--- FINAL APPROVED --

VIRGINIA BOARD OF MEDICINE

LEGISLATIVE COMMITTEE MINUTES

Friday, January 19, 2018 | Department of Health Professions | Henrico, VA

CALL TO ORDER: The meeting convened at 8:37 a.m.

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

MEMBERS PRESENT:
Ray Tuck, DC, Vice-President, Chair
Barbara Allison-Bryan, MD
David Giammittorio, MD
Jane Hickey, JD
David Taminger, MD
Svinder Toor, MD

MEMBERS ABSENT: Isaac Koziol, 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
Elaine Yeatts, DHP Senior Policy Analyst
Erin Barrett, JD, Assistant Attorney General
Sherry Gibson, Administrative Assistant

OTHERS PRESENT:
Ryan LaMura, VHHA
Ajay Manhapra, MD, Hampton VA Medical Center
Tiffany Dews, Sickle Cell Chapter of Richmond
Julie Galloway, MSV
George Harris, Statewide Sickle Cell Chapters of VA
Dionne Bobo, Statewide Sickle Cell Chapters of VA

EMERGENCY EGRESS INSTRUCTIONS

Dr. Allison-Bryan provided the emergency egress instructions.

APPROVAL OF MINUTES OF MAY 19, 2017

Ms. Hickey moved to approve the meeting minutes of May 19, 2017. The motion was seconded and carried unanimously.

ADOPTION OF AGENDA

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

PUBLIC COMMENT

Dionne BoBo addressed the Committee saying that she has two children who have sickle cell disease. She asked the Committee to consider adding an exemption in the proposed opioid regulations to ensure that prescribers that treat patients with sickle cell disease know that they can provide adequate doses of opioids to control the pain.

Tiffany Dews, with Statewide Sickle Cell Chapters of Virginia and mother of two children with sickle cell, asked the Committee to exempt this population from the opioid regulations.

George Carter, with Statewide Sickle Cell Chapters of Virginia, requested an amendment to 18VAC85-21-10(B) that would include a fourth exception to the guidelines for "patients diagnosed with Sickle Cell Disease".

Ajay Manhapra, MD provided his perspective regarding the difficulty of opioid tapering in high-dose patients. He stated that restricting the writing of opioid prescriptions is not the solution and that the other side of this action is an alarming rate of suicide. Dr. Manhapra said that the policy seems based on feelings and not science. Regarding buprenorphine, it is not a detox medication or substitute therapy. The principle is that buprenorphine saves lives, and the lack of buprenorphine does not. He quoted a recent study that showed the use of buprenorphine mono-product nationwide was 8.8%. He asked the Committee to consider convening an ad hoc committee to look at the regulations again before going forward.

Julie Galloway expressed MSV's support for the existing emergency regulations.

The floor closed at 8:56 a.m.

DHP DIRECTOR'S REPORT

No report.

EXECUTIVE DIRECTOR'S REPORT

No report.

NEW BUSINESS

1. Report from the General Assembly

Elaine Yeatts distributed the most current report from the 2018 Session of the General Assembly and reviewed the bills that were of interest to the Committee. This report was for informational purposes only. No action was required.

2. Chart of Board of Medicine Regulatory Actions

Elaine Yeatts provided a brief overview of the Board's ongoing regulatory activity. She noted that the comment period on the proposed regulations for the prescribing of opioids and buprenorphine ends on January 26, 2018.

3. Review of Comments/Discussion of proposed regulations for opioid prescribing

Ms. Yeatts presented the proposed regulations. She noted that the major change from the initial emergency regulations was to incorporate the language below into the amended emergency regulations signed by Gov. McAuliffe August 24, 2017. The language below was presented to the Committee in the proposed regulations for consideration.

For patients who have a demonstrated intolerance to naloxone; such prescriptions for the mono-product shall not exceed 3.0% of the total prescriptions for buprenorphine written by the prescriber, and the exception shall be clearly documented in the patient's medical record.

Dr. Allison-Bryan noted that there was no language in the regulations about tapering or inpatient treatment. She noted that the amended emergency regulations do not limit the prescriber in terms of appropriate doses, and perhaps the regulations are being misunderstood. Now may be the Board's opportunity to reach out to prescribers and provide factual reassurance to those that have become reluctant to treat patients with adequate doses.

Dr. Harp stated that, based on the e-mail inquiries and phone calls he has received, a significant number of physicians have not read the regulations.

Dr. Toor agreed that sickle cell disease is like cancer; it is a chronic and deep wound pain that is not visible from the outside. In pediatric sickle cell patients, opioids are used very liberally, but that is only one part of the treatment. He feels that it would be reasonable to add sickle cell disease as an exemption, so the patients can receive proper care.

Ms. Deschenes said that public comment regarding the inclusion of an exemption for sickle cell disease was brought to the attention of the Executive Committee and discussed; however, the debate came down to, although sickle cell disease is an example of pain that requires large doses of opioids, so do many other diseases. How would the Board keep from expanding the list of such diseases/conditions? The fact remains that the practitioner needs to read and understand the regulations.

In response to Dr. Allison-Bryan's inquiry about how 3% became the threshold for total mono-product prescriptions, Ms. Yeatts advised that the Board considered 5%, which was intended to include patients with financial issues. However, the Board agreed to leave the financial piece out of the regulations, so the 3% is strictly for those that have documented naloxone intolerance.

Dr. Harp pointed out that half of the experts on the Regulatory Advisory Panel that practice medication-assisted treatment with buprenorphine did not believe in naloxone intolerance; the other half did. He said he found little information in the literature about naloxone intolerance to report to the May 2017 Legislative Committee, so it decided on 3%.

Ms. Yeatts then noted that a large number of people on treatment for chronic pain are financially strapped by the requirement for urine drug screens. The current regulations require drugs screens 2-4 times per year. She suggested looking to the Centers for Disease Control (CDC) guidelines for a different standard.

Dr. Allison-Bryan referred to page 73 of the CDC guidelines. CDC recommends that, in the context of chronic pain, clinicians should order urine drug testing before starting opioid therapy and consider urine drug testing at least annually. Such testing is to check for compliance with the prescribed regimen, other prescribed medications, and illicit drugs. Dr. Allison-Bryan said that screens are extremely helpful in disciplinary hearings. She noted that there are inexpensive screens that provide qualitative results. She believes there is still much prescriber education to be done.

Dr. Toor noted that CDC has no data to show drug testing is helpful. He thinks it should be done when the prescriber thinks it is needed. There should be some degree of freedom for those that are doing a good job. Not everyone should suffer for the mismanagement of the few.

Dr. Harp added that, anecdotally, buprenorphine + naloxone is abused as is the mono-product. A Richmond area organization that educates teenagers about drug abuse says that buprenorphine + naloxone is the most abused opioid by the youth they serve.

After discussion, the Committee agreed on the following recommendations to the Board:

- 18VAC85-21-10(B)(1) – 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.

- 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.

- Drug screens should be conducted initially and then randomly at the prescriber's discretion, at least once a year.

- Insert (atypical opioid) after tramadol, where applicable, in acute pain, chronic pain and buprenorphine. This should decrease the confusion that tramadol is not considered an opioid.

4. **Proposed Consent Order**

Ms. Deschenes and Caroline McNichol presented a Consent Order for reinstatement of a physician's license. Dr. Allison-Bryan moved to accept the Consent Order as presented. The motion was seconded and carried unanimously.

5. **Reminder:** Dr. Tuck reminded the Committee members to submit their travel expense reimbursement vouchers by February 19, 2018.

ANNOUNCEMENTS

There were no additional announcements.

Next meeting – May 18, 2018

Adjournment - With no other business to conduct, the meeting adjourned at 10:45 a.m.

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Ray Tuck, Jr., DC
Vice-President, Chair

William L. Harp, MD
Executive Director

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Colanthia Morton Opher, Operations Manager
Recording Secretary