FINAL APPROVED

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

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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.

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.

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

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 "<u>may</u> 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.

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.

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Adjournment

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

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Barbara Allison-Bryan, MD
Chairperson

William L. Harp, MD
Executive Director

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Alan Heaberlin
Deputy Director Licensure