistants**

Ms. Yeatts noted that the purpose of this proposed regulatory action is to simplify and clarify the definitions of various terms for supervision to provide more consistency with the Code and with actual practice of physician assistants and supervising physicians.

She pointed to a comment on page 118 of the agenda packet from the Virginia Academy of Physician Assistants, which supports the proposed regulatory changes.

Also included were regulations for prescribing weight loss drugs, which included importing language from the physician regulations to the physician assistant regulations.

The definition of supervision has suggested amendments to revise the terms "Alternate Supervising Physician", "Direct Supervision", "General Supervision", "Personal Supervision", "Supervising Physician" and "Continuous Supervision". The new language would read, "Supervision means: the supervising physician has ongoing, regular communication with the physician assistant on the care and treatment of patients, is easily available and can be physically present or accessible for consultation with the physician assistant within one hour.

18VAC85-50-115 Responsibilities of the physician assistant has suggested amendments to include: B. An alternate supervising physician shall be a member of the same group or professional corporation or partnership of any licensee, any hospital or any commercial enterprise with the supervising physician. Such alternating supervising physician shall be a physician licensed in the Commonwealth who has registered with the board and who has accepted responsibility for the supervision of the service that a physician assistant renders.

18VAC85-50-181. Regulations for Pharmacotherapy for weight loss has suggested amendments to include C: If specifically authorized in his practice agreement with a supervising physician, a physician assistant may perform the physical examination, review tests, and prescribe Schedules III through VI controlled substances for the treatment of obesity, as specified in subsection B of this section.

Dr. Archer asked what drugs can a physician assistant prescribe under direct supervision.

Ms. Yeatts stated that they are allowed to prescribe Schedule II-VI drugs under general supervision and as determined by their practice agreement.

Dr. Harp noted that physician assistants have their own DEA number.

Dr. Toor moved to accept the regulations with revisions. The motion was seconded and carried.

- **Regulatory Action for Genetic Counselors**

Ms. Yeatts explained that this recommendation by the Advisory Board changes subsection C regarding temporary licenses to clearly state that a temporary license expires after the failure of the ABGC certification examination.

Dr. Walker, moved to accept the revision. The motion was seconded and carried.

- **Regulations Governing Prescribing for Opioids and Buprenorphine**

The Board of Medicine adopted emergency regulations for prescribing opioids, and those regulations became effective in March 2017. Upon adoption of emergency regulations, boards are required to immediately begin promulgating final regulations.

The Public Comment Period on the proposed regulations ended January 26, 2018, and the Board received a fair amount of comment. The Legislative Committee met just prior to the end of the comment period and had the benefit of reviewing the comments received by the time of its

meeting.

Dr. O'Connor suggested reviewing the regulations on pages 154-166, recommendations from Executive Committee on page 33, and recommendations from the Legislative Committee on page 38. The recommendations from the Legislative Committee repeat on page 167.

Ms. Yeatts guided the Board through a review of the regulations and comments. The Legislative Committee recommendations captured the elements of the comments on pages 129-153 and pages 168-177. Major themes in the comments included the addition of Sickle Cell Disease as a condition for exemption from the regulations.

Another major theme was the percentage of patients that can receive buprenorphine mono-product. The emergency regulations limit prescriptions for mono-product tablets to 3%, and only for those patients that have demonstrated, documented intolerance to naloxone.

The third theme was the cost of urine drug screens. The Legislative Committee looked at the CDC guidelines and decided to adopt those guidelines, one drug screen initially, and then at least one a year thereafter. The annual test should be random.

The fourth theme was confusion about tramadol. It appears that tramadol is clinically understood to be different from opioids, but it is in fact an atypical opioid. The Board may want to consider treating tramadol differently.

Finally, the Advisory Board on Physician Assistants voted to recommend to the full Board that opioid prescriptions note the indication for the prescription, whether post-op, chronic or acute pain so that the pharmacist knows this is proper prescribing. It was discussed that such a notation will save phone calls to the physician from the pharmacist.

Ms. Yeatts stated that today the Board is adopting final regulations. The Board 's action will make changes to the emergency regulations already in effect.

Dr. O'Connor requested the Board review the recommendations for adoption in the final regulations.

He recommended that the Board review the first bullet point, which includes Sickle Cell Disease as exempt from the regulations.

Dr. Ali, asked the Legislative Committee what was the genesis of this discussion?

Dr. Allison-Bryan stated that the Legislative Committee heard from members of the public in charge of local and statewide groups. These representatives said that they have constituents who have had difficulty obtaining sufficient pain control for Sickle Cell. It was pointed out that the Board's regulations say nothing about limiting the dose of opioids for Sickle Cell patients; the regulations only say that documentation of the rationale is required. Education of caregivers is necessary. However, since Sickle Cell patients are all across the state and some prescribers may not be as knowledgeable about the regulations, it didn't seem like a big give to exempt Sickle Cell.

Dr. Ali replied that the Board's regulations are perfectly aligned with the CDC regulations and their carve-outs. Dr. Ali noted that there is an initial backlash from providers that don't understand the regulations. All the Board wishes to achieve is guidance on thoughtful prescribing and enhanced safety for patients. Providers just have to document the rationale for the doses they prescribe. He said he didn't see how the regulations prevent prescribing for anything from Sickle Cell to fibromyalgia. Would the Board be diluting the regulations by including more carve-outs? What are other means of educating the community?

Dr. Toor stated his agreement with Dr. Ali, but if you specifically include cancer, as has been done as a carve-out, he doesn't see that treating Sickle Cell is different than treating cancer.

Dr. Ali stated the reason the CDC has these requirements is for the treatment of terminal patients.

Dr. Brown asked, what is in these regulations that prevents the treatment of cancer by opioids?

Nothing, Dr. Ali replied. There are more chronic pain conditions other than cancer and Sickle Cell. What other carve-outs might the Board make? He thinks educating providers is the better way to make sure the needs of patients are met.

Dr. Lee suggested that the Board require reading the regulations and to provide education for prescribers. She has seen, first-hand, surgeons that did not provide narcotics after a surgery that requires narcotics, because the surgeon is unfamiliar with the regulations.

Dr. Edwards noted his concern is for the patient because people don't read. If we need to put in a laundry list of what could be carved out, we should do it.

Dr. Ali says he is not arguing that chronic pain should not be treated. He is only noting that the Board should follow CDC requirements. He stated he doesn't have a specific problem with putting Sickle Cell on the exempt list, but then the Board could end up including several more carve-outs. Dr. O'Connor said that you must separate medicine and the purpose of the regulations and depoliticize it. The ultimate aim of the regulations is to improve patient safety. He noted a problem making carve-out after carve-out after disease carve-out. Will we be here next year putting another disease carve-out in the regulations?

Dr. Archer stated that he heartily endorses Dr. Ali's position. Leaving the regulations as they are ought to be enough for the average physician to know how to treat patients. What isn't in regulations is how to get the patients off the opioids. Physician education is important. The Board is not trying to cause harm, just require that documentation includes the rationale for the treatment provided.

Dr. Walker stated he believes in the process of the Committees and supports the process through which the regulations were drafted. Second, the regulations should not be political, but these regulations are political enough in that the public wants them. He ended by stating he thinks the Board should support the findings of the Legislative Committee.

Dr. Tuck asked what authority the Board has to educate doctors.

Dr. Harp stated that the Board of Medicine does not have an educational authority in the laws and regulations. The Board does not provide continuing medical education. The education on opioids provided by the Board started with the Prescription Monitoring Program in 2006. Four weekend events were offered around the state in two years. Does the Board have the manpower and resources to do this education? Probably not. The Board issues its newsletter that lists educational opportunities and will have an article demystifying the regulations in the next edition. But as far as education goes, physicians are behind the 8 ball in opioid education. Since 1996 the Board has had a guidance document on opioid prescribing. The forerunner guidance documents and the current regulations are meant to ensure good, safe medical care. Unfortunately, the prescribers who have not read the regulations believe they are required to reduce care rather than to facilitate good patient care. Dr. Harp said he does not have a vote, but he did not have a problem with including Sickle Cell, as it may help some providers to provide good patient care.

Dr. Edwards moved to approve the first bullet point that shall read: The treatment of acute or chronic pain related to (i) cancer, (ii) sickle cell disease, (III) a patient in hospice care, or (iv) a patient in palliative care.

The motion was seconded; a discussion was called.

Dr. Archer stated that every time the Board puts in a recommendation for a new regulation, it restricts the practice of physicians in some manner. The idea is to allow people who have pain to be prescribed appropriate medication. He doesn't think that the Board should be identifying specific groups.

Dr. Miller stated that the Board needs to first determine what Sickle Cell is.

Dr. Allison-Bryan noted Sickle Cell is a defined disease.

Dr. Toor said that the Board should keep in mind that Sickle Cell is not just a pain syndrome. We have to see it in a social context. It does affect people of lower socioeconomic status, who may not have access to quality medical care. Sickle Cell pain is real.

Dr. Ali replied that he is not advocating that Sickle Cell is not a real, chronic pain syndrome, but the Board is not here to include each pain syndrome that exists in the regulations. His point is that the current regulations do not restrict the treatment of Sickle Cell, so long as a practitioner provides competent patient care.

The discussion concluded, and Dr. O'Connor asked for a vote.

There were twelve "aye" votes. The six Board members voting against the motion were Dr. Miller, Dr. Conklin, Dr. Archer, Dr. Ali, Dr. O'Connor and Dr. Clements.

Recommendation point 2. Page 167: Although it is difficult to pinpoint a percentage of patients that demonstrate naloxone intolerance, the rate allowed by the regulations should be increased to 7%. Dr. Harp stated that the increase is justified based on clinical comments to the Board.

Dr. Harp, stated that he is going to pull back from the 7% and provided a brief history of this issue during the development of regulations. When the Board started the regulatory process, mono-product buprenorphine could only be used for pregnant women. When naloxone intolerance was first addressed by the Legislative committee in 2017, it voted to recommend that only pregnant women be prescribed mono-product. The Emergency Regulations became effective and Board staff began to get a lot of communication from people who said the mono-product "saved my life." The Board also heard from physicians who said that mono-product should be available. The Regulatory Advisory Panel (RAP) was reconvened and the experts on the RAP were split 50-50, with half believing that sensitivity to naloxone existed and half that did not. The RAP voted to recommend 3-5 % to the Legislative Committee. Even after doing a further search of the literature, Dr. Harp stated he could not find an estimate of naloxone intolerance in those taking buprenorphine.

Dr. Harp recalled that Dr. Aii asked at the May 2017 Legislative Committee meeting whether the number should be 3% or 5%. Dr. Harp responded that 3% should cover naloxone-intolerant patients. Dr. Harp referenced Dr. Manhapra, who said that more buprenorphine saves lives, less does not. Dr. Manhapra recommended that 15% of prescriptions for buprenorphine mono-product should be allowed.

Dr. Harp reiterated that he believes 7% is too high. In fact, the current 3% has resulted in less communication to the Board than anticipated. The Board can gauge the effect with 3% for a year and then perhaps consider a small increase if warranted. The data points the Board will need to see are the decrease in criminality associated with buprenorphine and the statistics for opioid overdose deaths. The Board has heard from physicians that if patients can't get the mono-product, they may go to the street to get heroin or fentanyl. Dr. Harp said leaving it at 3% and reviewing the data in a year would be a sound approach.

Dr. Conklin moved to reject the Legislative Committee's recommendation for the second bullet point.

The motion was seconded, and a discussion was called.

Dr. Tuck said the Legislative Committee had a 0-10% range and did not think the Committee was adamant about 7%.

Dr. Archer stated he doesn't believe a percentage is necessary.

Dr. O'Connor noted that the Board has a percentage that appears to be working.

Dr. Archer stated that if Dr. Harp can't find a percentage in the literature, where did the doctor that commented find his data?

Dr. Harp stated that Dr. Manhapra drew the percentage from national commercial insurance data, which is the best available. By that data set, in 2010, the percent of Subutex or mono-product prescriptions was 5.8%, and in 5 years it went up to 8.8%. Dr. Harp said it was difficult to understand the 3% increase in 5 years. The Board has decided on 3%, and that may well be

sufficient.

Dr. Walker stated that people who can't get mono-product may go out into the street and die. He didn't see anything wrong with increasing it a few percent. .

Dr. Toor stated his agreement with Dr. Walker.

The motion to increase the percentage was called; the vote was held ending in a 9-9 tie, so the motion failed. There will be no change regarding this point in the final regulations.

Recommendation point 3 page 167. Drug screens should be conducted initially and then randomly at the prescriber's discretion, at least once a year.

Dr. Allison-Bryan stated that this revision is entirely in line with CDC recommendations.

Dr. Edwards moved to approve the recommendation. The motion was seconded and carried.

Recommendation point 4, page 167. After the word "tramadol" in the regulations, add in parentheses "an atypical opioid."

Ms. Barrett stated that this is just adding a descriptive phrase. This is making no changes to the regulations.

Dr. Ali moved to accept the recommendation. The motion was seconded and carried.

Recommendation from the Advisory Board on Physician Assistants, Page 167 Number 2.

Dr. Allison-Bryan commented that this would save phone calls and reduce the risk of error by putting a cross check on the pharmacist.

Dr. Ali stated that pharmacists do call. For example, Sickle Cell is a condition when pharmacists will call.

Dr. Miller stated that his employer now requires prescriptions for all controlled substances to include a diagnosis.

Dr. Archer doesn't see anything wrong with having a physician put this on as communication to the pharmacist.

Dr. O'Connor stated that this appears to be a solution without a problem.

Ms. Yeatts stated that this would be an amendment to the regulations that will require prescribers to place a notation on prescriptions for opioids. It is not just guidance for good practice.

Dr. Archer recommended that the Board reject the recommendation of the Advisory Board.

Ms. Yeatts stated there needs to be a motion to adopt the final regulations with the amendments already discussed and approved.

Dr. Allison-Bryan made the motion, which was seconded and carried.

Licensing Report

Mr. Heaberlin noted the Board currently has approximately 69,000 licensees and registrants, which is an increase of about 6,000 individuals and six professions in the past five years.

Disciplinary Report:

Ms. Deschenes discussed security for Board members. She reviewed the process of obtaining security for disciplinary conferences and hearings.

Dr. Giammittorio recommended screening of everyone that comes into the hearing room

Dr. Brown stated that this is a conversation that should happen not just at the Board of Medicine. Some staff have had active shooter training. On what occasions is screening necessary? Do staff and Board members need to be screened? Screening doesn't take place at schools or colleges. What is going on in other state agencies and other state boards of medicine? Have there been incidents?

Dr. Ali stated that by the time respondents get to the Board, they have been beaten down. They are sometimes in bad condition, and this does raise the level of concern regarding the Board's safety.

Dr. Brown recommends a full discussion; the Board of Health Professions might be the place for input from all boards. In the meantime, Board staff should arrange rooms so that Board members can make a quick exit if need be. He believes that having someone do a safety assessment of the building would be a good idea with consideration for state of the art security.

4. **Appointment of the Nominating Committee**

All Board members interested in serving on the Nominating Committee, please contact Dr. Harp over the next week or so.

5. **Announcements** – Reminders Page: The next meeting date is June 14, 2018, and turn in your travel vouchers within 30 days.

6. **Adjournment**

ADJOURNMENT

Dr. O'Connor adjourned the meeting at 12:50 p.m.

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Kevin O'Connor, MD
President, Chair

_____
William L. Harp, MD
Executive Director

_____
Alan Heaberlin
Acting Recording Secretary