

**VIRGINIA BOARD OF MEDICINE
Buprenorphine Work Group**

Friday, May 13, 2016

Department of Health Professions

Henrico, VA

CALL TO ORDER: The meeting was called to order by Dr. Kenneth Walker at 10:16 a.m.

MEMBERS PRESENT: Kenneth Walker, MD, Chair
David Buchsbaum, MD
Martin Buxton, MD
Lawrence Conell, MD
Margaret Gregorczyk, MD
Caroline Juran
Robert Lowe, MD
Mary McMasters, MD
Mark Mattingly, MD
Ralph Orr
Donna Proffitt
Mellie Randall
James Reinhard, MD
Mark Stevens, MD

STAFF PRESENT: William L. Harp, MD, Executive Director
Colanithia Morton Opher, Operations Manager
Lisa Hahn, MPA, DHP Deputy Director
Elaine Yeatts, DHP Senior Policy Analyst

OTHERS PRESENT: Cal Whitehead, Commonwealth Strategy Group
Kirsten Roberts, MSV
Anne Marie Williams
Michael Zohab, Captain RPD

Meeting Summary

Dr. Walker asked the Work Group members to introduce themselves. After the introductions, the floor was opened for public comment.

Anne Marie Williams addressed the Work Group and voiced her concerns over the varying amounts of buprenorphine found in buprenorphine products. She said that there are two products on the market that have significantly less buprenorphine, but that those products work in addiction treatment because they offer greater bioavailability. She suggested that Virginia follow the lead of Tennessee and Maryland in order to reduce the amount of buprenorphine on the streets that can be misused or abused.

Dr. Walker thanked Ms. Williams for her comments. There being no further comment, the floor was closed.

Dr. Harp began by stating that the charge of the Work Group came from Governor McAuliffe's Task Force on Prescription Drug and Heroin Abuse established September 2014. The Task Force recommended that the Board of Medicine, with the assistance of the Department of Behavioral Health and Developmental Services, convene a group to review the standards of care in the literature and to make evidence-based recommendations to the Board of Medicine for possible promulgation of regulations. Dr. Harp also explained the difference between a guidance document and regulations.

The Work Group agreed to focus on the creation of a guidance document that would inform practitioners how to properly treat opioid addiction with buprenorphine products in the context of medication-assisted therapy. The Work Group briefly reviewed several documents including:

- SAMHSA Advisory – *“Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder: Review and Update”*
- Kentucky's *“Professional Standards for Prescribing or Dispensing Buprenorphine Mono-Product or Buprenorphine Combined with Naloxone”*
- Alabama's Administrative Code – *“Guidelines for the Treatment of Opioid Addiction in the Medical Office”*
- Substance Abuse and Mental Health Services Administration's – (SAMHSA) *“Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction”*
- American Society of Addiction Medicine's (ASAM) *“National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use”*
- Federation of State Medical Board's (FSMB) *“Model Policy on Data 2000 and Treatment of Opioid Addiction in the Medical Office”*

Dr. Harp offered up two options to the members for their consideration. The first option was to review and revise a draft outline of major items that was quilted together from all the resources that were provided to the members in advance. After settling on the major items, the group could add further information to fill out the document. The second was to follow the suggestion by Ms. Yeatts to use the Model Policy from FSMB as a basis for the guidance document. The group chose to work with the Model Policy from FSMB.

The Work Group members placed several concerns on the table to be considered in the development of the guidance document.

- The notion that Suboxone is safer and less abusable and should not have the same guidelines and monitoring that other opiate-replacement treatment requires.
- Minimal training requirements in order to obtain a waiver to prescribe buprenorphine
- Lack of physicians treating addiction in the office setting
- Insurance companies guiding their subscribers with more oversight into seeing that they receive counseling while in medication-assisted treatment
- Minimum standards of care to improve the quality, reduce cost and avoid harm to the public

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- Medication-assisted harm avoidance model versus a liability model
- Physical examinations should be performed during the initial assessment
- Physical examinations in the outpatient setting
- Double standard regarding physical examinations which are required to begin methadone
- Bona fide doctor patient-relationship
- Overdoses may not be overdoses, but rather synergy between opioids and benzos
- General practitioners with an 8-hour course expected to perform as addictionologists

PROPOSED REVISIONS AND ADDITIONS TO THE FSMB MODEL POLICY

SECTION I:

- Preamble

Dr. Gregorzcyk and Ms. Randall volunteered to revise the Preamble to include language on how the brain is hijacked by addiction and to add a minimum number of required continuing medical education hours specific to addiction medicine.

- Federal Requirements to Prescribe Buprenorphine for Addiction

No changes can be made to federal requirements.

- Prescription Requirements

No changes can be made to federal requirements.

- State Medical Board Requirements

No changes suggested.

SECTION II: Guidelines

- Physician Qualifications - the members agreed to the following language change:
 - The diagnosis and medical management of the disease of addiction and opioid addiction should be based on current knowledge and research, ...
- Ensure language includes: These guidelines are not intended to define complete or best practices but rather to communicate what the Board considers to be within the boundaries of accepted professional practice.
- Patient Assessment
 - Add language – release of information from other providers.

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- Add language - The following is not meant to be an all-inclusive list but suggestive of what needs to be in the assessment. For more details, refer to ASAM.
- Add language - Along with the documentation of use of other substances, including alcohol and other drugs of abuse, the documentation of route of administration, intranasal use, injection history, age of onset of substance use or misuse, date of last use, history of seizures, presence of track marks
- Instead of the sentence on the bottom of page 6 that indicates an assessment is of higher quality when the following are incorporated, these should be included as minimal standards for beginning medication-assisted treatment
 - o Medical and psychiatric history
 - o Substance abuse history
 - o Evaluation of family and psychosocial supports
 - o Pregnancy test for all women of childbearing age
 - o Appropriate physical examination focused on neurocognitive function, sequelae of opioid addiction, and hepatic dysfunction
- Treatment Planning
 - Adding sentence above treatment planning that says, Therefore, an individualized treatment plan is critical to the patient's ultimate success in returning to productive functioning.
 - [53] – Add in bold print – **The monoprodut should be used only rarely except in pregnant women, for whom it is the formulation.**
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 - Educating the Patient
 - o Last sentence on bottom of page 7 –
- Informed Consent – no changes
- Treatment Agreement – no changes
 - o Induction, Stabilization and Follow-up – page 9,
 - o 1st paragraph [60] – The goal of induction and stabilization is to find the lowest dose of buprenorphine at which the patient discontinues the use of illicit ~~or markedly reduces the use of other~~ opioids without experiencing withdrawal...[violation of agreement]
 - o 4th paragraph [64] – stabilize on eight to 24 16 mg of buprenorphine per day, although some may need doses of up to ~~32~~ 24 mg per day.

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- Other language to incorporate in the guidance document where appropriate:
 - A physician may prescribe or dispense a buprenorphine product to a patient who is also being prescribed benzodiazepines, other sedative hypnotics or stimulants without consultation in order to address an extraordinary or acute medical need not to exceed a combined period of 30 days.
 - Language to strongly recommend that prescribers have access to licensed behavioral health professionals who can assess the psychosocial support system and need for counseling and ensure these issues are addressed

- Special populations – include:
 - Ages 15-18
 - Pregnant women
 - Chronic Pain
 - Incarcerated and Recently Released
 - Geriatrics
 - Health Care Professionals
 - Military Personnel

At the end of the discussion, Dr. Harp said that the proposed revisions would be incorporated into the FSMB Model Policy and sent to each member individually for review prior to the next meeting.

Staff will also send out Doodle for a meeting date for late July early August.

With no other business, the meeting adjourned at 3:11 p.m.

Kenneth Walker, MD, President, Chair

William L. Harp, M.D.
Executive Director

Colanthia M. Opher
Recording Secretary