Legislative Committee Meeting

Virginia Board of Medicine

May 19, 2017
8:30 a.m.

Legislative Committee

Virginia Board of Medicine
Friday, May 19, 2017, 8:30 a.m.
9960 Mayland Drive, Suite 200
Board Room 1
Henrico, VA 23233

Page

Call to Order – Kevin O'Connor, MD, Chair

Roll Call

Egress Instructions i

Approval of Minutes of January 27, 2017 1-4

Adoption of Agenda

Public Comment on Agenda Items (15 minutes)

DHP Director Report ..... -----

Executive Director Report ..... -----

New Business

1. Chart of Board of Medicine Regulatory Actions 5-5
2. Consideration of the Recommendations from the Regulatory Advisory Panel, Supporting Documents, and Public Comment 6-102
3. Draft Regulations for Licensure by Endorsement 103-120
4. Reminder 121

Announcements

Next Meeting: September 8, 2017

Adjournment

PERIMETER CENTER CONFERENCE CENTER
EMERGENCY EGRESS OF BOARD AND TRAINING ROOMS
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Board Room 1

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VIRGINIA BOARD OF MEDICINE
LEGISLATIVE COMMITTEE MINUTES

Friday, January 27, 2017 | Department of Health Professions | Henrico, VA

CALL TO ORDER: The meeting convened at 8:40 a.m.

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

MEMBERS PRESENT:
Kevin O'Connor, MD, Vice-President, Chair
Barbara Allison-Bryan, MD, President
Syed Salman Ali, MD
David Giammittorio, MD
Wayne Reynolds, DO

MEMBERS ABSENT:
Svinder Toor, MD
The Honorable Jasmine Gore

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
David Brown, DC, DHP Director
Erin Barrett, JD, Assistant Attorney General
Joy Langford, Administrative Assistant

OTHERS PRESENT:
W. Scott Johnson, JD, HDJN
Sara Heisler, VHHA
Tim Bunton, MD, VATAC
Sergey Zhitar, MD, VATAC
Kate Neuhausen, MD, DMAS
Zia Uddin, MD, VATAC
Tom Reach, MD, Watauga Recovery Center
Lauren Bates-Rowe, MSV
Peter Breslin, MD

EMERGENCY EGRESS INSTRUCTIONS

Dr. O'Connor provided the emergency egress instructions.

ADOPTION OF AGENDA

Dr. Reynolds made a motion to accept the agenda as presented.

The motion was seconded and carried unanimously.

APPROVAL OF MINUTES OF SEPTEMBER 16, 2016

Dr. Ali moved to approve the meeting minutes of September 16, 2016 after an edit to include "Virginia" in the title of "Scott Johnson, General Counsel to the Medical Society of." The motion was seconded and carried unanimously.

PUBLIC COMMENT

Tim Bunton, MD, Virginia Addiction Treatment Access Coalition (VATAC)
Dr Bunton noted that VATAC supports screening for communicable diseases. However, medical practices will benefit from guidelines rather than mandates to screen. VATAC believes the guidelines will reduce the impact of opioid addiction.

Sergey Zhitar, MD, VATAC,
Dr. Zhitar noted that he was pleased the recommendations from the Board are based on scientific evidence. He pointed out that there may be circumstances other than pregnancy in which Subutex might be indicated.

Dr. Tom Reach, MD Watauga Recovery Center
Dr. Reach stated that addiction medicine is a new field. Ideally, addiction treatment should be undertaken by those with a specialty in addiction medicine. Dr. Reach believes the most important goal is to be able to increase the access of care for those who need it.

Kate Neuhausen, MD – Chief Medical Officer, Virginia Department of Medical Assistance Services (DMAS)
Dr. Neuhausen said that Subutex (buprenorphine mono-product) is now a drug of abuse in Southwest Virginia because the cost is significantly less than Suboxone (buprenorphine + naloxone) and is more abusable. She pointed out that the Butrans (buprenorphine mono-product) patch is effective and is covered by DMAS as an alternative to the Fentanyl patch and Oxycontin. She added that DMAS would like to see language in the regulations that includes the appropriate use of buprenorphine mono-product patches.

Lauren Bates-Rowe, Medical Society of Virginia (MSV)
Ms. Bates-Rowe noted that the Center for Disease Control guidelines do not apply to post-surgical pain. In the future, MSV would like to work with the Board to encourage clinically appropriate use of opioids. She asked that the Board clarify if the dosages in the regulations were absolute. Finally, MSV would like to partner with the Board of Medicine in disseminating any information that would be helpful to its physicians in the use of opioids.

Peter Breslin, MD – VATAC
Dr. Breslin pointed out that buprenorphine mono-product might be indicated in circumstances other than pregnancy. Infectious disease testing prior to treatment should be encouraged.

DHP DIRECTOR'S REPORT

Dr. Brown provided a brief report. He noted that the current bills affecting the Department of Health Professions (DHP) in the General Assembly reflect the agenda of DHP and the Board of Medicine.

EXECUTIVE DIRECTOR'S REPORT

Dr. Harp noted that from now on the Board of Medicine will post the agenda packet in advance of its business meetings.

Dr. Harp reviewed correspondence from MSV in support of the Board's regulatory effort to streamline the licensure process for physicians and other health care professionals.

Dr. Harp also reviewed correspondence to Dr. Brown from legislators that noted a shortage of anesthesia providers in Virginia and asked for a feasibility study to determine if certified anesthesia assistants should be regulated by the Board of Medicine. Dr. Brown responded that the feasibility study will be undertaken by the Board of Health Professions, and a report will be submitted to Sen. Newman and Del. Orrock by November 2017.

NEW BUSINESS

1. Chart of Board of Medicine Regulatory Actions

Elaine Yeatts provided a brief overview of this item. No action was required.

2. Legislative Review of the 2017 Session of the General Assembly

Elaine Yeatts provided an overview of the current bills that would have impact on the Board of Medicine. No action was required.

3. Review and Revision of Draft Guidance Document on the Use of Buprenorphine for Addiction.

Dr. O'Connor suggested that this item be tabled; the Committee was in agreement. The guidance document will be revisited after the Legislature has finished its work this Session, and the regulations are in final form.

4. Review and Revision of Draft Regulations for Pain Management and Buprenorphine.

Ms. Yeatts reviewed the draft regulations with the Legislative Committee Members who requested several revisions. Upon completion of the review, Dr. Allison-Bryan moved to accept the draft regulations with revisions and recommend them to the full Board at its February meeting. The motion was seconded and carried.

5. Reminder: Dr. Harp reminded the Committee members to complete their travel expense reimbursement vouchers.

ANNOUNCEMENTS

There were no additional announcements.

Next meeting – May 19, 2017

Adjournment - With no other business to conduct, the meeting adjourned at 12:30 p.m.

_____
Kevin O'Connor, MD
Vice-President, Chair

_____
William L. Harp, MD
Executive Director

_____
Alan Heaberlin, Deputy Director, Licensing
Recording Secretary

Agenda Item: Regulatory Actions - Chart of Regulatory Actions

As of May 11, 2017

Chapter		Action / Stage Information
[18 VAC 85 - 20]	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic	Licensure by endorsement [Action 4716] NOIRA - *Register Date: 1/23/17* *Comment closed: 2/22/17*
[18 VAC 85 - 21]	Regulations Governing Prescribing of Opioids and Buprenorphine	Initial regulations [Action 4760] Emergency/NOIRA - *Register Date: 4/3/17* *Effective: 3/15/17*
[18 VAC 85 - 50]	Regulations Governing the Practice of Physician Assistants	Elimination of required submission of certain documents [Action 4629] Fast-Track - *Register Date: 5/15/17* *Effective: 6/29/17*
[18 VAC 85 - 80]	Regulations for Licensure of Occupational Therapists	NBCOT certification as option for CE [Action 4461] Proposed - *At Secretary's Office* [Stage 7756] Will be withdrawn
[18 VAC 85 - 170]	Regulations Governing the Practice of Genetic Counselors	Initial regulations for licensure [Action 4254] Final - *Register Date: 5/15/17* *Effective: 6/14/17*

Agenda Item: Consideration of the Recommendations from the Regulatory Advisory Panel, Supporting Documents, and Public Comment

Staff Note: This section contains the Regulations Governing Prescribing Opioids and Buprenorphine, Frequently Answered Questions, Public Comment from Townhall, and Questions and Comments received at the Board. A hard copy of the recommendations from the Regulatory Advisory Panel will be handed out at the meeting. As soon as the recommendations are prepared, they will be sent electronically to you prior to the meeting. The recommendations are the result of a panel of physicians and a Doctor of Pharmacology, arrived at after consideration of the public comment, input from the Virginia Department of Health, the Department of Medical Assistance Services, the Department of Behavioral Health and Developmental Services, and the Department of Health Professions.

Action: The Legislative Committee needs to make recommendations to the full Board of Medicine for consideration at its June 22, 2017 meeting.

Commonwealth of Virginia

REGULATIONS

GOVERNING PRESCRIBING OPIOIDS AND BUPRENORPHINE

VIRGINIA BOARD OF MEDICINE

Title of Regulations: 18 VAC 85-21-10 et seq.

Statutory Authority: § 54.1-2400 and Chapter 29 of Title 54.1 of the *Code of Virginia*

Effective Date: March 15, 2017

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Part I. General Provisions.

18VAC85-21-10. Applicability.

A. This chapter shall apply to doctors of medicine, osteopathic medicine, and podiatry and to physician assistants.

B. This chapter shall not apply to:

1. The treatment of acute or chronic pain related to cancer, a patient in hospice care, or a patient in palliative care;

2. The treatment of acute or chronic pain during an inpatient hospital admission, in a nursing home or an assisted living facility that uses a sole source pharmacy; or

3. A patient enrolled in a clinical trial as authorized by state or federal law.

18VAC85-21-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Acute pain" shall mean pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances may be prescribed for no more than three months.

"Board" shall mean the Virginia Board of Medicine.

"Chronic pain" shall mean non-malignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.

"Controlled substance" shall mean drugs listed in The Drug Control Act of the Code of Virginia in Schedules II through IV.

"FDA" shall mean the U.S. Food and Drug Administration.

"MME" shall mean morphine milligram equivalent.

"Prescription Monitoring Program" shall mean the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

"SAMHSA" means the Substance Abuse and Mental Health Services Administration.

Part II. Management of Acute Pain.

18VAC85-21-30. Evaluation of the acute pain patient.

A. Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days.

B. Prior to initiating treatment with a controlled substance containing an opioid for a complaint of acute pain, the prescriber shall perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in § 54.1-2522.1of the Code of Virginia and conduct an assessment of the patient's history and risk of substance abuse.

18VAC85-21-40. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

1. A prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record. This shall also apply to prescriptions of a controlled substance containing an opioid upon discharge from an emergency department.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

C. Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

D. Buprenorphine is not indicated for acute pain in the outpatient setting, except when a prescriber who has obtained a SAMHSA waiver is treating pain in a patient whose primary diagnosis is the disease of addiction.

18VAC85-21-50. Medical records for acute pain.

The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan and the medication

prescribed or administered to include the date, type, dosage, and quantity prescribed or administered.

Part III. Management of Chronic Pain.

18VAC85-21-60. Evaluation of the chronic pain patient.

A. Prior to initiating management of chronic pain with a controlled substance containing an opioid, a medical history and physical examination, to include a mental status examination, shall be performed and documented in the medical record, including:

1. The nature and intensity of the pain;

2. Current and past treatments for pain;

3. Underlying or coexisting diseases or conditions;

4. The effect of the pain on physical and psychological function, quality of life and activities of daily living;

5. Psychiatric, addiction and substance abuse history of the patient and any family history of addiction or substance abuse;

6. A urine drug screen or serum medication level;

7. A query the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia;

8. An assessment of the patient's history and risk of substance abuse; and

9. A request for prior applicable records.

B. Prior to initiating opioid treatment for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment to include securely storing the drug and properly disposing of any unwanted or unused drugs. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective.

18VAC85-21-70. Treatment of chronic pain with opioids.

A. Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.

B. In initiating and treating with an opioid, the practitioner shall:

1. Carefully consider and document in the medical record the reasons to exceed 50 MME/day;

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Prescribe naloxone for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present; and

4. Document the rationale to continue opioid therapy every three months.

C. Buprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose.

D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medications if prescribed.

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate healthcare provider, or refer the patient for evaluation and treatment if indicated.

18VAC85-21-80. Treatment plan for chronic pain.

A. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including but not limited to pain relief and improved physical and psychosocial function, quality of life, and daily activities.

B. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

C. The prescriber shall document in the medical records the presence or absence of any indicators for medication misuse, abuse or diversion and shall take appropriate action.

18VAC85-21-90. Informed consent and agreement for treatment for chronic pain.

A. The practitioner shall document in the medical record informed consent, to include risks, benefits and alternative approaches, prior to the initiation of opioids for chronic pain.

B. There shall be a written treatment agreement, signed by the patient, in the medical record that addresses the parameters of treatment, including those behaviors which will result in referral to a higher level of care, cessation of treatment, or dismissal from care.

C. The treatment agreement shall include, but not be limited to, notice that the practitioner will query and receive reports from the Prescription Monitoring Program and permission for the practitioner to:

1. Obtain urine drug screens or serum medication levels, when requested; and

2. Consult with other prescribers or dispensing pharmacists for the patient.

D. Expected outcomes shall be documented in the medical record including improvement in pain relief and function or simply in pain relief. Limitations and side effects of chronic opioid therapy shall be documented in the medical record.

18VAC85-21-100. Opioid therapy for chronic pain.

A. The practitioner shall review the course of pain treatment and any new information about the etiology of the pain and the patient's state of health at least every three months.

B. Continuation of treatment with opioids shall be supported by documentation of continued benefit from such prescribing. If the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

C. Practitioners shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

D. Practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter.

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate healthcare provider, or refer the patient for evaluation for treatment if indicated.

18VAC85-21-110. Additional consultations.

A. When necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment.

B. When a prescriber makes the diagnosis of opioid use disorder, treatment for opioid use disorder shall be initiated or the patient shall be referred for evaluation and treatment.

18VAC85-21-120. Medical records for chronic pain.

The prescriber shall keep current, accurate and complete records in an accessible manner readily available for review to include:

1. The medical history and physical examination;

2. Past medical history;

3. Applicable records from prior treatment providers and/or any documentation of attempts to obtain;

4. Diagnostic, therapeutic and laboratory results;

5. Evaluations and consultations;

6. Treatment goals;

7. Discussion of risks and benefits;

8. Informed consent and agreement for treatment;

9. Treatments;

10. Medications (including date, type, dosage and quantity prescribed and refills).

11. Patient instructions; and

12. Periodic reviews.

Part IV. Prescribing of Buprenorphine for Addiction Treatment.

18VAC85-21-130. General provisions pertaining to prescribing of buprenorphine for addiction treatment.

A. Practitioners engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a SAMHSA waiver and the appropriate Drug Enforcement Administration registration.

B. Practitioners shall abide by all federal and state laws and regulations governing the prescribing of buprenorphine for the treatment of opioid use disorder.

C. Physician assistants and nurse practitioners, who have obtained a SAMHSA waiver, shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a waivered doctor of medicine or doctor of osteopathic medicine.

D. Practitioners engaged in medication-assisted treatment shall either provide counseling in their practice or refer the patient to a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance abuse counseling. The practitioner shall document provision of counseling or referral in the medical record.

18VAC85-21-140. Patient assessment and treatment planning for addiction treatment.

A. A practitioner shall perform and document an assessment that includes a comprehensive medical and psychiatric history, substance abuse history, family history and psychosocial supports, appropriate physical examination, urine drug screen, pregnancy test for women of childbearing age and ability, a check of the Prescription Monitoring Program, and, when clinically indicated, infectious disease testing for HIV, Hepatitis B, Hepatitis C and TB.

B. The treatment plan shall include the practitioner's rationale for selecting medication assisted treatment, patient education, written informed consent, how counseling will be accomplished, and a signed treatment agreement that outlines the responsibilities of the patient and the prescriber.

18VAC85-21-150. Treatment with buprenorphine for addiction.

A. Buprenorphine without naloxone (buprenorphine mono-product) shall not be prescribed except:

1. When a patient is pregnant;

2. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days; or

3. In formulations other than tablet form for indications approved by the FDA.

B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed opioid treatment programs (OTPs). With the exception of those conditions listed in subsection A, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use offsite from the program.

C. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

D. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

E. Prior to starting medication-assisted treatment, the practitioner shall perform a check of the Prescription Monitoring Program.

F. During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on no more than 8 mg. of buprenorphine per day. The patient shall be seen by the prescriber at least once a week.

G. During the stabilization phase, the prescriber shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

H. Practitioners shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of the Prescription Monitoring Program. The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

I. Documentation of the rationale for prescribed doses exceeding 16 mg. of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 mg. of buprenorphine per day shall not be prescribed.

J. The practitioner shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance abuse counseling.

18VAC85-21-160. Special populations in addiction treatment.

A. Pregnant women shall be treated with the buprenorphine mono-product, usually 16 mg. per day or less.

B. Patients under the age of 16 years shall not be prescribed buprenorphine for addiction treatment unless such treatment is approved by the FDA.

C. The progress of patients with chronic pain shall be assessed by reduction of pain and functional objectives which can be identified, quantified and independently verified.

D. Practitioners shall evaluate patients with medical comorbidities by history, physical exam, appropriate laboratory studies, and be aware of interactions of buprenorphine with other prescribed medications.

E. Practitioners shall not undertake buprenorphine treatment with a patient who has psychiatric comorbidities and that is not stable. A patient who is determined by the prescriber to be psychiatrically unstable shall be referred for psychiatric evaluation and treatment prior to initiating medication-assisted treatment.

18VAC85-21-170. Medical records for opioid addiction treatment.

A. Records shall be timely, accurate, legible, complete and readily accessible for review.

B. The treatment agreement and informed consent shall be maintained in the medical record.

C. Confidentiality requirements of 42 CFR, Part 2 shall be followed.

D. Compliance with Board of Medicine Regulation 18VAC85-20-27, which prohibits willful or negligent breach of confidentiality or unauthorized disclosure of confidential Prescription Monitoring Program information, shall be maintained.

Virginia Board of Medicine

Frequently Asked Questions about the Prescribing of Buprenorphine for Addiction

1. **Can I continue to prescribe mono-product for my patients that have a demonstrated intolerance to naloxone –containing products?**

The answer by the current regulations is NO. There is no exception in the regulations that would permit prescribing of the mono-product in tablet form for naloxone intolerance. However, the buprenorphine mono-product may be prescribed in FDA-approved "formulations other than tablet form" pursuant to 18 VAC 85-21-150(A)(3). The Board of Medicine will consider this issue in the near future, and if a revision is made, it will be circulated to prescribers.

2. **What alternatives to buprenorphine mono-product for addiction are there?**

This is not an endorsement for a particular medication, and there may be other alternatives unknown to the Board at this time. The only other mono-product currently FDA-approved for the treatment of addiction is the Probuphine implant. Formulations with low-dose naloxone include Zubsolv sublingual tablets and Bunavail buccal film. Methadone and Vivitrol are also options.

3. **Is there a grace period for switching patients to a naloxone-containing product?**

It is lawful to prescribe up to 7 days of mono-product in the switching of a patient from methadone to a naloxone-containing product or for 7 days in switching a patient from the mono-product to a naloxone-containing product.

4. **Is there a grace period for tapering patients off the mono-product if they choose not to take a naloxone-containing product?**

There is no grace period in the regulations, other than what is stated above. The Board does expect that sound medical judgement and safety of the patient will be paramount in the tapering process.

5. **When do I have to stop prescribing the mono-product?**

The regulations became effective March 15, 2017.

6. **Are buprenorphine and naloxone safe for mothers and their breastfeeding infants?**

The American Society of Addiction Medicine National Practice Guideline adopted June 2015 stated, "It was shown that the amount of buprenorphine metabolites secreted in breastmilk are so low that they pose little risk to breastfeeding infants." In the May 11, 2016 issue of the ASAM Magazine, a question about breastfeeding was addressed by a Providers' Clinical Support System expert, "While buprenorphine levels transfer to breastmilk in very low levels, naloxone is even much less detectable, if at all." An August 2016 article from the Journal of Human Lactation confirmed that infant plasma levels were low or undetectable. A consultant to the Board, an OB-GYN who provides MAT,

opines that naloxone-containing products prescribed to the mother can be considered safe for breastfeeding infants.

7. Is the prescribing of tramadol subject to these regulations?

YES, tramadol is an opioid and is therefore subject to these regulations.

8. Can I use the mono-product for induction and then switch to the naloxone-containing product?

The regulations do not speak to induction with the mono-product and then switching to a naloxone-containing product. The regulations state that 7 days of mono-product can be written in the switching from mono-product to a naloxone containing product.

9. Can a pharmacist dispense a prescription of the mono-product for a non-pregnant individual after March 15, 2017?

It is recommended that the pharmacist contact the prescriber to discuss the prescription and to make sure the prescriber is aware of the regulations.

10. Can my staff see the patient during the induction phase?

The regulations require that the patient be seen "by the prescriber" at least once a week during induction.

11. Does the Board have a list of "sedative hypnotics"?

No.

12. Can I continue to prescribe benzodiazepines with buprenorphine?

The regulations allow for benzodiazepines in the lowest effective dose required for the treatment of co-morbid conditions. Extenuating circumstances must be documented in the medical record to support the prescriber's rationale.

13. Is there an exception for financial hardship that allows a patient to take Subutex instead of Suboxone?

NO. There is no such exception in the regulations. However, the Medical Society of Virginia has developed the following list of resources for patients that may need help with the expenses of treatment with naloxone-containing products. https://www.msv.org/sites/default/files/patient_assistance_resources.pdf

Virginia Board of Medicine

Frequently Asked Questions about the Prescribing of Opioids for Pain

1. **Do I need to refer a patient being treated for chronic pain to a pain management specialist before exceeding 120 MME/day?**

The regulations require the prescriber to document the reasonable justification for the increase OR refer to or consult with a pain management specialist.

2. **If a patient being treated for chronic pain admits to occasional marijuana use or has a positive screen, what should I do?**

This issue is not addressed in the regulations. The Board of Medicine expects physicians to use good judgement in their care of patients and fully document what you do and why in the chart.

3. **If a patient I am treating for chronic pain is on a benzodiazepine from another provider, must I prescribe naloxone?**

YES. The regulations are meant to save lives. There would need to be coordination with the other practitioner so that you are on the same page. Controlled substances from more than one prescriber could lead to an inadvertent overdose. There is a provision for "extenuating circumstances" in the regulations, in case the benzo is absolutely essential to the patient's well-being.

4. **What if the benzodiazepine is only PRN?**

The Board of Medicine cannot recommend deviation from the regulations.

5. **Must I drug screen all patients that I will be putting on opioids for chronic pain?**

YES, that is what is required by the regulations.

6. **What is the Board's policy on PRN pain medications?**

The regulations require drug screens for patients on chronic opioid medications. The Board cannot recommend deviation from the regulations. The Board would make the determination about the standard of care in such a case, based upon the documentation of the treatment.

7. **Is it true that I can only prescribe 1 week of opioid for acute pain?**

Prescribing is limited to a 7-day supply unless "extenuating circumstances are clearly documented in the medical record."

8. Can I write for more than 14 days for post-operative pain?
Prescribing is limited to a 14-day supply unless "extenuating circumstances are clearly documented in the medical record."

9. Is tramadol an opioid?

YES. It is an opioid and a Schedule IV drug.

10. Is tramadol subject to these regulations?

YES.

11. How can a pharmacist determine that a physician is prescribing for acute pain, post-op pain, or chronic pain?

It has been suggested that prescribers put a notation on the prescription as to whether the drug is for acute pain, post-op pain, or chronic pain. The Board sees this as an excellent communication between professionals involved in the patient's care.

12. Does the Board of Medicine have a list of "sedative hypnotics"?

NO

13. Must patients that have been stable on their current dose of opioid analgesic for a long time be drug tested?

YES, the regulations require testing every 3 months during the first year of treatment and every 6 months thereafter.

14. Do I have to ensure that a patient fills the prescription for naloxone?

NO, the prescriber's responsibility is to prescribe the naloxone, but the regulations do not require that the prescriber ensures that the patient gets it filled. However, a prescriber may wish to revisit the dose of opioid prescribed, if warranted.

15. Can a pharmacist fill an opioid prescription exceeding 120 MME/day, or with concomitant benzodiazepine, if a patient does not present a naloxone prescription?

The answer is YES, but it would be within your discretion to call the prescriber to ask if that is what he/she intended.

16. Must naloxone be prescribed for lower doses of opioids in the presence of benzodiazepines?

YES, the regulations state that is the case.

17. Can I use Subutex and Suboxone off-label for the treatment of pain?

Currently the regulations only allow drugs that have an FDA indication for the treatment of pain. The Board is convening a Regulatory Advisory Panel that will review this issue and revise the regulations if warranted.

18. Does the physician have to see pain patients every 3 months or can a nurse practitioner or a physician assistant see a patient, assess the opioid therapy, evaluate for opioid use disorder and document findings in the medical record?

The regulations use the term "practitioner" and state these issues need to be addressed every 3 months. Nurse practitioners and physician assistants can perform acts of medicine through a practice agreement with a physician. As long as the NP and PA are trained and competent to accomplish the assessments required, and the physician maintains responsibility for patient care, it would appear that the requirements of the law would be met.

19. If a patient is held in the ED or other part of the hospital for 24-48 hours, do the regulations apply?

The regulations do not apply to pain treated during an inpatient hospital admission. Observation is an administrative status for a patient that is under clinical watch and care within the hospital, therefore the regulations would not apply. However, when the patient is discharged, the regulations would apply in regards to the 7-day limit of opioid or more if extenuating circumstances are documented.

TOWNHALL QUESTIONS AND COMMENTS

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Logged in as
Elaine J. Yeatts

Department of Health Professions

Board **Board of Medicine**

Chapter **Regulations Governing Prescribing of Opioids and Buprenorphine [18 VAC 85 - 21]**

Action	Initial regulations
Stage	Emergency/NOIRA
Comment Period	Ends 5/3/2017

All good comments for this forum Show Only Flagged

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Commenter: Kyle Miles

4/4/17 9:22 am

Buprenorphine regulations are hurting people with a documented allergy.

These new regulations are hurting people that have a documented hypersensitivity/allergy on record. They are already being turned away from treatment because the doctors hands are tied. According to the legislative site the bill was never signed. When I called the Governors office on march 16th I was told the bill hadn't been signed. It was put into effect anyway. I can understand regulations on medications but to turn patients away because they cannot have the combination drug is wrong. These patients have been trying to get their lives together, and as far as I know most doctors won't write buprenorphine mono unless they have a reason too in the first place. I urge you all to amend the regulations and allow people with a hypersensitivity/allergy to also be allowed to get a prescription at the very least. I believe OTP cinics should also be allowed to dispense it in take homes, because patients that go to these clinics have earned their take homes just like a methadone patient did. They went for months on end to earn their couple of take homes and after around 9 months they earn a week. Switching what medications an OTP can dispense increases cost to the patient and the clinic. The patients that do have a documented allergy on file should be allowed to continue to get a prescription. It isn't their fault they cannot have the combination drug. I'm sure if they could they would rather do that than lose treatment all together. The 2 closest clinics in my area are both around 50 miles away one way. One of them is in Virginia, and this town has no doctors in it so a lot of the people that are struggling with opiate dependency are now back on the streets. I am from Virginia originally and live right on its boarder now. In this war on addiction kicking people out of treatment because of something they cannot control doesn't do anything but hurt the communities around us.

Commenter: Dg

4/4/17 10:36 am

HB 2163, SB 1178

Did anyone research and think about the side affects of naloxone. There are people allergic to it and just simply can't take it or if they dont have insurance they can't afford it. They are running people back to the streets and the drug cartels are going to have heroin everywhere now. Why put

laws on the things that's helping. I have 3 children 2 teenagers and 1 that's 12, it scares the crap out of me and all the government is doing is making it worse.

Commenter: Jade

4/4/17 10:43 am

Buprenorphine laws

I don't?live in VA, but I have been taking buprenorphine for a few years now. It has saved my life along with countless others. We are all well aware of the fact that these drugs can and will be abused, but I am also very aware of the fact that whether it's plain buprenorphine or bup/ naloxone, those who are abusing these meds will not be deterred by the naloxone. The only thing this law is doing is hurting people who have serious allergies as well as those who can't afford the ridiculously high price of anything but buprenorphine (which from my experience can be around $100 less than buprenorphine/naloxone). If a doctor forced someone to take a certain brand of insulin that that patient was allergic to, that doctor could be sued for malpractice if said patient ended up having serious issues due to that allergy. Addiction treatment, just like all medical treatments, should be considered on a patient to patient basis. The government needs to stop trying to lump everyone into a single category, because we are all different and what works for one may not work for another and it saddens me to know that instead of thinking of us as different people trying to heal our ailments, we are all still considered just as bad as the guy shooting heroin on the street.

Commenter: Cathleen A Burns

4/4/17 11:58 am

HB2163

I am very concerned about this bill and the adverse affects on those individuals struggling with opiate addiction and allergic to naloxone. I personally am aware of one young one who has been successful with subutex who now has to start a new medication with a low dose of naloxone who after the first day is experiencing severe nausea and depression and has hives on her neck. She is a freshman at VCU and has done well on subutex over the past 7 months. After 2 years of multiple rehabs, IOP's, different medication management programs including suboxone which she is allergic to and has had ER visit for respiratory distress after starting suboxone. My understanding is that the SAMSHA recommendations include subutex for individuals who have medically been determined to have an allergy for naloaxone. I am perplexed why the Commonwealth of VA would go against those recommendations and outlaw any treatment for anyone with an opiate addiction that been successful and then mandate taking a medicine that one is allergic too as the only alternative for medication assisted treatment. Seems like a huge liability issue with the very real possibility of death either by overdose of an opiate after relapse because she can not tolerate the naloxone or a life threatening reaction to naloxone. This is a no brainer and breaks my heart after coming so far personally in this fight for this young girl's life. This law will fail her and most likely will be a death sentence for my loved one....I do not want to loose her and I am angry that this law is taking away the one treatment that has worked for her after so many failed attempts. I do not understand why goverment has to interfer with medicine especially when in this case the medical profession has done a good job in not giving up on this one precious being. I realize the subutex can be abused however why for those who it is working and have an allergy to naloxone and is not abusing this medication, why should the only available treatment that worked be taken away. I think the Commonwealth of VA is punishing and perhaps will cause death for this young girl who is working very hard to beat this addiction. You are setting her up to die in my judgement. My background is in nursing and I am an LPC in Fairfax. Prfessionally and personally I oppose this bill and know first hand there will be fatal outcomes.

Commenter: Pamela sickal 4/4/17 5:24 pm

Hb 2163

I am writing today about hb2163 bill. I have been sober since 2013. When I first went to get help for my addiction I was prescribed suboxone. After my first dose I broke out in hives, had severe itching, and a migraine. It was then I learned I was allergic to the naloxone in suboxone. I was then switched to a subutex. It was life changing. I got my life back. Since then I have become a mother, a fiancée, a full time worker, and a good person. When I went to my doctors appointment this month I was switched back to suboxone because of this bill, despite my documented allergy. I'm not even sure how this can be legal. So now I have to suffer fromantic hives, itching and migraines everyday.

Commenter: A concerned mother 4/4/17 5:32 pm

Hb 2163

I am very concerned for my daughters health. She has been sober for years and this bill jeopardizes her sobriety, she is allergic to suboxone but yet she's forced to take it so she doesn't relapse. She is so scared that she will all because of the government had dictation over her medical care. Would you make someone with an infection take a antibiotic that they are allergic to? I didn't think so, so why make all these patients take a medication that could potentionally be life threatening? Please reconsider this bill or put in a clause for the patients who have a documented drug allergy. I'm begging you for my daughters life/sobriety.

Commenter: Amanda Robertson 4/4/17 6:41 pm

Bill

I feel this bill is a little ridiculous. People are going to abuse any drug, no one will stop them. Their are so many people who are allergic to the nalaxone, I know when I had to make the switch back it was very hard and I was sick for a very long time, and still am. I think passing this bill will cause the ones who really cannot handle the nalaxone to stop taking their medication and end up relapsing because they simply could not handle the affects they get from just the nalaxone. I feel this bill is putting those people at risk and is just going to cause more problems. Its already hard enough to get the medicine we need. And this is making it harder. I hope that you consider our petition. And help save lives.

Commenter: Carrie R 4/4/17 6:41 pm

Naloxone can be harmful to some!

I am highly allergic to naloxone and while I agree in emergency forms it's a miracle medication, to some it could also be deadly. When on SUBOXONE I had a lot of "illnesses" passing out, legs going numb, hives, throat feeling as if it was swelling along with MAJOR weight loss I was being tested for cancers and thyroid issues as I had these severe lumps in the back of my neck due to the naloxone also being only 98 lbs and when starting out in late 2013 I was 175. I was switched and my life, depression and health suddenly changed drastically for the better! 16 months on buprenorphine I am completely back to normal with NO strange symptoms, until the switch back tommro which I will be back to losing extreme amounts of weight in which I plan to document daily. I got pregnant when I made the switch however also HAD to stay on (I was tapering off because of how sick I was on suboxone, at 1 mg) I agree that laws DO need to be in place but the allergy tests

cannot be faked if one is truly allergic as many others and myself are. Many people I know may relapse because of this people that have lived normal lives on MAT doing the program right up until this was in place. If you're allergic to peanuts, you cannot have them. It's the same thing with this. I know some do abuse this life saving medication but I can promise it's a lot less than the ones actually doing right by it! Please reconsider the allergy test exception because there IS people who cannot take it but want to do right in life. I am tapering again now off the MAT program but wanted to at least taper comfortably and safely without hospitalizations and health issues as I am a mom to 2 small children!

Commenter: Amanda P

4/4/17 7:08 pm

Buprenorphine without naloxone should be still prescribed to individuals who have been on years

I have been on Subutex for multiple years and now, I am no longer able to get prescribed it in Va. The only alternate offered give me terrible side effects which are equivalent to withdrawal. It is not tolerable and after over 10 years of sobriety, I am apprehensive about being just taken away with the minimal alternatives.

Commenter: Chelsea

4/4/17 7:24 pm

Ridiculous

i agree with amanda and some of the other comments. For some of us we have been on this for years and its not okay to do this when ACTUAL people have had long sobriety runs while taking this medication and are unable to take the other options. If this works for people and has been keeping them sober for YEARS how can you guys do this. Do you understand what is gonna happen or what you guys have done to those this medication has been a life saver for?? This is not right.

Commenter: R. Kinsey

4/4/17 7:51 pm

HB 2163

Let me start off by saying that Buprenorphine has saved my life. I was on heroin for 7 years and lost everything that meant anything to me, including myself. I went to prison, lied to, and stole from every person in my life. I was in and out of rehabs for years, Nothing worked to keep me clean and keep me as a functioning human being. It wasn't until I discovered Buprenorphine that I was able to get my life on track and start on a positive path to living a clean, sober, happy, productive life for my son and I. I honestly believe it is a miracle medication, and without it I would be dead today. However, I do have Naloxone sensitivity and I am not able to take Suboxone, only Subutex. Severe panic attacks, nightmares, and migraine headaches are just a few of the debilitating side effects I have when taking Naloxone. I have to mention that I have a severe panic disorder, and this being one of the main reasons I began using heroin and other opiate substances, to try and self medicate to not feel the panic attacks. This is just my story of why I can't take Suboxone versus Subutex. There are many other people, like me, with many other legitimate health issues against Naloxone that still do need the Buprenorphine. I do realize that some people abuse the Subutex because it does not contain the Naloxone, but the Buprenorphine is most certainly still an opiate blocker in itself as well, and there will always be some people that abuse things and make it harder for people like myself. I hope that you can understand not everyone is going to do that and there truly are some people that have legitimate reasons for needing the Subutex in place of Suboxone.

Commenter: Sara Y

4/4/17 9:14 pm

Naloxone Dangerous for Some

I fully appreciate and understand the current opiate crisis our country, and specifically our state, is experiencing. However, these new regulations are putting many stable patients at a great risk for severe illness, or worse. I sincerely hope that this may be revised to include exceptions where medically indicated for those who are unable to safely take Suboxone/Naloxone due to debilitating side effects. These drugs were created to help sick patients, not make patients more sick..

Commenter: Bobbi Woolum

4/5/17 2:27 am

Please do not stop any form of medication assisted treatment!!!

All forms of medication assisted treatment are the proven most effective treatment for opiate addicts. Restricting anyone from any one form of medication makes no sense. Suboxone and Subutex or generic buprenorphine work exactly the same way and many patients on buprenorphine alone are able to live without chronic headaches and other additional side effects. It is also the least expensive form of medication and not allowing patients to begin or continue this medication is immediately life-threatening. So many people will return to relapse and drug use without the medication that has proven to be effective for them. It is also the least expensive of pharmaceutical treatments so anybody who is paying cash is dependent on a medication they can afford. There is absolutely no reason to demand these patients be switched to a medication with naloxone that is three or four times more expensive when the new loxone has been proven to be inactive. I don't know what occurred to encourage this change but it is not the right way to go. Take some time to get to know the patients who all their lives two these life-saving medications. Or those lives worth compromising for the change that has been set in place? I think all of us can agree that they are not. I would be curious to know why these changes have been set in place and I'm 100% positive that some very simple Research into the matter would show that it is unnecessary and also detrimental. If anyone takes the time to read this I very much appreciate it.

Commenter: Bobbi Woolum

4/5/17 2:38 am

Naloxone not effective

The research clearly shows that naloxone is not effective in any route of administration when combined with buprenorphine. Even those who choose to use their medication intravenously will Almost Never become ill with withdrawal symptoms. Buprenorphine itself has a much stronger binding affinity to opiate receptors and last several times as long as naloxone meaning that the buprenorphine we'll find stronger and longer to receptors then the naloxone ever could. It is truly useless in the presence of buprenorphine. So there is no reason two insist that that formulation is best. All it is is way more expensive. The buprenorphine alone will block a patient from being able to use other full Agonist opiates and achieve a high. Then the lock Zone does absolutely nothing and is a waste of time money and resources. This is very simple science that can be confirmed on any reputable website or other source. It is widely misunderstood but it is the scientific truth. Please don't make those in recovery suffer because of false information. Thank you

Commenter: Ashley Powell

4/5/17 5:49 am

I have been on subutex for four to five years only thing that has worked for me I've tried dverythin

Commenter: Nicole Shank, SWA

4/5/17 8:24 am

Not Prescribing Subutex Even With Documented Allergy

I am in Ohio AMD currently pregnant and on subutex. What I've found is that some people are actually allergic to the nalaxone in Suboxone and can become very sick when it is taken. We do not prohibit a person with allergies to an antibiotic from receiving the next best option so why is it fair to do with Subutex? The government is stepping in where they should be monitoring prescription distribution and the policies required for the doctors prescribing Subutex. Everything is abused if it has any desirable traits. To make people trying to better their lives from a past addiction to lose any chance at receiving their medication is unfair and unjust. We are being treated differently because we are addicts. Most opiate addictions stem from doctors over prescribing narcotic pain meds. It's time to move forward in the battle against heroin addiction and passing this bill is pushing hundreds or thousands of recovering addicts back into addiction because without their medicine they are very sick, just like a diabetic without insulin or a cancer patient with no access to pain relief or chemotherapy. You're playing with people's lives when people are dying left and right due to opiate addiction. Please reconsider this decision. Thank you.

Commenter: Miranda

4/5/17 2:54 pm

Subutex allergies

Subutex should allowed to be given, not taken away. Some people are allergic to the naloxone, or cannot afford Suboxone. Anything that can help our addicts get clean legally and responsibly should be allowed. If abuse or illegal selling is a worry, then reduce the prescription length, and keep the practice of counting pills. Or do something like they do with suboxone strips--put each pill in an individual packet and have them counted at the doctors office--used ones and unused ones!

Commenter: Michael Dowdy

4/5/17 8:01 pm

Subutex

Please reconsider adding a clause to this bill to include people with a hypersensitivity to naloxone if it isn't included what is a person to do the only option is methadone a far more dangerous drug

Commenter: Lori Miller

4/5/17 11:19 pm

HB 2163

HB 2163 will do harm to those that can not afford suboxone and to those that have a legit hypersensitivity to naloxone. This is not a one size fits all situation. Some people who can not take suboxone are unable to get to a methadone clinic everyday or can not afford it. Suboxone and methadone are both abused and sold on the streets, and in my opinion methadone is so much worse than plain buprenorphine/subutex. This law wouldn't be a bad idea if it included that people with a legit reaction to naloxone, documented and seen by a doctor could still receive mono-buprenorphine/subutex. And also allow people to still continue getting take homes from the clinics. I feel like something needs to be changed in this law cause people are going to resort back to illicit street drugs because they are either allergic to or can not afford suboxone or even get to a methadone clinic every day. Over doses are going to go back up. In my opinion addicts are going

to use no matter what, but it would be safer for them to take a life saving drug than to take heroin. Please rethink this bill.

Commenter: Denise 4/6/17 6:38 am

Bup

Seems a lack of knowledge is going on stop being so ignorant and focus on helping people.

Commenter: Ashley Jones 4/6/17 9:42 am

Hb 2163 dangerous

I am a patient who has been on buprenorphine mono (subutex) for 3 years. I am asking that you please overturn this bill as it endangers the sobriety and lives of people like me. I have a bad reaction to naloxone, so being forced to take suboxone has been a nightmare, but i have no other option because of the governments decision to only allow pregnant women to have it. I cannot allow myself to go back to the lifestyle i was living before I was put on this medication. I have been very successful in recovery, I have been able to hold a full time job, i volunteer in my community as a soccer coach, and i volunteer my time in a classroom working with kindergartners every Tuesday. I have 2 children who need their mom to be 100%, and without this nedication, I am not able to provide that. Put more strict rules down, call for mandatory pill counts, whatever is necessary, but please allow those of us who have done so well on this medication, to continue living fulfilling lives. This will turn so many back to the streets, and so many lives will be lost to the nasty throws of addiction because those people wont be able to get the treatment they need. Please help us who are trying to help ourselves and overturn this bill.

Commenter: Nicole Holmes 4/6/17 6:47 pm

Allergy to Naloxone

I myself also have an allergy to Naloxone, and would like for you to please reconsider allowing ppl with allergies to stay on this medication. It really scares people to think their only option to stay clean is going to be taken away from them. So please reconsider this.

Commenter: Ashley Tucker 4/6/17 7:13 pm

New law will cost more lives!

I'm not sure why this has been done since my doctor said there's not alot of propping mixing subutex with opiates and dying but there are people selling it. If that's the reason well it's still gonna be on the street and I would have to assume the street value probably doubled making it more enticing for people to sell. It's not fair for so many of us to suffer for the mistakes of a few. Why not make it up to the doctor and make the guidelines that he would have to have explanations to back up his reasoning. I have a strict doctor who doesn't give subutex unless it's necessary. I have a severe migraine disorder with over a decade of medical records. My neurologist as well as my subutex doctor agree I can't take suboxone. Unfortunately my migraines are so severe that I wouldn't be able to work and finish college and raise children if I were on suboxone so I'm being weaned off of subutex and I'm definitely not ready. I have a chronic pain disorder which is how I ended up on pain meds to begin with. The subutex helps with my pain as well as keeps me off the opiates. I'm gonna try but I'm very concerned that I will be back on pills. We are begging

you,please fix this. Too Manu people will go back to pills and heroin and now there tolerance is gonna be messed up and we could end up dead. This will cost more lives than it saves.

Commenter: Sarah W

4/6/17 9:24 pm

Take it back! Please.

Please undo this new regulation. I am on subutex and it has saved my life. I was pregnant and breastfeeding and I'm allergic to naloxone. I really really loved my pharmacy and the people who work there. Please take this back!

Commenter: Chrissy Winslow

4/7/17 12:37 am

Treatment for Herion/MAT

Medicated assisted therapy is PROVEN TO SAVE LIVES! WHY WOULD YOU EVEN NOT WANT TO HELP SAVE THE LIFE of someone addicted to opioids?

Commenter: Lacey Patterson

4/7/17 3:53 pm

HB 2163

HB2163 will hurt people more than help, it will cost lives. Please take it back, don't do this. Addicts deserve to be rehabilitated, they deserve all the resources they can get, they are not scum or worthless so please don't treat them as such. Some people are allergic to naloxone and honestly it doesn't matter whether a drug has naloxone in it or not, if the person wants to abuse it they will. I was on suboxone treatment for several months and it worked wonders, but I wasn't ready to stop using and my partner was using and I wasn't willing to get away from him so I started back up. Now I'm on methadone because it's cheaper and works even better for me. Please don't make it even harder for people who have it hard already and feel so much guilt and remorse. Don't be inhumane.

Commenter: Dg

4/7/17 4:20 pm

18VAC85-21-150. Treatment with buprenorphine for addiction. Hb2163 sb1178

I think the governor and all of the other dumbasses in Richmond that just voted yes to these bills to get their heads out of each others asses and listen to the practicing Doctors about this instead of listening to the media that has glorified naloxone in the past and realize that there is a such thing as an allergy to this stuff. I have been successful only on buprenorphine monotherapy, I have tried it all and this is the only way I can have a productive life. Please give us our lives back. It's not right to take it away from the ones that have allergies or are hypersensitive to naloxone. Terry McAulliffe get you head out of your ass!!!

Commenter: Dg

4/7/17 4:34 pm

Hb2163 sb1178

Another thing you are setting us up for the biggest heroin epidemic there ever was, because the addicts are out here and u are restricting addiction doctors and pain management doctor where else are they going to go besides the heroin that is most likely laced with something that will kill them. Just wait and see all you dumbasses in Richmond with a blind eye, or should I say with a brown eye, GET YOUR HEADS OUT OF EACH OTHERS ASSES, RICHMOND!!!

Commenter: CONNECTICUT NAMA 4/8/17 9:36 am

benzodiazepines / methadone and or naltrexone

I will make this short. I hate to see tgesecregs changed because of people who abuse these meds or don't follow protocols. I have been on methadone and clonopin for 22 years. I am in perfect health, have never had an overdose or and medical problems related to these meds. Please contact me if you would like more info.

Commenter: Paul, CT NAMA 4/8/17 9:57 am

New drug rules

I don't understand the DEA, FDA, gov't etc. All these new rules and recomrecommendations for prescribing solves NOTHING. All it will do is push people on pain management to start doing illegal activities such as purchasing pills on the street and when that gets too expensive they will go to heroin and there will be more deaths.why do you think overdoses have increased over the past 5-8 years? Because that is when doctors started to get scared of the DE A and FDA and started cutting people who have legitimate chronic pain diseases such as M.S. or different types of Neuropathy. Before I started methadone I lived in a bed except to use the bathroom and showered 2 or 3 times a week. Since methadone I am as normal as can be with my disease. I only use the bed to sleep 6 or 7 hours a night. But I'm getting off topic. Trillions of dollars have been spent since Nixon started the war on drugs and where has it gotten us? NOWHERE. As long as there are humans walking on this planet there will be a desire, need, want for drugs and that will never change. Someone get in touch with me. I have studied this for 19 years now. I am extremely educated and can offer some good ideas. Thank you.

Commenter: Greg casey 4/8/17 10:34 am

Reconsider this bill

Commenter: Andrew Marshall 4/8/17 11:03 am

Reconsider exemptions for this law

I have been in a subutex outpatient program for about a year now. I have tried other rehab programs in the past, including methadone, but subutex is by far the best. Methadone is extremely hard on your body and the withdraws actually motivate you to keep taking it instead of trying to lower your dose and get clean. Subutex, on the other hand hasn't had any negative impact on my body and I have easily decreased my dose from 24mg per day down to 6mg per day in a matter of three months. I am unable to take suboxone because I have an allergy to naloxone that is a

legitimate threat to my wellbeing. My response to naloxone is rapid heart rate, wheezing, dizzy, faint, throat swelling, and without the doctor who recognized the reaction, I may not be here today. I can't believe that this bill was rushed through without any consideration for the people who were benefiting from its use, or people who couldn't take suboxone as an alternative.

There definitely needs to be provisions to this awful law which consider those patients who are allergic to suboxone.

Commenter: Safepointsinnorcali@gmail.com 4/8/17 12:27 pm

Not a good idea

My opinion. Don't do it.

Commenter: Kyle Miles 4/8/17 3:04 pm

Buprenorphine laws. Patients with an allergic reaction have no true alternative

People that are truly allergic are losing treatment totally. Doctors that know their patient is allergy/hypersensitivity they will not write you suboxone or generiic buprenorphine/naloxone PERIOD. I know because someone close to just went throught it. The doctor told them to seek treatment in another state, that they would not right them because of the tongue swelling, and throat swelling. This patient has a true hypersensitivity/allergy and the doctor was so scared of the reaction he wouldn't try to give him the combination tablet because of the tongue swelng. What is a patient to do then, when the doctor cares for the patient but cant treatment. He won't take a chance on writing the Suboxone or the Generic. These patients deserve treatment with this medication too, and methadone isn't a option. He shouldnt have been punished for something he cannot control. What is he supposed to do now?

Commenter: Tim W 4/8/17 4:19 pm

allow naloxone allergy exception

My fiance is highly allergic to naloxone and tapering off but now suffering from allergy while tapering. She is swelling up, vomiting, cannot move, pain has doubled and very sick. We have two small children and she cannot have these reactions, that's just NOT fair because some abuse it! Drugs will always be a thing, but if the addict wants help thats the only way it will stop. Not allowing the allergy acception is discrimination. These people are living ordinary lives and this is messing with their sobriety. Some with allergies being so bad they're forced out of treatment! Shes been clean for 4 years and now being punished for others who arent truly ready to be clean and do right! Naloxone is poison to these peoples bodies who are allergic! Generally out of 100 patients only 5-10 is allergic! Its also more common for abusers to sell suboxone for their drug of choice than it is subutex!

Commenter: Kimberly W. 4/8/17 5:55 pm

Subutex

This is the most ridiculous thing the government can take away from people in the recovery stage..all you are going to do is force some really sincere people that want to get clean hit the streets. Maybe have more overdoses. There is a lot of people that just can not take suboxen due

to the huge allergy to naloxen. I have a very close person to me and if something happens to her, the board of medicine will be hearing from me...i vote to keep subutex for the indviduals that cant take suboxen.

Commenter: Barbara Vargas 4/9/17 12:08 am

Please leave things as they are.

Commenter: Kelly Miles 4/9/17 11:54 pm

My son lost treatment because his doctor is scared for his life to switch him.

Why should my son lose treatment after he has done nothing but follow the rules. His doctor won't even write it unless he cannot have suboxone. Is it fair suboxone patients get to keep on getting treatment, but people like my son that allergies, hypersensitivity whatever you want to call it have tongue swelling, throat swelling, and Hives documented just lose treatment. My son was getting his life together, and doing well on buprenorphine treatment, and he has no alternative. He cannot go to a methadone clinic everyday, and everyone knows methadone is a far more powerful drug. Please reconsider this bill before people lose their kids to the streets.

Commenter: Sharon Thomas 4/10/17 11:06 am

HB2163 disregards SAMSHA recommendations

SAMSHA recommends use of Buprenorpine mono product when there is an allergy or other adverse medical reaction to products containing Naloxone. My 19 year old daughter has only had success on Subutex. Naloxone resulted in hives, rash, nausea, depression and a respiratory reaction requiring ER intervention. This mandate not only ignores established guidelines, it is punitive in nature in that patients who have followed protocol and have demonstrated success are being denied proven effective treatment. Any drug can be abused: this mandate is not going to assist or deter active addicts who are not invested in recovery. It will put the fragile recovery of many others at risk and denies physicians the right to use sound clinical judgement in continuing Bupe only protocols with patients who have demonstrated success and have documented sensitvity to Naloxone. A well intended law with potentially fatal outcomes.

Commenter: Amanda Key 4/11/17 11:59 am

Allow patient's with a documented allergy to continue to be prescribed Subutex.

My husband is allergic to nalaxone when he first started taking suboxone he woke up in the middle of the night with a severe reaction. He broke out in hives, and he swelled up. Why is it because his body doesn't agree with a medication is he being punished? You want to help addicts. All you are doing is hurting them. People are losing there doctor. God forbid something happens to someone you will have one help of a lawsuit. This is a joke and the sad thing is you are playing with so many people's lives. What if it was your brother, mother, father, sister? Would you have thought more about what you are doing to addicts?

Commenter: Liz 4/11/17 5:44 pm

Please do not take subtex away due to people having allergies to Suboxone

Commenter: Kristy boyce 4/11/17 11:14 pm

Are you a doctor? Do you know what's best for the addict?

first I've been clean for 5 1/2 years! I've been taking subutex because I'm allergic to the naloxone. I had to leave my doctor of 5 1/2 years to go to another states so I won't relapse! As my treatment is none of the governments business in the first place!!! I understand people abuse this medication but in all HONESTY YOU WHAT MEDICATION ISNT ABUSED! Are you going to pass bills for all medication?!?!?!?! Did you go to school as long as my doctors did? Do you know the first thing about and addict???? I don't think you do! NO ADDICT GOES THROUGH CHANGE WELL! I pray this doesn't turn people back to the horrible herion that's going around killing people! Better yet WHY DONT YOU BAN THE OPIATES? That's the reason behind this! Opiates don't take the pain away but subutex does! You can't even die from it! The sad part is whoever reads this don't care about us addicts. Oh and no matter what you pass it's NOT GOING TO STOP THE FEW IDIOTS THAT ABSUE MEDICATION! Let our doctors do their jobs and you do yours by governing not by taking away the one medication that saves lives!

Commenter: Caitlin Laws 4/12/17 12:36 pm

I do agr

Commenter: Caitlin Laws 4/12/17 12:49 pm

Long time MAY patient

Let me first start by saying that I absolutely think there DO need to be stricter laws and regulations on subutex. But, I think that if a person can prove that they have a legitimate allergy, they should be exempt from that. I have been on suboxone for over 10 years. I know more about this medication than most doctors. I have researched it. I have become passionate about it. I have had 8 major reconstructive surgeries while on it. I have had a vaginal delivery while on it. I have had a c section while on it. I know for a fact that suboxone is often misused and abused as well. And aren't all medications? People abuse medications all the time. That is What lead most people to seek the assistance of Buperenorphine in the first place. There are some people that have legitimate naloxone allergies and sensitivities that will suffer from the fact that allergy exemptions are not allowed. Do we really want to exclude them? People with children to take care of, jobs to go to go to, lives to live, and this medication helps them do that. Yes, there do need to be some stricter regulations. Absolutely. But if a person can show that they are truly allergic to the naloxone, or truly are effected by the naloxone, then they need to be exempt. O

Commenter: Abby Coulter, MMTSA Org. 4/12/17 7:46 pm

There IS A BETTER WAY

As an MMT (methadone maintenance treatment) Patient & MAT Advocate, I am so SADDENED and honestly ANGRY about what this mandate is doing to my peers who have found Recovery thanks to Mono-Buprenorphine. I cannot IMAGINE after years of habing my life saved by my treatment only to have it RIPPED AWAY by some half baked legislation. Sure there are always reasons to regulate medications. We MMT Patients have TONS of regulations we follow in our treatment. HOWEVER NONE of those regulations strip us of our treatment. To take away a LIFE SAVING TREATMENT OPTION in the midst of the Opioid Epidemic that kills thousands every year is shameful! Its insanity and it WILL COST MORE LIVES! Im not saying 'dont' bc like I said, regulations need to exist. But government practicing medicine simply bc they have the 'Medical Board' of the state backing their play is WRONG! All we are asking is simply to ALLOW those with documented hypersensitnvity to naloxone to receive Mono-Buprenorphine. To GOVERNMENT its simply WORDS TO PAPER. To a Recovering Addict who NEEDS this TREATMENT, its their LIFE! Do whats RIGHT! Not whats the 'easy road'. We HAVE to work to save lives. NOT SHATTER them. Change this legislation. Dont sign it into effect as is. AC

Commenter: Carrie Pearson

4/13/17 8:45 pm

Proof from a government website, allergies exist!!!!

This was given to me by the FDA. Allergy exceptions are needed or people are going to relapse or die from this. This is NOT SAFE!

"SUBOXONE and SUBUTEX should not be administered to patients who have been shown to be hypersensitive to buprenorphine, and SUBOXONE should not be administered to patients who have been shown to be hypersensitive to naloxone."

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=97677ce7-9562-43d0-8b99-8d1f37c1e3c6

Commenter: Alison Taylor

4/14/17 1:01 am

allergies exist

I would never want to be forced into taking a drug I'm allergic too.

Commenter: Sandra Goshorn

4/14/17 3:37 am

Put this law on hold NOW!

I'm afraid to say that whoever is trying to pass this does not have the proper information about these addiction medications. Doctirs understand their patients and treat them accordingly and the government needs to stay out of that. You are taking people that are in recovery, and making it impossible to continue on their Ned's. A lot of people are allergic to the Nalaxone. The fact that pregnant women should not take it should he your first sign on how dangerous Nalaxone can be. There are different degrees of addiction. Some are not as serious as others but the withdrawal is still just as hard. Why force someone to take a medication that makes them more sick when another is there that does the same?? You really need to put a halt on this law, asap until you can do further research. The only thing that will come out of this, is causing thousands of people to relapse which in turn can be fatal.

Commenter: Susan J

4/14/17 11:57 am

HB2163

This is well intended law, however deeply flawed. It ignores established guidelines. It puts the recovery of citizens at risk and does not allow doctors the right to use sound clinical judgement. This law should be modified.

Commenter: Carrie Pearson

4/15/17 2:55 pm

Allergies are needed to be acknowledged!

Giving buprenorphine to pain patients and animals but not the ones allergic to suboxone.. Don't you know subutex was MADE FOR ADDICTION not for pain not for animals none of that however it helps but don't ignore the reason why it was made and it legally is FDA approved FOR ADDICTION!! You can abuse anything.. I'm wondering if the plan was to start a heroin epidemic here a bigger one because I'm not sure how taking away an addicts addiction medicine solves anything.. As the board of medicine you should know that not everyone is the same, not everyone can tolerate naloxone! Go after the pain drs overprescribing to these "pain patients" which we all know half of them don't need hard medications like that and keep in mind THATS what got the addicts to need addiction medicine to begin with.. A good amount do not start out on heroin, in fact I've never met one who did it all started with the oxys, morphine, percocets you know thepharmaceuticals!

Commenter: Allison Grey

4/15/17 3:14 pm

Naloxone allergy...shooting up suboxone

Although I understand the need for stricter laws on the drug Subutex, I am extremely upset to see that individuals with allergies to the medication WITH proof of said allergy are still required to take Suboxone. So if they are deathly allergic to Naloxone, they either come off the drug harshly (because jumping from a high dose will almost guarantee relapse) or they are stuck on suboxone? That is EXTREMELY inhumane and I ask that you please educate yourself on the drug and I encourage law makers to talk to patients on this drug or who have tapered off to find out just how tricky it.is to come off the drug. It is VERY disappointing to see addicts in recovery be treated this way. I do understand that yes, FEW people inject Subutex but I have been on suboxone for a little over six years and I have seen on forums and threads that FAR MORE people inject their SUBOXONE and fewer people who are on Subutex inject it. In your case study that you found Subutex to be more valuable vs Suboxone isn't that what you were looking for? I find that convenient. That's ONE example. It doesn't mean much to me. Because suboxone is just as injectable and I have yet to hear of any individual go into these terrible withdrawal from injecting it. I find it funny how injecting/abusing suboxone was never brought up on this bill.i find it ironic that everything addressed on the addict part of the bill fit the law makers agenda. I suggest that law makers and law enforcement and anybody else involved with making this bill rethink your agenda. Buprenorphine will be abused by few no matter if it's Suboxone or Subutex. Patients on this drug with an allergy to Naloxone are paying a huge price, whether medically or detoxing when they shouldn't have to be. A dr wouldn't prescribe somebody Allergic to Amoxicillin that specific drug, so why should this be any different?

Commenter: Megan McKinley

4/16/17 8:24 am

Subutex

Please reconsider an allergy acception for being prescribed subutex. There are some people who simply can not take suboxone. There are ways to screen people for an actual allergy. Allow it for only those who have a documented reaction. Taking away a life saving medication simply because you do not understand how it works is unfair to the people who really need it! Bio fills the receptors and blocks any other opioids from attaching/ it is not just nalaxone that blocks getting high. You could give someone who has been on subutex they're drug of choice and they will not get high. There is only potential for abuse in patients that do not want to be clean. Please don't take this medicine from those who truly need it and have not abused it, you will turn them back to active addiction!!

Commenter: Dylan Quinn

4/16/17 10:15 am

This is going to cause thousands to relapse

My name is Dylan and I've been prescribed suboxone for over a year now and it has changed my life dramatically. I have been able to remain abstinent from all other drugs during this time for the first time in my life. I truly believe there is a huge misunderstanding of the role naloxone plays when combined with buprenorphine. As you know, the name brand "Subutext" is just buprenorphine with no naloxone. But this doesn't change the way buprenorphine works at all. The naloxone in suboxone is strictly there as a deterrent to try and prevent people from using the drug intervaneously. It does not effect the way the drug works at all when taking sublingually. The problem is that many people are severely allergic to naloxone. And I'm not just talking about it may cause them to have head aches every once and a while. I mean it is life threatening and there is no way that they can have it. There has to be an exception for this new law. If not, thousands can, and will relapse. These people are not shooting , snorting, or abusing their medication. It is ludicrous to punish them bc a few people who aren't really ready to be clean are. I live in NC but am connected to a lot of suboxone/subutext users in your state via Facebook groups. These people are suffering as we speak. There has to be an allergy exception for this bizarre new law.

Thank you, Dylan

Commenter: Angela DiMattina

4/16/17 11:32 am

You can't choose to help some and not other

The fact that subutex is now only being administered to people who are pregnant and taken away from people with legitimate allergies to naloxone is ludicrous. That is essentially like telling a child with a severe peanut allergy "sorry kid but your only allowed to eat peanut butter and jelly sandwiches hope you pull through." I understand many people view addiction in a negative light because in some cases it was self inflicted but if someone is asking for help because they desperately want to get clean and turn their life around how could you be so cruel as to tell them they can only have it if they are willing to submit to seizures and other awful things because they are allergic. Every person is different as is every path to recovery but that is just inhuman to turn your back on people who are trying so hard and fighting to save their own lives.

Commenter: Dustin Walker

4/17/17 12:13 am

Less regulations = greater chance at recovery

Less access and less regulations will in fact make these drugs that treat addiction more accessible and easier access will lead to greater successfully recovery! Once an addict has decided that they need to seek help there isn't anything that anyone could do to justify addicts not being able to access these drugs that literally save people's lives! My best friend was cut off at the methadone clinic due to failing a drug test and he was put on an administrative taper and less then 10 days after they refused to dose him anymore he was shot and killed in a drug deal gone bad in January of this year! These programs and these drugs literally save people's lives, so please do not take away more people's access and send them into the streets of Richmond city to try and score their drugs just so that they can maintain and not get sick and be able to maintain their jobs and go to work every day and be a positive contributer to out city and our population! You guys are literally playing with life and death for these addicts and with great responsibility it requires great knowledge so I beg of you all to research what these drugs have done to help out members of our society! We don't need anymore Joseph Boyle's out here being murdered in your city all because yall wanted to further regulate something to pad out Dr's and other people's pockets! This is literally life or death! And if you disagree with what I am saying please look up my best friend Joseph Boyle who was shot and killed in Richmond right off of broadrock on Sneed road just a few months back!

Commenter: Koreyna Patterson

4/18/17 8:27 am

Wrong just wrong

how can you sit here and choose what someone can be on when you don't even know there history they maybe allergic or it doesn't work for them.

Commenter: Katie

4/22/17 2:53 am

This will only make things worse

As a recovering addict I can personally tell you that if I had been forced out of my treatment like this I would be dead. You are only exacerbating the drug and overdose problem by doing this. Did no one there bother to ask a professional addiction doctor or counselor about this before it was voted on? Maybe you should go to the SAMSHA webpage and do some research...

Commenter: Betty Taylor

4/22/17 8:47 pm

Carring About Thr Lives of Others

It is unfair to ruin and indanger the lives of many people because of the poor choices of a few. You are taking away peoples ability to live their everyday lives. People are still allowed to drink even though some people drink and drive. Why is this diffrent.

Commenter: Brandy Patterson

4/22/17 9:37 pm

Don't punish someone for having an allergy

I am embarrassed and ashamed that we even have to sign this ! Is this really an issue ? Wow ...

Commenter: Dondee Carver 4/22/17 10:02 pm

People need uniterupted treatment

Commenter: Jeffrey T Junig MD PhD, SuboxoneTalkZone 4/23/17 1:57 pm

Truth about buprenorphine diversion/risks

Please understand the truth about buprenorphine diversion. I work with hundreds of opioid addicts. Some injected buprenorphine or bupe/naloxone. When asked, all say the same: "you can't get high from it." Then ask, so why did you inject it? "Because 8 mg will last 5 days that way to keep me from getting sick".

Note that when they inject bupe/naloxone, they feel about the SAME.

Remove buprenorphine and fewer people will be able to afford treatment. The response will be more injecting-- of buprenorphine, or of a bupe/naloxone product. That means more hepatitis C.

Finally, look at the numbers of people who die with buprenorphine in their bloodstream. Death on buprenorphine is RARE, and only occurs in opioid-naive individuals. Buprenorphine clearly prevents death, even when taken improperly. Nationwide, about 40 people die with buprenorphine in their bloodstream. Most would have lived, if MORE buprenorphine had been present.

You are fixing a problem that doesn't exist- and worsening another problem in the process.

Commenter: Amber 4/23/17 6:30 pm

This is a total outrage

I cannot believe this is even happening. Government has NO PLACE IN HEALTHCARE! medication And treatment options are between the doctor& patient! This isn't going to help or solve anything. This will force so many people out of treatment And cause the opioid/overdoes epidemic rates to greatly multiply. The reasoning in the choice between subutex And suboxone varies so greatly that one law or blanket regulation cannot be laid upon every case! I believe it would be to great benefit to lift the the regulation And Work with the doctors And patients. Maintenance medications save lives And give people the tools they need to live productively. Please please reconsider this decision, it's a possible death sentence for so many people.

Commenter: Wesley Marin 4/24/17 6:29 am

This makes no sense.

This is craziest thing I have ever heard of! This is going to cause the overdose rate to triple! Please put this back in the hands of the patients and physicans. People that don't have a option for treatment will go back to using. This is a devasting disease that took control of my life, but with subutex I have been able to maintain a steady job for 5 years now with promotions and start a family and even buy a house. YOU ARE GOING TO LOSE A LOT OF HUMAN BEING OVER THIS . I understand other opiates but not Subutex it saves lives.

Commenter: Dr. Rod M. Rogge, DDS 4/24/17 4:56 pm

regulate pharmacy wholesalers

I hope that Virginia and other states sue enough drug wholesalers to lead to a federal law requiring tracking and reporting of large amounts of opioids. Big pharmacy companies know where the big opioid shipments are headed, and they accept no responsibility for what happens, since they make huge amounts of cash. Everyone in the chain needs to be responsible. The intent of the new regulations is good, but if you don't slow down the supply, and track sales, nothing will change. Look what making pseudophedrine OTC did to the methamphetamine mess we are in - all produced by big pharmacy greed.

Commenter: Alfred Stahlin, a random swede. 4/25/17 2:06 am

Do i need to spell it out for you, why this is wrong?

I'm sure that you already know all of this. But incase you don't, this is why this bill is stupid.

Suboxone, containing buprenorphine and naloxone, can be injected, and abused in the SAME WAY, and to the SAME DEGREE as any medication containing only buprenorphine.

Everybody knows this. The only one who has something to gain from passing a bill like this is reckitt benckiser, who produce suboxone. They have the patent. They would have a lot to gain from having a LAW remove their competition.

In my head this is all insane. Are you in reckitt benckiser's pocket, or why the h*ll would you want to pasa a bill like this?

No matter if there are allegic people or not, there is no reason for the naloxone. It's just more expensive.

I guess im lucky i'm not a US citizen so i don't have to worry about [redacted] like this, but i do feel for you people over there. I'm sorry for you that a doctor cannot choose a medicin for you because lawyers and politicans opinions (that are based on nothing but misinformation)

Commenter: heather redmon 4/25/17 11:03 am

no!!!

taking away a lifesaving med is disgusting!

Commenter: Kyle Miles 4/26/17 4:09 am

Buprenorphine saves lives

This is my third comment, but I cant help it. I have seen other patients that were good patients lose treatment because they had a documented allergy on file. All this done is cut people off from the life-saving treatment they were getting. Supposedly the whole reason behind this is because someone testified that they bought one on the streets. Well if thats the truth why haven't went after Opana, Methadone, Percocets, OxyContin, Valium, Xanax, Klonopin, People are reporting they are still able to get a prescription and get them filled in Virginia but some of us are suffering. All this bill did is either create a worse black market or sent people that were in treatment back to the streets. If a person has an allergy on file there doctor would be reluctant to switch them, some people just cannot tolerate it. Buprenorphine is the safest out of all three of the drugs used for treating

addiction, and the only problem we have with it is there aren't enough doctors to stem the tides of addiction and putting up more barriers to treatment. Every one of these medications has their uses but to punish someone because suboxone makes them feel horrible or swells their throats shut is outrageous when suboxone is still available for patients that can have it. Bupe with or without Naloxone is a miracle drug, and taking one of them away because someone cannot have the other is a horrible mistake.

Commenter: Patrick Turner, Family Practice Specialists of Ricmond 4/26/17 12:35 pm

Opioid Recommendations - Comment Period

thank you all for the opportunity to submit comments regarding these regulations.

my experience has largely been positive. i am happy to see that providers are now protected to have tighter regulations on prescribing opioids.

the largest difficulty my practices faces is action upon urine drug testing that is positive for marijuana (THC). this is because we encounter patients who will intermittently use marijuana in states where it is legally obtained, and because of rapid changes in state legality, are unsure of how to act with regards to continue viewing THC as an illegal substance / drug of abuse. we have also seen cases of physician reprimand by the board of medicine for inappropriate prescribing, where urine drug testing with positive THC testing has been cited as further evidence of physician neglect. any formal guidance form the board of medicine on how to view THC in the context of management of chronic nonmalignant pain with narcotics would be incredible helpful with this common dilemma.

additionally, we are seeing limited numbers of pharmacies that are carrying naloxone, and it seems as though the intra-nasal / atomized formulation of naloxone is the only affordable option for patients when it is recommended. how is the state addressing this mandate to increase access to this important therapy?

thanks for your consideration,

Patrick Turner, MD.

Commenter: Ronald L Schubert 4/26/17 12:44 pm

Opioid prescription regulations

The bulk of my patients on chronic opiod medication are elderly with complex spinal disease with multiple compression fractures etc. They are not amenable to any more interventions. These folks feel very villified by the current regulatory invironment.

Physicians must be free to treat and diagnose and finally give comfort to the suffering when there is no definative way to cure an individual. The source of pills on the streets have largely been from a few unscrupulous physicians writing large number of prescriptions for nebulous reasons. The sources of pills are largely drying up as shown by the rising use of heroin and on line designer drugs. Please keep this in mind when drafting regulations. It could be your mother or father who

needs treatment some day!.

Respectfully submitted,

Ronald L Schubert, MD

Commenter: mark meijer md

4/26/17 1:51 pm

opiod rx

what is the probability of any random, narcotic naive, regardless of family history, patient to be genetically pre-wired to be addicted to narcotics when exposed to the first dose as some addicts are known to be? Patients discharged on narcotics 10 years ago from randomly selected hospital, how many are now addicted to narcotics through insurance diagnosis, DUI, death by overdose or excessive Rx on state data base? How many patients die from pain? ONLY with this data can we begin to determine the risk/ benefit ratio on patients with non terminal pain. Without that data (and lots more), how can we lecture physicians on the safe use of narcotics? We are not even sure narcotics give long term benefits to many patients. This makes any risk/benefit ratio even worse. Safe prescribing of any drug requires an acceptable risk/benefit ratio. Has the medical board really answered that answer. Don't lecture any doctor on safe prescribing without that information.Maybe the medical board should ask the legislators if patients have the "right" to be treated by insurance companies for pain?

Pain should not be a vital sign in all charts (as a standard of cae) until these questions are answered. Pain control should not be a "right" which every medical facility mentions when patient register to be seen. Pain control should not be a quality measure for insurance re-imbursement. Emergency dept should not be penalized for refusing to give narcotics or tranquilizers.

Look at the legislation/regulations 10-20 years ago. That is what created this mess.

I don't know why I wrote his since no one really cares anymore.

Commenter: Jason Nolet

4/26/17 4:22 pm

Long time Subutex patient concerns

Good Afternoon,

I have been a long time patient taking Subutex for my opiate dependence. This is the very first time I have commented or even signed a petition like this. I am an ex-heroin addict who after a month in detox continued to use this drug "legally" when I transition to my doctor.

My doctor initially put me on Suboxone, and I immediately noticed frequent migraines, nausea, and body discomfort. At the start I did not know what was causing me to feel so poorly and after doing a little research online I noticed other people were having similar symptoms. I then asked my doctor to please switch me over to the Naloxone free "Subutex" medication. Right away I noticed my migraines, stomachaches, and other discomforts went away.

I have been sober for over 10 years now, I have a good full-time job working with the federal government, and most importantly: stability. Now I fear that will all change because of this bill you're passing to switch me back over to a medication that makes me feel sick and does more harm than good, at least to me. Please don't punish people like myself who have followed the law and not abused this medication and who have benefited tremendously into living a life without going back on the street for drugs. There will always be people who are going to abuse drugs and find new ways to do so. I am very sorry to hear that so many are suffering right now because of these new implementations. I am very concerned and worried about what I'm going to do as I do not want to nor do I feel that methadone is a good fit for me treatment wise. My doctor just

informed me today about these new changes and even he is unsure what to do nor does he agree with it. This "uncertainty" is causing a lot of anxiety for my future. Thank you

Commenter: Mindy Thomas, Gloucester Mathews Care Clinic 4/28/17 1:43 pm

Wow, just wow

I just want to start by saying I honestly can't believe that law makers would even consider (much less make a law) restricting ANY type of recovery option. We are facing such an epidemic with the opiate crisis, we should be lifting restrictions instead of applying more! I seriously hope the practitioners will keep track of the patients who drop out of treatment due to allergies, commit crimes to get money to stop withdrawal, or end up in prison (or worse dead). There blood will be on your hands! Hope you're okay with that when you shut your eyes every night. God forbid one of your loved ones ever face this situation!

Commenter: Lorraine Murphy 4/29/17 9:18 am

Subutex vs. Suboxone

To whome this concerns,

I am an administrator for a Face Book Suboxone support group. We have over 6000 members whome all have tapered from or are on suboxone, subutex or the few other brands of buprenorphine medication. Members receive doses and a timeframe according to their needs. We have had women who became pregnant and switched to subutex, but we also have members who had to switch due to alergies to Naloxone.

The main concern doctors have with prescribing naloxone is a belief that it is a deterant for addicts who use Buprenorphine IV, when in fact any addict who has used this medication IV has done so with suboxone as well. The naloxone does not have any effect in detering addicts as the amount of naloxone in suboxone is not enough to get an addict sick, which is the desired result from adding the naloxone.

I wish you can hear the testimony from the recovering addicts in my group who have this allergy, they are now forced with having to go off of subutex when they are not ready and they are scared. I myself suffered from addictio for 30 years and found suboxone to be the one thing that enabled my recovery, I couldnt imagie having to be forced off this medication when I wasnt ready, and thanks to suboxone I can now face my life sober.

We have an opiate epidemic, with thousands of addicts losing their fight each year I cant understand why limits are being put on the one medication that is saving thousands of other lives. The members I have that have this allergy to naloxone are not kids seeking a cheap thrill, it is mothers and fathers whose recovery depends upon this medication.

We also have members who are in recovery with the use of suboxone that still suffer an addiction to the high of using a needle, this is how I know people are still using suboxone with no ill effects from the naloxone what so ever. Sometimes in addiction we dont do everything correctly right away, so breaking the the habbit of the needle takes time.

If suboxone users are still using this medication IV, why insist that subutex be only used for pregnant women? why cant a doctor who has proof of their patients alergy be able to prescribe it as well?

One day you are going to hear stories about these individuals relapsing because they had no alternative to suboxone, I hope you are preparred to take the blame for those such individuals.

Thank you,

Lorraine

Commenter: Michael Petrizzi 4/30/17 1:16 pm

Board of Medicine Opioid Regulations

Thank you for the opportunity to comment

1- It would be helpful to have a Google Drive Document that had the most up to date contact information for Pain Management Practices.

I would see if it was possible to be monitored by the Board Of Medicine, be search able by Zip Code, Insurance Company, Self Pay policies and or Medicare , Medicaid status with a real time next appointment date. It happens all to frequently that we try to give a Bridge prescription only to find the next appointment cannot be until 3 months from now or they don't take insurance.

2- I would ask that each time a patient fills a prescription for a controlled substance that they are given a copy of their PMP. I know that in the past we were not supposed to put a copy in the chart or give it to the patient. It is very time consuming to run a report the way we are supposed to FOR EVERY PATIENT NEEDING A REFILL OF A CONTROLLED SUBSTANCE. My rationale is that if it was used as a "ticket" to entry into the process of getting a refill it would be a more proactive step as compared to having the Physician need to deny the refill in the middle of a day of patient care.

ype over this text and enter your comments here. You are limited to approximately 3000 words.

Commenter: Julie Galloway, Medical Society of Virginia 5/2/17 11:00 am

MSV Comment: Regulations Governing Prescribing of Opioids and Buprenorphine 18 VAC 85-21

May 2, 2017

William L. Harp, M.D.

Executive Director

Board of Medicine

9960 Mayland Drive, Suite 300

Henrico Virginia 23233

RE: Regulations Governing Prescribing of Opioids and Buprenorphine 18 VAC 85-21

Dear Dr. Harp:

The Medical Society of Virginia (MSV) appreciates the opportunity to provide public comment on the Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21). MSV greatly appreciates the work of the Board to develop regulations that promote appropriate prescribing of opioids and buprenorphine, while maintaining physician discretion to offer treatment that best meets the medical needs of patients in extenuating circumstances.

Further, MSV supports the multi-stakeholder approach that incorporated best practices and considered the practical application in clinical settings. We look forward to continued work with the Board of Medicine, physician experts, and community stakeholders, on the implementation of

these regulations, as well as future regulations on these topics.

MSV continues to support the Board in its efforts to reduce opioid addiction in the Commonwealth and is committed to working collaboratively to address the opioid crisis.

Sincerely,

Bhushan Pandya, M.D.

President

CC:

David Brown, D.C., Director, Department of Health Professions

Elaine Yeatts, Policy Analyst, Department of Health Professions

Melina Davis-Martin, Executive Vice President, MSV

Scott Johnson, General Counsel, MSV

Lauren Bates-Rowe, Assistant Vice President of Health Policy, MSV

Ralston King, Assistant Vice President of Government Affairs, MSV

Commenter: Brenda

5/2/17 5:23 pm

SUBUTEX SAVED MY LIFE

Hello, I'm writing about the decision that was made to take my treatment away! I've been on Subutex for a little over a year now, well until a little over a month ago that is, when my doctor notified me that i would no longer receive my Subutex! I'll NEVER forget that day! I literally sat in the parking lot after my appointment for almost 2 hours crying! I felt like my life was over, because how can I continue to work and maintain a normal, productive life when I'm now SICK all the time again! I'm already sick of being SICK! I'm in fear of losing my job as I've already had to call in several days this past month due to being sick! And if i have to call into work, then my paycheck is short, hence me and my 2 teenage daughters will lose our home and everything! This bill being passed literally just took me back a million steps in recovery, because now I'm back on the streets as I've refused the suboxone treatment because i would rather be SICK than feel the side effects from Suboxone! I tried Suboxone first for awhile, but left that treatment because of how it made me feel like i was literally dying! It speeds my heart up, makes me feel like I'm struggling to breath, gives me horrible headaches, makes me sweat so bad i cannot cope as my clothes are soaked shortly after taking it, sweat literally dripping from my eyelids, made me intolerable to be around, says my kids as I'm so irritable on it, and last but certainly not least I am 38 years old, a little overweight, but still NEVER in my life, not even through 2 pregnancies have i ever had high blood pressure, but after only 30 to 45 minutes after taking Suboxone, my blood pressure shot up dramatically, and stayed up until i removed myself from that treatment! Raised it so much so, that the doctor wanted me to see another doctor about my blood pressure, which i could not afford! So, like i said I quit that treatment, and went back to the streets for a couple years, until i found my current doctor that wrote the prescription for Subutex! So after 10 plus years of being an addict, stealing, lying, in and out of jail, all the while my kids paying a huge price for my addiction, i FINALLY had a chance at LIFE again, my 2 teenage girls could even explain the 100 percent difference in me, in our life! After being put on Subutex, i immediately found employment, paid $7,000.00 in fines, got my license back, a car, a house, a LIFE again! All for this bill to be passed, and in such short time I'm already at risk of losing it ALL! I would ask for all involved to PLEASE reconsider what they've done in allowing this bill to be passed!!! MY LIFE AND FAMILY DEPEND

ON IT!! Thanks for giving me the opportunity to express my feelings and my desperate need for this bill to be reversed!!

Commenter: Virginia Hospital & Healthcare Association (R. Brent Rawlings on behalf of) 5/3/17 9:55 am

VHHA Comment on Regulations Governing the Prescribing of Opioids and Buprenorphine

May 3, 2017

William L. Harp, M.D.

Executive Director

Board of Medicine

9960 Mayland Drive, Suite 300

Henrico Virginia 23233

Re: Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21)

Dear Dr. Harp,

The Virginia Hospital & Healthcare Association (VHHA) supports the efforts of the Board of Medicine to develop these Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21) with input from stakeholders and other concerned citizens. The thoughtful approach taken to developing these regulations strikes an appropriate balance in establishing clear guidelines for health care providers without impeding the delivery of effective patient-centered care. We note that many of the guidelines are consistent with the Virginia Hospital Emergency Department Opioid Prescribing Guidelines jointly developed by VHHA and the Virginia College of Emergency Physicians in January 2016. Having these accepted practices incorporated into regulation will further promote appropriate prescribing of opioids and buprenorphine and better patient care across the Commonwealth.

There is far more that can and must be done, but these regulations are another important step in attempting to reduce the prevalence and incidence of substance abuse and opioid related deaths. VHHA and its members are committed to continuing to review and update these regulations as the medical standard and best practices evolve to ensure that Virginians are protected from harm and receive the best patient care possible.

Sincerely,

R. Brent Rawlings

Vice President and General Counsel

Commenter: S. Thomas 5/3/17 10:31 am

Already experiencing bad outcome as result of med change

It has been one month since the option of Subutex was taken off the table for my recovering daughter. Nausea, rash, depression and debilitating fatigue. In addition, the pharm compound she is now taking is a financial stress as we have to dip into her college fund to pay the out of pocket expense. My guess is that the impact of this reg has not saved one life or diverted an active addict who will find their high no matter what law is in place, but it has certainly had a negative impact on those recovering addicts who were successful and compliant with Subutex. Her qualified doctor

should be making these life altering decisions, not the state of virginia.

Commenter: Lindsey Vaughn, VAFP 5/3/17 3:15 pm

VAFP Comment: Regulations Governing Prescribing of Opioids and Buprenorphine

May 3, 2017

William L. Harp, M.D.
Executive Director
Board of Medicine
9960 Mayland Drive, Suite 300
Henrico Virginia 23233

RE: Regulations Governing Prescribing of Opioids and Buprenorphine

Dear Dr. Harp:

The Virginia Academy of Family Physicians (VAFP) appreciates the opportunity to provide public comment on the Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine. The practice of medicine is best regulated by the physicians and so the VAFP supports the Board's evidence based process to develop appropriate regulations concerning the prescribing of opioids and buprenorphine.

VAFP received a substantial number or responses from its membership in response to the Board's emergency regulations. A summary of the comments received by VAFP is included here. Please note that the summarized comments below do not necessarily reflect the views of the VAFP or its general membership.

Summary of comments received:

- Need to develop exclusions, reduced visit requirements, or reduced documentation requirements based on patient age (i.e. geriatric patients) or clinical criteria.
- Need to develop a process for withdrawing patients if a provider decides to stop prescribing opioids in response to these regulations.
- Clarification is needed as to the responsibility of Narcan prescribing; Narcan prescriptions should appear on the PMP.
- Clarification is needed as to whether or not the regulations apply to Tramadol. Many members expressed a need for confirmation that the regulations do not apply to Tramadol.
- Clarification is needed as to whether or not the regulations apply to cough syrups including codeine or hydrocodone.
- Many comments requested a definition of "opioid" be included in the regulations.
- Need clarification as to whether Narcan is required to be prescribed in conjunction with sedation medications.
- Flexibility is needed regarding the 3-month assessment requirement; individualization should be considered to allow for 3-6 month assessments with 3 month assessments reserved for patients at higher morphine equivalent doses. Frequent office visits may preclude access to primary care for other patients given limited primary care resources.
- Clarification is needed as to how patients who use opioids intermittently (i.e. opioid for back pain prescribed prn) must be managed under the regulations.
- Responsibilities should be clarified when one physician is prescribing an opioid and another physician is prescribing a benzodiazepine for the same patient.
- Clarification is needed as to how to handle a patients positive drug screen for THC if the THC was lawfully obtained.
- Many members expressed concern that the administrative requirements imposed by the regulations would have the consequence of impeding legitimate patients from accessing necessary medication as providers would be forced to see and prescribe opioids for fewer patients. Some

members reflected to VAFP that they have or will simply stop prescribing opioids entirely to avoid doubt over compliance and due to administrative burdens.

Again, thank you for the opportunity to provide comment on this matter. VAFP is committed to continuing to work with the Board of Medicine to advance public health and safety through the appropriate regulation of the prescribing of opioids and buprenorphine.

Respectfully,
Lindsey Vaughn, M.D.
President, VAFP

GENERAL QUESTIONS AND COMMENTS

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Friday, March 17, 2017 4:45 PM
To: 'gidoc73@gmail.com'
Cc: Morton, Colanthia D. (DHP)
Subject: RE: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

Dear Dr. Parker:

Thank you for your message.

Kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Friday, March 17, 2017 11:55 AM
To: Harp, William L. (DHP)
Subject: FW: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

From: Charles Parker [mailto:gidoc73@gmail.com]
Sent: Wednesday, March 15, 2017 7:51 PM
To: Board of Medicine
Subject: Re: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

Thank you for trying to turn practitioners into policemen.

On Mar 14, 2017 7:13 PM, "Virginia Board of Medicine" <medbd@dhp.virginia.gov> wrote:

Virginia Department of Health Professions

Virginia Board of Medicine

Virginia Board of Medicine

Dear Prescriber,

In response to the escalating opioid crisis in Virginia – and recently passed legislation – the Board of Medicine has promulgated regulations on the prescribing of opioids for pain. These regulations, which take effect March 15th, will:

- Provide clear, evidence-based guidance on the proper prescribing for acute and chronic pain.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Friday, March 17, 2017 5:07 PM
To: 'carolbender@rcn.com'
Cc: Morton, Colanthia D. (DHP)
Subject: RE: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

Dear Dr. Bender:

Thank you for your message and your service on the Maryland Board.

Unfortunately the Board does not have the authority to change the system as you describe.

I would suggest you contact the Medical Society of Virginia and your state senator and delegate and express your concerns to them.

Kindest regards,

William L. Harp, D
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Friday, March 17, 2017 11:50 AM
To: Harp, William L. (DHP)
Subject: FW: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

From: Carol L. Bender [mailto:carolbender@rcn.com]
Sent: Wednesday, March 15, 2017 12:47 PM
To: Board of Medicine
Cc: MSV Communications
Subject: Re: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

Dear Dr. Harp,

I fully agree that medicine should be practiced this way. How will you deal with physician employer mandates that only allow physician employees insufficient time to do this? My Boston University Opioid CME of several years ago said 4 hours are required to initially evaluate a patient before opioids are prescribed.

I would guess what you are mandating would take at least 30 minutes or more and this doesn't include anything else that physicians are required to do in the 15-30 minute visit for obesity, hypertension, diabetes out of control, COPD, etc that must also be treated.

Please do something about the system that fosters poor care and will make it impossible for physicians to obey the law on opioid prescribing.

In 32 years of practice I don't think I ever wrote for oxycontin, fentanyl ,etc.

When I sat on the Maryland Board of Quality Assurance 1999-2003) now Maryland Board of Physicians we had a Pharmacist from Purdue pharma explain why we should give more opioids. My comments to my colleagues after he

left were much opposed to his "educational" concepts.
I will look forward to your reply and help any way I can.

Warm regards,

Carol Bender, M.D.

Internal medicine

From: Virginia Board of Medicine <medbd@dhp.virginia.gov>
Date: Tuesday, March 14, 2017 at 7:05 PM
To: <cb289@cornell.edu>
Subject: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

Virginia Department of Health Professions

Virginia Board of Medicine

Virginia Board of Medicine

Dear Prescriber,

In response to the escalating opioid crisis in Virginia ? and recently passed legislation ? the Board of Medicine has promulgated regulations on the prescribing of opioids for pain. These regulations, which take effect March 15th, will:

- Provide clear, evidence-based guidance on the proper prescribing for acute and chronic pain.
- Decrease the number of patients who abuse or develop an addiction to opioids.
- Rein in intentional and indiscriminate overprescribing by practitioners who treat pain.

The Board worked diligently with pain experts, addiction experts and stakeholders to develop regulations that will not hinder the good practice of medicine but will prevent the diversion of opioids for non-medicinal use.

As you consider these regulations, make sure that the needs of patients currently receiving opioids for chronic pain are taken into account. It is critically important that no patients in Virginia find themselves looking for narcotics outside of the medical system ? ie, on the street.

Here is a link to the new regulations. Please take the time to review them. Some of the key provisions are listed below.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Wednesday, March 15, 2017 2:09 PM
To: Morton, Colanthia D. (DHP)
Cc: Deschenes, Jennifer (DHP); Wood, Jennie (DHP)
Subject: RE: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

Dear Dr. Nard:

Thank you for your e-mail.

Kindest regards,

William L Harp, MD
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Wednesday, March 15, 2017 12:35 PM
To: Harp, William L. (DHP)
Subject: FW: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

From: Nardsvabch5@aol.com [mailto:Nardsvabch5@aol.com]
Sent: Tuesday, March 14, 2017 8:47 PM
To: Board of Medicine
Subject: Re: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

Obviously you don't know how to use spell checker. We are Prescribers!!

Looks like it is time for me to retire; Dr. Harpe. You are tying my hands behind my back by citing only numbers not one patient case.
Doctor-Administrators such as you always cite numbers to back up what you want those of us in the trenches to obey. My suggestion is people like you do not deserve to be called doctors because you are more interested in rules and numbers.

Being a Psychiatrist who sees substance abusers, what you and the so-called experts are doing is cutting off patients from proper pain relief overseen by doctors
What my heroin addicts tell me is they started using it for pain because they could not get their strong and lasting pain medication.
Even my 89 y.o. mother is now suffering as her doctor is too scared not to follow the guidelines and has cut her back on her meds and refuses to write a script for her and send it to the pharmacy without a visit to his office. BTW my mother is bed bound and cannot get to the doctors.
I was a victim of the days when doctors did not treat pain aggressively and I was grateful that the pendulum swung and we were educated by the leaders to help patients pain. Now by not following your so-called guidelines(why not call them what they really are; strict rules), a doctor will be pursued as an outlier for helping his/her patients.
When the pendulum swings back towards treating pain as we were taught, I will be the first to identify you as one of the uncaring administrators who caused many patients to switch to heroin and many who committed suicide because of untreated chronic severe pain.

No wonder the young doctors cannot handle the patients who are outliers. All they have to do is look up stupid guidelines in their computers put there by people like you.

MSV℠ MEDICAL SOCIETY OF VIRGINIA

2924 Emerywood Parkway
Suite 300
Richmond, VA 23294

TF 800|746-6768
FX 804|355-6189

www.msv.org

May 2, 2017

William L. Harp, M.D.
Executive Director
Board of Medicine
9960 Mayland Drive, Suite 300
Henrico Virginia 23233

RE: Regulations Governing Prescribing of Opioids and Buprenorphine 18 VAC 85-21

Dear Dr. Harp:

The Medical Society of Virginia (MSV) appreciates the opportunity to provide public comment on the Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21). MSV greatly appreciates the work of the Board to develop regulations that promote appropriate prescribing of opioids and buprenorphine, while maintaining physician discretion to offer treatment that best meets the medical needs of patients in extenuating circumstances.

Further, MSV supports the multi-stakeholder approach that incorporated best practices and considered the practical application in clinical settings. We look forward to continued work with the Board of Medicine, physician experts, and community stakeholders, on the implementation of these regulations, as well as future regulations on these topics.

MSV continues to support the Board in its efforts to reduce opioid addiction in the Commonwealth and is committed to working collaboratively to address the opioid crisis.

Sincerely,

Bhushan H. Pandya

Bhushan Pandya, M.D.
President

CC:
David Brown, D.C., Director, Department of Health Professions
Elaine Yeatts, Policy Analyst, Department of Health Professions
Melina Davis-Martin, Executive Vice President, MSV
Scott Johnson, General Counsel, MSV
Lauren Bates-Rowe, Assistant Vice President of Health Policy, MSV
Ralston King, Assistant Vice President of Government Affairs, MSV

Harp, William L. (DHP)

From: Rawlings, Brent <brawlings@vhha.com>
Sent: Wednesday, May 03, 2017 10:02 AM
To: Harp, William L. (DHP)
Subject: Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21)
Attachments: VHHA Comments - Opioid and Buprenorphine Prescribing Regulations.pdf

Dear Dr. Harp,

Please see the attached public comment on Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine submitted on behalf of the Virginia Hospital & Healthcare Association. The public comment was also submitted electronically online through the Virginia Regulatory Townhall.

Thanks for all of your work on this important matter.

Brent

R. Brent Rawlings
Vice President and General Counsel
Virginia Hospital & Healthcare Association
4200 Innslake Drive, Suite 203
P.O. Box 31394, Richmond, VA 23294
Phone: (804) 965-1228
Mobile: (804) 307-0366
brawlings@vhha.com

VIRGINIA HOSPITAL & HEALTHCARE ASSOCIATION
4200 INNSLAKE DRIVE, SUITE 203, GLEN ALLEN, VIRGINIA 23060-6772
P.O. BOX 31394, RICHMOND, VIRGINIA 23294-1394
(804) 965-1227 FAX (804) 965-0475

May 3, 2017

William L. Harp, M.D.
Executive Director
Board of Medicine
9960 Mayland Drive, Suite 300
Henrico Virginia 23233

Re: Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21)

Dear Dr. Harp,

The Virginia Hospital & Healthcare Association (VHHA) supports the efforts of the Board of Medicine to develop these Emergency Regulations Governing the Prescribing of Opioids and Buprenorphine (18 VAC 85-21) with input from stakeholders and other concerned citizens. The thoughtful approach taken to developing these regulations strikes an appropriate balance in establishing clear guidelines for health care providers without impeding the delivery of effective patient-centered care. We note that many of the guidelines are consistent with the Virginia Hospital Emergency Department Opioid Prescribing Guidelines jointly developed by VHHA and the Virginia College of Emergency Physicians in January 2016. Having these accepted practices incorporated into regulation will further promote appropriate prescribing of opioids and buprenorphine and better patient care across the Commonwealth.

There is far more that can and must be done, but these regulations are another important step in attempting to reduce the prevalence and incidence of substance abuse and opioid related deaths. VHHA and its members are committed to continuing to review and update these regulations as the medical standard and best practices evolve to ensure that Virginians are protected from harm and receive the best patient care possible.

Sincerely,

R. Brent Rawlings
Vice President and General Counsel

BUPRENORPHINE QUESTIONS AND COMMENTS

Harp, William L. (DHP)

From: Paul Spector <specrab@verizon.net>
Sent: Wednesday, March 29, 2017 2:34 PM
To: Harp, William L. (DHP)
Subject: Re: Intolerance to Naloxone

Hi Bill, Paul here. The issue with Naloxone is a scam. The amount of Naloxone in the system if taken orally is all but immeasurable. The street word is that it is a way to convince doctors to prescribe single agent buprenorphine. I have insisted that I will not prescribe single agent to addicts and lo and behold after minor complaints their "headaches " are not a factor. I have never seen an allergy to naloxone (and it can not occur on a first dose-any doctor should know that.). The addicts have also confessed to me that it is a way to get and divert single agent.

Paul Spector
specrab@verizon.net

-----Original Message-----
From: Harp, William L. (DHP) (DHP) <William.Harp@DHP.VIRGINIA.GOV>
To: Art Van Zee <avzee@stonemtn.org>; jsreinhardmd <jsreinhardmd@gmail.com>; Neuhausen, Kate (DMAS) (DMAS) <Kate.Neuhausen@dmas.virginia.gov>; Lawrence Conell <ljconellmd@gmail.com>; hsmomof3blessing <hsmomof3blessing@aol.com>; mstev59587 <mstev59587@aol.com>; Mpsdaa <Mpsdaa@aol.com>; Mary McMasters <mary.mcmasters@gmail.com>; baristabob2018 <baristabob2018@gmail.com>; specrab <specrab@verizon.net>
Sent: Wed, Mar 29, 2017 11:55 am
Subject: Intolerance to Naloxone

Dear Colleagues:

Thank you for all you have done to help the Board along with its guidance and regulations.

I need to again ask for your experience and expertise on one issue, and that is intolerance/hypersensitivity/allergy to naloxone.

The Board has heard from a number of MAT physicians about this phenomenon, and also from some of you.

If you have seen this with your patients, could you please provide your observations and thoughts to the Board?

A quick response would be great, including from those of you that have made comments to the Board previously.

If you could just respond only to me, not everyone, your help will be much appreciated!

Thanks in advance and kindest regards,

Bill
William L. Harp, MD
Executive Director
Virginia Board of Medicine

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Thursday, March 30, 2017 9:44 AM
To: 'Mary McMasters'
Subject: RE: Intolerance to Naloxone

Mary:

Thanks for taking the time to respond to my e-mail.

As you might anticipate, clinicians have divergent perspectives on this phenomenon.

Hope all is well with you, and thanks very much!

Bill

From: Mary McMasters [mailto:mary.mcmasters@gmail.com]
Sent: Thursday, March 30, 2017 9:31 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Re: Intolerance to Naloxone

I've had several patients say they were "allergic" to naloxone. Since very VERY little naloxone is absorbed via the GI system, I declined to prescribe buprenorphine without naloxone. After explaining that I don't prescribe "plain" buprenorhpine, there was only one patient who continued to insist he was allergic. I told him to take his first dose (he was transferring care) in the emergency room. No allergic reaction.

I had a patient with ulcerative collitis and I was concerned the naloxone would cross the GI tract due to erosions and possibly cause a reaction. I talked to GI at UVA and they said that even with erosions, Naloxone doesn't cross into the blood easily.

I think a lot of people confuse the precipitated withdrawal phenomena with allergic reactions. Buprenorphine, not naloxone, given before the patient is in enough withdrawal, will cause precipitated withdrawal. This can look very much like an allergic reaction.

My patients tell me that the street value of the plain buprenorphine is considerably higher than the street value of the combination product. They say the single product is much more misuse-able and thus more expensive on the street.

I know that the single product is cheaper than the combo (but how much?). I think we are weighing risks and benefits. Putting A LOT of plain buprenorphine on the street will save lives (ex: France), but buprenorphine IS NOT the solution to the disease of addiction. It is just an adjunct to the important, and very hard work, of relearning how to think.

On Wed, Mar 29, 2017 at 11:55 AM, Harp, William L. (DHP) <William.Harp@dhp.virginia.gov> wrote:

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Friday, March 17, 2017 5:46 PM
To: 'Art Van Zee'
Cc: Morton, Colanthia D. (DHP)
Subject: RE: Draft Regs

Good evening, Art:

Thanks again for your tip about naloxone intolerance.

Your comments and those from others were considered during the development of the regulations.

Basically, there were believers and skeptics of naloxone intolerance, and in the final analysis, an exception was not included in the regulations.

So Section 18VAC85-21-150 stands.

I would emphasize (A)(3).

A. Buprenorphine without naloxone (buprenorphine mono-product) shall not be prescribed except:

1. When a patient is pregnant;

2. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days; or

3. In formulations other than tablet form for indications approved by the FDA.

B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed opioid treatment programs. With the exception of those conditions listed in subsection A of this section, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use off site from the program.

C. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

D. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

E. Prior to starting medication-assisted treatment, the practitioner shall perform a check of the Prescription Monitoring Program.

F. During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on no more than eight milligrams of buprenorphine per day. The patient shall be seen by the prescriber at least once a week.

G. During the stabilization phase, the prescriber shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

H. Practitioners shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of the Prescription Monitoring Program. The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

I. Documentation of the rationale for prescribed doses exceeding 16 milligrams of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 milligrams of buprenorphine per day shall not be prescribed.

J. The practitioner shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance abuse counseling.

I hope this is helpful.

Kindest regards,

Bill
William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Art Van Zee [mailto:avzee@stonemtn.org]
Sent: Friday, March 17, 2017 5:17 PM
To: Harp, William L. (DHP)
Subject: RE: Draft Regs

Hi Dr. Harp,
As I read the new regulations, it is essentially forbidden to prescribe the mono product buprenorphine except to a pregnant woman. No exceptions. Is that correct?—Art Van Zee

From: Harp, William L. (DHP) [mailto:William.Harp@DHP.VIRGINIA.GOV]
Sent: Monday, February 06, 2017 9:09 AM
To: Art Van Zee
Subject: RE: Draft Regs

Art:

Thank you very much.

I forwarded your previous comments and will do so again.

Kindest regards,

Bill

From: Art Van Zee [mailto:avzee@stonemtn.org]
Sent: Monday, February 06, 2017 5:58 AM
To: Harp, William L. (DHP)
Subject: RE: Draft Regs

Hi Dr. Harp,
The proposed regulations to me seem appropriate, but I have some reservations about a few things. One is the use of the mono-product. I mentioned this is a previous email---

(1) ----I use the monoproduct in select situations: (a) (eg, when a patient's lack of insurance coverage and financial resources
would not make it possible to afford the combo-product, which could cost $350-$400 as opposed to $150-200/month in our area for the mono-product (this is important in our area—which is one of the poorest counties in Virginia)(; (b) in the uncommon situation where the combo-product produces oral sublingual ulcerations, and the mono-product does not (has to be
demonstrated to me on a clinical trial (I have two patients like this) ; (c) in the uncommon situation where the bup/naloxone causes such nausea/vomiting to be clinically significant (eg, weight loss) (I have had a few patients like this in 13 years of buprenorphine prescribing)----------I understand the importance of having the

language read such so as to discourage mono-product use in the non-pregnant patient, but am concerned that it would not be allowed in special extenuating circumstances---could there be language such as: --eg, "Since the mono-product does have higher diversion and abuse potential, it should be used very seldom except in pregnant women, and the reasons for doing so should be well documented in the medical record."

(2) As written in the proposed regs, the mon-product is not approved for use in the breast-feeding mother. I have been following the older guidelines and may be behind the ball on this one. Do experts feel current evidence clearly supports use of the combination product in breast-feeding mothers?

Thanks for sharing the regulations with me. –Sorry that I could not have been more involved in the Richmond meetings.—best wishes, Art

From: Harp, William L. (DHP) [mailto:William.Harp@DHP.VIRGINIA.GOV]
Sent: Thursday, February 02, 2017 6:11 PM
To: Art Van Zee
Subject: Draft Regs

Art:

Here is the latest version of the regs.

The full Board will review, revise and approve on February 16th.

If you have any comments, I'll make sure they get consideration.

Kindest regards,

Bill

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Thursday, March 30, 2017 9:36 AM
To: 'Art Van Zee'
Subject: RE: Intolerance to Naloxone

Art:

As always, your thoughtful responses to the issues facing the Board of Medicine are very helpful.

Thanks very much.

WLH

From: Art Van Zee [mailto:avzee@stonemtn.org]
Sent: Wednesday, March 29, 2017 4:50 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: RE: Intolerance to Naloxone

Hi Dr. Harp,
For me, there are two issues with restricting the mono-preparation to pregnant women.

(1) The question of intolerance or "allergy"---of the about 150 patients I have in buprenorphine treatment, I have about 36 on the monopreparation. About five of these are pregnant, about 8 others report to me a convincing history of intolerance, and the remainder I have put on the monopreparation because of cost reasons (eg, no insurance and the mon-preparation could cost $200-$300 less than the bup/naloxone) and these are people that struggle financially
The intolerance history can be anything from oral ulcerations under the tongue that are very painful, that occur with the combo preparation, but
Go away with change to the monopreparation. And has happened more than one occasion---I have documented 2-3 of these. And then there are more vague, less documentable complaints---that is chronic, daily nausea, for weeks to months, sometimes associated with weight loss, that seems to resolve when switching to the mono-preparation. Some report have rash, red face, bad headaches, generally feeling poorly.----These are indeed tricky calls, because there clearly are people that give you a story like that—just to get the subutex—either for abuse, or diversion. In general, I like to have demonstrable reactions in the office before I would allow the subutex---

This is a really hard call for the Board, I'm sure. Subutex is certainly over-prescribed and inappropriatedly prescribed, has become a big street drug ($50 per 8 mgm pill here, vs. $20 for the suboxone)---but some people will be hurt by the mandate.------One of the biggest factors driving diversion, however, is the cash-only clinics—charging $100 per week. As a new patient said to me yesterday, "everyone I know sells their suboxone so they can afford to go back to the clinic"—she had stopped going because she did not want to have to sell drugs to afford to go to the Suboxone clinic, and her jaw dropped when I told her our community health center takes her Medicaid.----

From: Harp, William L. (DHP) [mailto:William.Harp@DHP.VIRGINIA.GOV]
Sent: Wednesday, March 29, 2017 11:56 AM
To: Art Van Zee; jsreinhardmd@gmail.com; Neuhausen, Kate (DMAS); Lawrence Conell; hsmomof3blessing@aol.com; mstev59587@aol.com; Mpsdaa@aol.com; Mary McMasters; baristabob2018@gmail.com; specrab@verizon.net
Subject: Intolerance to Naloxone

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Thursday, March 30, 2017 9:25 AM
To: 'Barista Bob'
Subject: RE: Intolerance to Naloxone

Dr. Lowe:

Thanks for your help on this issue.

It will help guide the Board in its development of the regulations.

Kindest regards,

WLH

From: Barista Bob [mailto:baristabob2018@gmail.com]
Sent: Thursday, March 30, 2017 1:10 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Re: Intolerance to Naloxone

Hello Sir!
It was a great pleasure to work with everyone. Such brilliant dedicated group.
Thank you
We have found in our work here at A.P.A.C.H.E. medication assisted treatment systems a well defined and indeed small number of patients who cannot tolerate naloxone. Headache seems to be the determining factor. By decreasing the milligrams, the side effect appears to diminish. I tend to suspect this is the major contributory factor in the initial reports for the trial of the Suboxone product adverse reaction reports. The headaches tend to vanish with mono product use.
The use of monoproduct for solely "economic" benefit to the consumer is I'll advised as discussed, however we believe that there is this sub population that does exist.
At this time we do have clinical evidence although maybe considered by some anecdotal evidence that 0.5 mg/day or less of the naloxone in combination with buprenophine appears to solve this dilemma and use of other delivery systems may be employed.
Robert Noyes Lowe, M.D.

On Mar 29, 2017 11:55 AM, "Harp, William L. (DHP)" <William.Harp@dhp.virginia.gov> wrote:

Dear Colleagues:

Thank you for all you have done to help the Board along with its guidance and regulations.

I need to again ask for your experience and expertise on one issue, and that is intolerance/hypersensitivity/allergy to naloxone.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Thursday, March 30, 2017 9:27 AM
To: 'Lawrence Conell'
Subject: RE: Intolerance to Naloxone

Larry:

Your comments are most appreciated.

They will help the Board as it reviews the emergency regulations.

Kindest regards,

ill

From: Lawrence Conell [mailto:ljconellmd@gmail.com]
Sent: Wednesday, March 29, 2017 10:59 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Re: Intolerance to Naloxone

Hi Bill,

As I have expressed to you previously this is a serious problem with a few patients with reactions including skin reactions, severe headaches, dizziness, nausea/vomiting and others.

In addition I would still like to again lobby for discretionary use, for at least a few months, in selected patients of buprenorphine mono product, in situations of severe financial hardship. This would be especially applicable for those already stable on mono product, or those who lose their insurance while on a combo product. This would allow time for patients and the treatment team to explore resources, alternatives, and/or obtain insurance. In fact, I just saw a patient today who has been stable on Suboxone 16 mg per day for one year, with a past history of multiple relapses. He will turn 26 on 4/2/17 and lose his parents' insurance. His next prescription for a buprenorphine product cannot be filled until 4/6/17, and since he is without regular employment, he feels he will be unable to afford a combo product, even with his parents' help. Thus, putting him at high risk of relapse once again even though he has done well over the last year.

Providers need this prescribing discretion. As you know, even the generic combo product is extraordinarily expensive. We need help in treating these patients, not more constraints and handcuffs making it more difficult than it already is to treat this challenging population. One possible approach could be to limit prescribing of the mono product to those board certified in addictions, and limiting the duration to a maximum of 6 months at a time, to allow time for other arrangements to be made, whether tapering off or establishing other means of paying for the medication.

Again, Bill thanks for your consideration of these concerns, and hopefully advocacy for these positions, to the Board and our state legislature.

Thank you,
Larry

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Friday, April 21, 2017 8:46 AM
To: 'Lawrence Conell'
Subject: RE: May 15th

Thanks, Larry.

I'll try to get your comments to the Panel.

Bill

From: Lawrence Conell [mailto:ljconellmd@gmail.com]
Sent: Thursday, April 20, 2017 9:35 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Cc: Morton, Colanthia D. (DHP) <CoCo.Morton@dhp.virginia.gov>
Subject: Re: May 15th

Hi Bill,
Thanks so much for trying to accommodate. I would very much like to attend but just can't see how, as have 21 patients scheduled that day, and a packed week with no place to reschedule, especially as will be leaving later in the week to go to the APA. Please keep me informed, as the change in the regulations has severely adversely effected a number of my patients.

In addition to considering allowing mono product for those with a history of adverse reaction(s) to naloxone, would ask for a time limited provision of perhaps 6 months for the occasional selected and trusted patient, to allow time to obtain insurance if they don't have it, or have lost it for some reason.

Many thanks again for considering these concerns and pursuing my input.

Larry

Thanks,

Lawrence J. Conell, M.D., DLFAPA
110 Newman Ave.
Harrisonburg, VA 22801

Phone: (540) 442-9909
Fax: (540) 442-9901
Web: www.drconell.com

On Thu, Apr 20, 2017 at 1:59 PM, Harp, William L. (DHP) <William.Harp@dhp.virginia.gov> wrote:

Larry:

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Wednesday, March 29, 2017 3:37 PM
To: 'Marty'
Subject: RE: Intolerance to Naloxone

Marty:

Thanks very much for your quick response.

Hope all is going well, and see you next week.

Bill

From: Marty [mailto:mpsdaa@aol.com]
Sent: Wednesday, March 29, 2017 3:13 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Re: Intolerance to Naloxone

Bill,
I've not seen adverse reactions although infrequently patients have c/o having vague complaints that led me to suspect manipulation. On rare, very rare occasions I've dc'd secondary to rising Lfts. Sherman reported a case of liver toxicity with it. I can see the conundrum trying to discern truth from manipulation. Perhaps methadone in these cases. Marty

Sent from my iPhone

On Mar 29, 2017, at 11:55 AM, Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV> wrote:

> Dear Colleagues:
>
> Thank you for all you have done to help the Board along with its guidance and regulations.
>
> I need to again ask for your experience and expertise on one issue, and that is intolerance/hypersensitivity/allergy to naloxone.
>
> The Board has heard from a number of MAT physicians about this phenomenon, and also from some of you.
>
> If you have seen this with your patients, could you please provide your observations and thoughts to the Board?
>
> A quick response would be great, including from those of you that have made comments to the Board previously.
>
> If you could just respond only to me, not everyone, your help will be much appreciated!
>
> Thanks in advance and kindest regards,
>
> Bill

Harp, William L. (DHP)

From: Board of Medicine
Sent: Friday, March 17, 2017 11:56 AM
To: Harp, William L. (DHP)
Subject: FW: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

From: Jann Holwick [mailto:jholwick60@gmail.com]
Sent: Thursday, March 16, 2017 8:15 AM
To: Board of Medicine
Subject: Re: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

Patients who cannot afford Suboxone will be looking for narcotics on the street with this new law. Chances of overdose death from diverted or misused buprenorphine are minuscule compared to the risk we are now exposing our compliant, destitute patients to.

On Tue, Mar 14, 2017 at 7:16 PM, Virginia Board of Medicine <medbd@dhp.virginia.gov> wrote:

Virginia Department of Health Professions

Virginia Board of Medicine

Virginia Board of Medicine

Dear Prescriber,

In response to the escalating opioid crisis in Virginia – and recently passed legislation – the Board of Medicine has promulgated regulations on the prescribing of opioids for pain. These regulations, which take effect March 15th, will:

- Provide clear, evidence-based guidance on the proper prescribing for acute and chronic pain.
- Decrease the number of patients who abuse or develop an addiction to opioids.
- Rein in intentional and indiscriminate overprescribing by practitioners who treat pain.

The Board worked diligently with pain experts, addiction experts and stakeholders to develop regulations that will not hinder the good practice of medicine but will prevent the diversion of opioids for non-medicinal use.

As you consider these regulations, make sure that the needs of patients currently receiving opioids for chronic pain are taken into account. It is critically important that no patients in Virginia find themselves looking for narcotics outside of the medical system –

Harp, William L. (DHP)

From: Board of Medicine
Sent: Tuesday, May 02, 2017 4:02 PM
To: Harp, William L. (DHP)
Subject: FW: Ban of buprenorphine, Dr Holwick endorsing letter from our clinic

From: Jann Holwick [mailto:jholwick60@gmail.com]
Sent: Sunday, April 30, 2017 9:34 AM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Ban of buprenorphine, Dr Holwick endorsing letter from our clinic

Dear Dr Harp: Re:18VAC85-21-140

The above legislation which went into effect last month has made my job, helping addicts find recovery, much more difficult. Here in southwest Virginia, we continue to deal with high rates of mortality from opioid overdoses. Heroin is cheap, and medications we offer are expensive.

One third of my patients had been taking buprenorphine monoproduct (Bup-MP), mainly for financial reasons (low income, no or little insurance) and were coping with a cost of around $3.00/pill for the 8mg pill, at a dose of 2/day ($180/month-if bought all at once, much more if bought a few at a time). A fewer number were were on Bup-MP for allergy to naloxone, or severe side effects to naloxone containing preparations (usually nausea, or migraine type headache).Elimination of the Bup-MP option for those patients has resulted in many of them trying to get off all meds prematurely, going back to street drugs, or going to other practioners who would prescribe opioids which got them into trouble in the first place (ie, methadone clinics).

This has already begun to happen, and if it becomes widespread, it will have undone the the hard won progress of many former patients, and will lead to an outcome unintended by that legislation. I have attempted to switch many to the naloxone containing products, but the cost is at the minimum (if a whole month is purchased at once) $6.00/day ($360/month) for the generic and $10.00/day ($600/month) for the Film. My uninsured/underinsured patients cannot afford these prices. Drug company reps will tell you that discount coupons are available, or that free medicine is offered for those that qualify. They will also admit that even coupons do not decrease cost anywhere near to $3.00/pill and that free med is available to only 3 patients/year and those for only one year. I expect that even those prices will go up, because of changes in market share (as per the recent issues with Epipen)

None of the above even gets to the heart of the matter, which involves the chemistry of buprenorphine (bup). Most of the fatal overdoses (ODs) in our area involve methadone and heroin-fentanyl mixtures, often associated also with alcohol or benzodiazepines (bzos). I am not aware of any fatal adult ODs due to only Bup-MP or Bup with naloxone. The reason bup is so effective, and less dangerous, is that it stimulates only 40% of available opiate receptors (and blocks the rest). So the only way to get a fatal OD on Bup-MP or Bup naloxone is to mix them with alcohol or other respiratory depressants. Taking methadone or heroin on top of either type of bup will lead to those drugs being blocked. Drug company reps will also tell you that the addition of naloxone to bup prevents diversion, or IV use, and lessens the likelihood of a fatal OD, but my patient say that the amount of naloxone is too low to result in any benefit.

Any form of bup, with or without naloxone, is used on the street primarily for prevention of withdrawal when addicts cannot get their drug of choice (either preparation costs $25-35/ 8mg pill on the street). Yes, there are those who still use either for IV purposes, but these are in the minority. The key fact here is that all

Bup products are saving addict lives, preventing other crimes (assault, robbery, breaking and entering to obtain drugs or money for drugs for those in withdrawal). And that bup with or without naloxone, by itself, even in high doses, will not shut down the respiratory center.

I would therefore propose that Bup-MP be available also to those without financial means to pay, and to those few who demonstrate and allergy/intolerance to naloxone. and would also propose that the price for naloxone containing Bup products be halved.

I hope all of this helps you understand some of the issues we face. I and my 2 colleagues practice only addiction medicine, and do not prescribe medication for addiction as a sideline to the main work as a general practitioner or psychiatrist. We are all ASAM certified, and require that our patients change their way of living, and join a support group for assistance, along with taking their meds (ie, we are not "scrip docs). And last, please understand that this letter is about our patients' lives, and not our income.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Monday, April 17, 2017 1:03 PM
To: 'Jann Holwick'
Subject: RE: Virginia State Laws re buprenorphine

Thank you, Dr. Holwick.

WLH

From: Jann Holwick [mailto:jholwick60@gmail.com]
Sent: Monday, April 17, 2017 11:23 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Virginia State Laws re buprenorphine

Kindly add exceptions nursing mothers and for those patients with potential or real hepatic disease, e.g., cirrhosis, hepatitis, liver nodules/masses, steatohepatitis, etc. Holwick, MD

Harp, William L. (DHP)

From: Board of Medicine
Sent: Wednesday, March 15, 2017 12:30 PM
To: Harp, William L. (DHP)
Subject: FW: New guidelines on opioid prescription

-----Original Message-----
From: Manhapra, Ajay [mailto:ajay.manhapra@yale.edu]
Sent: Tuesday, March 14, 2017 7:40 PM
To: Board of Medicine
Subject: New guidelines on opioid prescription

Dr. Harp
I practice in the area of pain and addiction. I am an addiction medicine trained physician from Yale and practicing at VA hospital in Hampton VA. I also am a researcher in this area.
I have to scientifically disagree with your rulers regarding buprenorphine. It does not appear it has any meaningful input from any addiction specialists. Many people cannot tolerate buprenorphine/naloxone combination because of the peculiar nature of naloxone metabolism. So we have to use buprenorphine alone in a few. Banning use of buprenorphine puts patients and physicians in a tough spot.

There are few people who need 32 mg of buprenorphine. Banning it us legislating medical practice. It is better left to physicians and their patients. Buprenorphine very rarely kills people, lack of buprenorphine regularly kills people. Hope you would be more kind to people and act based on science and not fear.
Respectfully

Ajay Manhapra MD

Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Friday, March 17, 2017 8:35 PM
To: Harp, William L. (DHP)
Subject: Re: New guidelines on opioid prescription

Oh boy.

Sent from my iPhone

On Mar 17, 2017, at 6:26 PM, Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV> wrote:

> Dear Dr. Manhapra:
>
> I will need a little more time to give you a thorough response.
>
> Thank you,
>
> William L. Harp, MD
> Executive Director
> Virginia Board of Medicine
>
> **From:** Board of Medicine
> **Sent:** Wednesday, March 15, 2017 12:34 PM
> **To:** Harp, William L. (DHP)
> **Subject:** FW: New guidelines on opioid prescription
>
> **From:** Manhapra, Ajay [mailto:ajay.manhapra@yale.edu]
> **Sent:** Wednesday, March 15, 2017 6:59 AM
> **To:** Board of Medicine
> **Subject:** New guidelines on opioid prescription
>
> Dear Dr Harp:
> I am a Yale trained Addiction Medicine Physician who started a clinic for complex pain with opioid dependence, other substance use disorders, complex medical issues and psychiatric co-morbfdities at Hampton Veterans hospital. I am still academically affiliated with Yale and continue my research in this area.
>
> As I read through the new regulations, I see the good intentions clearly, but the regulations may practically impede appropriate treatment of opioid use disorder. This guidelines appear to be verbatim translation of parts of SAMHSA TIP 40 guidelines into regulation. The SAMHSA TIP 40 was written in 2004 and OUD treatment has progressed considerably since then. In addition, the TIP 40 accommodates for individualization of practice beyond the stated general recommendations (what is the current Virginia regulation) to match patient needs. It seems that these regulations have made those individualization options illegal, thus limiting patient treatment options. This is incredibly unfair to patients struggling with OUD and physicians who manage them. I am sure such a law would not be considered in management of any other chronic diseases like diabetes or hypertension. Addiction is a chronic disease which requires individualization of treatment. Denying these individualization of treatment through mandated "one rule fits all" directives will result in more harm than good. Many who deserve treatment and are willing to engage will not be participating in these treatments. These regulations

seriously impede the establishment and maintenance of OBOT practices that are desperately needed in these times of serious opioid epidemic.

My specific concerns are listed below:
1. This is making rules out of a guideline made in 2004 (SAMHSA TIP 40). OUD practice has evolved considerably since then.

2. The law mandates that Subutex can be prescribed only for pregnant patients and methadone transition. Realistically a proportion of people, especially those with liver disease cannot tolerate buprenorphine/naloxone combination and buprenorphine monoproduct has to be used. So, are we practicing illegally here?!!! The worry about buprenorphine diversion maybe overblown. There is no evidence that this is a significant problem. The incidence is way low and it does not make any sense to most with SUD to divert buprenorphine as the high obtained by buprenorphine is sub-optimal and heroin is so cheaply available.

3. Rule F. "During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on no more than 8 mg. of buprenorphine per day. The patient shall be seen by the prescriber at least once a week." This is an old practice when we did not know about buprenorphine that much. For those with OUD and pain we often start at 4 MG TID. This is an individualized decision that cannot be mandated. In addition, the transportation issue makes the weekly follow up impossible for many poor patients.

4. "The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter."
Serum drug levels are practically useless in buprenorphine monitoring as the level varies considerably.

5. "I. Documentation of the rationale for prescribed doses exceeding 16 mg. of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 mg. of buprenorphine per day shall not be prescribed."
This may be part of the regulation that makes the least scientific or medical sense. Although 32 MG is required in only a few, it is a life saver for those who need it, especially if they have comorbid pain. Doses beyond 32 MG are not effective for addiction, that's all. (It is not particularly associated with harm because of the ceiling effect associated with buprenorphine.)

6. "A. Pregnant women shall be treated with the buprenorphine mono-product, usually 16 mg. per day or less."
The practice in this area is emerging. Many use suboxone for pregnant women and find it safe and effective. Many may need more than 16 MG dose, otherwise putting them at great risk for relapse.

7. C. The progress of patients with chronic pain shall be assessed by reduction of pain and functional objectives which can be identified, quantified and independently verified."
How are physicians supposed to verify it independently when OUD and pain are intertwined with each other in complex ways?!!!

8. "Practitioners engaged in medication-assisted treatment shall either provide counseling in their practice or refer the patient to a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance abuse counseling. The practitioner shall document provision of counseling or referral in the medical record."
This regulation asks for professional counseling if buprenorphine is being provided. As data stands now, additional specialized counseling does not seem to provide any more benefit than standard physician counseling. Even the VA guidelines of 2015 has clearly stated that professional counseling is only needed when indicated. This appears to be a holdover from the past. This will thwart OBOT establishment significantly.

Overall these regulations make the establishment and maintenance of OBOT practices difficult, thus denying many patients the opportunity to get treatment that could save lives. These regulations are targeting the most vulnerable who have no voice, those with addiction. BUPRENORPHINE KILLS ALMOST NONE, BUT LACK OF BUPRENORPHINE KILLS MANY. These regulations will seriously impede access to appropriate treatment for many with OUD thus increasing their risk for mortality. I hope you can be persuaded to change these to some meaningful laws that help patients and not harm them as this one is expected to.

thanks and regards

Ajay

Ajay Manhapra, MD
ajay.manhapra@yale.edu
Cell: 231 288 4848

Advanced PACT Pain Clinic, VA Hampton Medical Center, Hampton, VA
Research Scientist, VA New England Mental Illness Research and Education Center, West Haven, CT
Lecturer, Department of Psychiatry, Yale School of Medicine, New Haven, CT

Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Tuesday, March 21, 2017 1:51 PM
To: Morton, Colanthia D. (DHP)
Cc: Harp, William L. (DHP)
Subject: RE: New opioid prescribing law and Virginia licensed physicians practicing at federal facilities

I spoke with Dr. Allen. He was very pleasant and had questions about state jurisdiction in the federal prison system. He noted that he appreciates the Regs and believes they are stating what the standard should be in this challenging area. He explained that the federal prison system has been working on and is in the process of implementing similar rules for some time now. He noted that they have not yet gotten to the point of mandated urine screens or the consents that are mentioned in our regs, but they hope to get there soon. He noted that prisoners do manage to get illicit drugs from family and in letters and that the urine screens would be helpful in better addressing these problems. In the meantime, he has discussed the issue of federal sovereignty and concerns raised by a Virginia licensed physician who works in one of their facilities. He noted they have two federal prisons in Virginia, housing inmates who are residents of Virginia and non-residents. Additionally, the physicians who work in these facilities are not all licensees of Virginia. We discussed the importance of him consulting with counsel for the federal prisons in this area. I also noted that the Board recognizes there are various limits or procedures in place in prison systems (state and federal) that may impact the way medicine is practiced (eg, nurses deciding whether a prisoner gets seen by the doctor). I told him we are in the process of working on FAQs and I would see if there was a way to address his concerns. We can speak more about this when you return. Thanks. Jen

Jennifer Deschenes
Board of Medicine
804-367-4462

From: Morton, Colanthia D. (DHP)
Sent: Monday, March 20, 2017 5:36 PM
To: Deschenes, Jennifer (DHP)
Subject: FW: New opioid prescribing law and Virginia licensed physicians practicing at federal facilities
Importance: High

FYI –

I'm not sure if Dr. Harp advised you about this email or not. Would you prefer to speak to him or answer his email and hope that's sufficient?

Co-Co

From: Harp, William L. (DHP)
Sent: Friday, March 17, 2017 4:21 PM
To: Morton, Colanthia D. (DHP)
Subject: FW: New opioid prescribing law and Virginia licensed physicians practicing at federal facilities
Importance: High

I told him to call your # next week.

I guess JD might be the best one to field the call.

From: Board of Medicine
Sent: Friday, March 17, 2017 11:56 AM
To: Harp, William L. (DHP)
Subject: FW: New opioid prescribing law and Virginia licensed physicians practicing at federal facilities
Importance: High

From: Jeffery D. Allen [mailto:jd1allen@bop.gov]
Sent: Thursday, March 16, 2017 10:25 AM
To: Board of Medicine
Subject: New opioid prescribing law and Virginia licensed physicians practicing at federal facilities
Importance: High

I am the medical director for the Federal Bureau of Prisons and also have a Virginia medical license.

I am writing to request clarification on the boards understanding / expectation of the intended scope of this new regulation as it pertains to

1) physicians licensed in the state of Virginia who practice medicine in federal facilities and

2) inmates who are incarcerated in a federal facility in the state of Virginia

I would appreciate the opportunity to discuss this by telephone with a subject matter expert at the Board of Medicine at your earliest opportunity. The Federal Bureau of Prisons has two facilities in the state of Virginia and a Virginia licensed physician practicing there who has voiced concerns about the impact of the law on their opioid prescribing practices. There is a need to clarify this quickly to avoid Virginia licensed physicians from inadvertently violating this new law or other unintended consequences.

My direct telephone number is 202-616-8371. I also called and left a voice message at the Virginia Board of Medicine's general number (804-367-4600) list on the web site.

Thank you in advance for your prompt attention to this request.

Jeffery D. Allen, M.D.
Medical Director,
Federal Bureau of Prisons

Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Tuesday, April 11, 2017 5:09 PM
To: Harp, William L. (DHP)
Cc: Wood, Jennie (DHP); Brown, David (DHP)
Subject: FW: subutex

Spoke to Dr. Bulette. He explained that he had a patient bring him a letter from her cardiologist stating that the patient developed an arrhythmia in reaction to the suboxone after he switched her from subutex. He had another patient who also seemed to have a legitimate reaction. He said he had other patients who claimed to have an allergy, but he has found that most are tolerating the naloxone without problem. His concern is with the small number, who do appear to have a problem with suboxone, and wondered if there is any leeway. He also noted that the cost is double for suboxone. In response to the cardiologist's recommendation, he did write subutex for the patient and wrote a note to the pharmacist explaining the issue, and documented in his record and included the cardiologist's report in an effort to comply with 18VAC -85-21-150(C). I told him that there is no exception in the regs for intolerance or allergy and 150C is directed at the decision to use the mono product in formulations other than tablet form. He understands what the Board is trying to do, and is supportive of the Board's efforts, but believes there should be an allowance for naloxone intolerance. He plans to write a letter and it sounds like he intends to reach out to some of his former patients who have now been recovered and off subutex to speak to how proper addiction treatment helped them and saved their lives.

From: Wood, Jennie (DHP)
Sent: Tuesday, April 11, 2017 4:23 PM
To: Deschenes, Jennifer (DHP)
Subject: subutex

Dr. Bulette left a vm (he left no 1st name). "wondering if there is any leeway going from subutex to suboxone" and the Board's thoughts. He's at his office T,W, Th from 10 to 6.
757-442-2504

Jennie F. Wood
Case Manager, Discipline & Compliance
Virginia Board of Medicine
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233
804-367-4571; Fax-804-527-4429

Sheila M. Furey, MD
7711 Kenmore Circle
Richmond, VA 23225
804-717-5181 phone
804-914-1949 mobile
888-374-3883 fax

April 6, 2017

Dear Dr. Harp and Board of Medicine:

I have multiple concerns and questions on behalf of my patients regarding the new regulations for opioids and buprenorphine. I became certified to prescribe buprenorphine/naloxone over 10 years ago. I understand the intent of the regulations, however, the abrupt onset of the changes has caused significant concerns for my long term patients.

Below are some of the case vignettes of patients. What are your guidelines on how to proceed? You stated in your letter to essentially, "do no harm," however, there does not appear to be any room for a medical decision based upon my assessment of the patient, knowledge, training, experience, and the steps I am taking to avoid misuse or diversion of the drugs.

The option of sending long term patients to a methadone clinic is unrealistic. Most of my patients are working full time and cannot leave their jobs or commute to a clinic on a daily basis. The other issue is cost. The cost of $15 per day is prohibitive to my patients who may be working full time, but do not have insurance. Additionally, the methadone clinics are not prepared to handle the influx of patients on the mono-product buprenorphine.

Patient 1. 30 year old woman 12 weeks pregnant and is on Subutex 8 mg BID. When she delivers, the protocol for the newborn is for Mom to continue to use Subutex and her breast milk is used in the weaning process. Thus, Subutex needs to be continued during lactation. The pediatricians do not want to introduce Naloxone to the new born.

Patient 2. Woman s/p delivery. Baby is now 5-6 months. Mother continues to breast feed. Her breast milk was used to wean baby while he remained at the hospital and mother continues to use breast milk at home as per the pediatrician.

Patient 3. Male in early 30s, had severe migraine headaches on combination product. He was missing work on a regular basis. I tried various interventions for the migraines without success. I moved him to mono product and he has not had a migraine headache since. He works full time and is compliant with therapy and clean. If he returns to combination product, he risks losing his job.

Patient 4: Patient on Suboxone with severe PTSD and Anxiety. Patient is prescribed benzodiazepines. There is no abuse or misuse of medications. I do urine drug screens at monthly appointments. I have been following for years. I have written for Evzio. It is unreasonable to taper benzodiazepines quickly and to what purpose if it is not helpful to the patient.

Patient 5: Patient on Suboxone film 8/2 mg daily. Co-morbid PTSD and seizure disorder.
Patient relies on Klonopin to help with seizure control in addition to high dose Neurontin.
Patient has aura prior to seizures and alerts to take Klonopin/Neurontin. The risk of DC or taper of Klonopin at this time is significant.

Patient 5: Chronic pain patient, age 40, from chronic kidney stones, passes 12-15 stones per month. He has brought the stones to my office. Additionally, he had back pain with radiation down his legs from injury approximately 15 years ago. He initially presented from his pain specialist because he wanted an alternative to his oxymorphone. I reviewed all the medical issues and he was aware that Suboxone may

not cover the pain of kidney stones. He was still willing to try. He was initially treated with Subutex during the induction. He did well. He then transitioned to Suboxone, however, this cause severe nausea and he was unable to tolerate it. He tried Suboxone for for one month and could not tolerate it anymore. He was switched back to Subutex and was stable. He was able to use Subutex part of the month and oxymorphone when he had severe kidney pain. However, in fall of 2016 kidney stone pain remained severe and had additional pain from his back. I encouraged him to have another back evaluation and he is currently post op.(February 28, 2017) lumbar back surgery, laminectomy for herniated discs. He reports significant improvement in back pain. He is no longer in constant pain with radiation down his legs from his back. He describes back pain with over exertion. However, he continues to struggle with pain from the kidney stones. He is currently prescribed Oxymorphone 10 mg (max of 8 tablets per day #240 for one month) He is compliant with medications. Subutex does not cover kidney stone pain.

This patient was told there was nothing more they could do in terms of his kidney stones by nephrology and urology. I have consulted with nephrologist at U of Pennsylvania. I had urine sent to lab specializing in chronic kidney stones. We have worked to change his diet and looked at alternative interventions for kidneys stones. I have him go to physical therapy not just for back pain but for pain from kidney stones and to teach him to relax muscles post waves of kidney stone pain. He comes to each appointment with his wife. Again, he desires to return to mono-product as soon as able to from back surgery and if he can obtain windows in which he is free from kidney stones.

Patient 6: 31 year old woman. NO insurance. Chronic Pain. Dependence s/p MVA with neck and back injury. Unable to afford Suboxone or combo product. Also, taking Xanax for panic attacks. Weaning from Xanax. With no insurance, she cannot afford alternative.

Patient 7: 38 year old male with Ehlers Danlos syndrome, rheumatoid arthritis and addiction. He had severe nausea with Suboxone and has none of those symptoms on Subutex. He is medication compliant. He works but has no health insurance. He has been prescribed Subutex 24 mg per day in divided doses. Again, this medication has provided him with stability he has not had in years.

Please respond to these and I will send additional questions as they come up. All patients on Subutex were willing to have weekly pill counts or whatever was necessary to keep the medication.

The alternative mono products are in micrograms. There is no data on how patients on milligrams will tolerate the transition to a product that is in micrograms. I understand the mechanism is different and absorption may be significantly improved but until the patients try, they will not know. However, this does not help patients who do not have insurance. Cost of mono product film is $500 plus dollars a month vs. buprenorphine tablets at $100-$200 per month depending on dose.

Respectfully,

Sheila M. Furey, MD

Harp, William L. (DHP)

From: Randall, Mellie (DBHDS)
Sent: Thursday, April 20, 2017 12:14 PM
To: Harp, William L. (DHP); Melton, Hughes (VDH); Neuhausen, Kate (DMAS)
Subject: RE: Frequently Asked Questions about the Opioid Regulations
Attachments: DBHDS to DHP re Parrino Letter Feb 17 2017.pdf

Bill – I have reviewed the comments provided by Hughes and Kate (and Donna) and don't have anything to add from a technical perspective.

As you recall, Jack Barber sent a letter to David Brown (attached) which stated the full support of DBHDS for the emergency regulations as they are now written. SAMHSA has designated DBHDS as the state agency with oversight over opioid treatment programs and the Code of Virginia designates DBHDS as the agency responsible for licensing these programs. DBHDS does not support any exemption for OTPs from these regulations at this time. I hope that the Board of Medicine will take these facts into account when considering any modification to the regulations.

Thank you for your ongoing communication about this issue.

Mellie

Mellie Randall
Substance Use Disorder Policy Director
Virginia Department of Behavioral Health and Developmental Services

P.O. Box 1797
Richmond, Virginia 23218

1220 Bank Street
Richmond, Virginia 23219

(804)371-2135

A Life of Possibilities for All Virginians

From: Harp, William L. (DHP)
Sent: Tuesday, April 18, 2017 5:17 PM
To: Melton, Hughes (VDH); Randall, Mellie (DBHDS); Neuhausen, Kate (DMAS)
Cc: Harp, William L. (DHP)
Subject: Frequently Asked Questions about the Opioid Regulations

Hughes, Mellie and Kate:

Here are some FAQ's and answers that stick closely to the emergency regulations.

I would like to get these out this week.

If you have a chance to scan them and make any comments you wish, I would be most grateful.

COMMONWEALTH of VIRGINIA

JACK BARBER, M D
INTERIM COMMISSIONER

DEPARTMENT OF
BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES
Post Office Box 1797
Richmond, Virginia 23218-1797

Telephone (804) 786-3921
Fax (804) 371-6638
www dbhds virginia gov

February 21, 2017

David Brown, DCM, Director
Department of Health Professions
9960 Mayland Drive
Richmond, Virginia

Re: Letter from Mark Parrino dated February 15, 2017

Dear Director Brown:

It has come to my attention that Mark Parrino, Executive Director of the American Association of Opiate Treatment, sent comments to the Board of Medicine for consideration at its February 16 meeting concerning proposed regulations concerning Prescribing of Buprenorphine (Part IV, 18VAC85-21-130 et seq). Mr. Parrino incorrectly asserts that "the Virginia Department of Behavioral Health and Developmental Services gave approval to OTPs to begin using the mono-formula of buprenorphine in OTPs under the rules and regulations that are in place for all methadone maintained patients." Mr. Parrino made us aware that he intended to submit these remarks on February 15, and staff were unable to respond to him in time to correct his impression.

As you know, DBHDS does not have the authority to determine what medications are used in facilities that are regulated by the federal government and otherwise licensed to dispense controlled substances and, until the current regulation is signed, it is (and was) legal for OTPs to dispense monoproduct buprenorphine for patients to take offsite. DBHDS staff took part in discussions on which these regulations are based, and I want to assure you that we are fully in support of the regulations that the Board of Medicine has adopted.

In closing, I want to assure you that DBHDS is appreciative of the close collaborative relationship with DHP, and very much appreciates the many hours of technical assistance your staff have provided, especially as we work to address the Commonwealth's significant issues with opioid abuse and addiction.

Please contact me if you have further concerns about this or other issues.

Sincerely,

Jack

Jack Barber, M.D.

c: Mark Parrino

Harp, William L. (DHP)

From: Tim OConnell <TimOCon@hotmail.com>
Sent: Friday, March 31, 2017 4:53 PM
To: Harp, William L. (DHP)
Subject: Re: Hi from Dr. Timothy O'Connell

Dear Dr. Harp,

Thank you for responding to my letter. I actually am seeing some good change with these new regulations and I thank the Board for taking action, to help guide us with our practice. Some of the patients are reducing their dosage to reduce the costs. It is difficult to truly assess the hives issue. I have asked these patients to dose in my office, under observation with benadryl and epinephrine available if needed. I will let you know if they have true adverse effects. All the best, Dr. Tim O'Connell

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From: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Sent: Friday, March 31, 2017 8:07 PM
To: timocon@hotmail.com
Cc: Morton, Colanthia D. (DHP); Deschenes, Jennifer (DHP)
Subject: RE: Hi from Dr. Timothy O'Connell

Dr. O'Connell:

Thanks for your questions.

The issues you address, intolerance to naloxone and the financial burden of a naloxone-containing product, were discussed by the Board during the development of the regulations, and at the end of the day, those exceptions were not included.

However, there have been a number of waivered physicians writing the Board about naloxone intolerance.

The Board will discuss the possible inclusion of an exception for naloxone intolerance next week at its Friday Executive Committee meeting.

However, the financial exception is not going to be discussed.

Kindest regards,

William L. Harp, MD

Executive Director

Virginia Board of Medicine

From: Board of Medicine
Sent: Thursday, March 30, 2017 5:17 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: Hi from Dr. Timothy O'Connell

From: Tim OConnell [mailto:TimOCon@hotmail.com]
Sent: Wednesday, March 22, 2017 10:48 AM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Hi from Dr. Timothy O'Connell

Dear Dr. Harp,

I am currently Board Certified with The American Board of Addiction Medicine. I am medical director of the American Addiction Treatment Center in Newport News, Va. which is a methadone clinic. I also run a private Suboxone practice, Addiction Medicine Specialists, Inc. which currently has over 200 patients under my care. I understand the concern regarding the use of buprenorphine only tablets. However, I have several patients that cannot tolerate the combination tablet, with two patients describing hives as a reaction to the naloxone. I also have many patients that have done extremely well that have enormous financial struggles now covering the additional cost of the generic suboxone tablet. They live in areas where access to a methadone clinic is too far . I will need some guidance how we should handle these patients. I am highly committed to these patients and these new regulations will force some to stop treatment. Thank you for your help. Dr. Timothy O'Connell, M.D.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Friday, March 17, 2017 4:44 PM
To: 'papa234@aol.com'
Cc: Morton, Colanthia D. (DHP)
Subject: RE: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

Dear Dr. Voth:

Thank you for your message.

Kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Friday, March 17, 2017 11:55 AM
To: Harp, William L. (DHP)
Subject: FW: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

From: Michael Voth [mailto:papa234@aol.com]
Sent: Thursday, March 16, 2017 12:01 AM
To: Board of Medicine
Subject: Re: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

A problem is that with decreased availability to obtain prescription
Meds, people are turning to more heroin which is apparently of variable potency
Making an overdose much more likely.
Michael voth, md

Sent from my iPhone

On Mar 14, 2017, at 19:26, Virginia Board of Medicine <medbd@dhp.virginia.gov> wrote:

Virginia Department of Health Professions

Virginia Board of Medicine

Virginia Board of Medicine

Dear Prescriber,

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Friday, March 17, 2017 4:58 PM
To: 'jianyi.zhang66@gmail.com'
Cc: Morton, Colanthia D. (DHP)
Subject: FW: Buprenophine regulation

Dear Dr. Zhang:

Below are the rules regarding Subutex and Suboxone. See Section 18VAC 85-21-150.

The Board wants patients to get good care and have an orderly transition in switching medications or tapering off.

http://townhall.virginia.gov/L/ViewXML.cfm?textid=11462

Kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Friday, March 17, 2017 11:50 AM
To: Harp, William L. (DHP)
Subject: FW: Buprenophine regulation

From: Jianyi Zhang [mailto:jianyi.zhang66@gmail.com]
Sent: Wednesday, March 15, 2017 12:47 PM
To: Board of Medicine
Subject: Buprenophine regulation

To whom it may concern:

My name is Jianyi Zhang, a physician in VA to treat addiction patients.

I get an email today regarding the regulation.

I have several patients in buprenophine mono treatment, I have witnessed rashes when they were on suboxone. I am not sure if I should stop the mono therapy, and switch them to suboxone or just give them nothing.

If you think that I still can give those patients the mono therapy, what kind documents I need to approve them allergic to naloxone?

Best regards;

Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Monday, April 10, 2017 3:26 PM
To: Harp, William L. (DHP)
Cc: Brown, David (DHP); Wood, Jennie (DHP); Juran, Caroline (DHP); Johnson, Sammy (DHP)
Subject: opioids and bupr call

[Caroline & Sammy—only yellow highlight might be of interest to you.]

Spoke with Dr. Greene.

His question related to co-prescribing opioids and sleep meds (ultram/soma) and the extenuating circumstances to document. He understands the need to document his medical rationale for such prescribing.

Additionally, he asked if there was an allergy exception for the mono-product. He said that he has a physician mentor in Vermont, who had suggested he write "allergy" on the prescription, but he has ceased that practice since becoming unsure as to whether there is such an exception in the regs. I told him there is no allergy exception in the regs. He noted that historically about 8-10% of his pts have claimed they have an allergy or intolerance. He said he is not sure if those numbers are accurate however, because he has since found that many who claimed to have or thought they had a problem, "lo and behold, they don't" when switched over. He does have one young lady who does insist she has nausea and is not sure how long she can tolerate the bi-product. He mentioned a compounding pharmacy that is offering a bi-product (combo tablet that goes under the tongue) with a very low dose (0.5 mg?) of naloxone and he wondered if that would be okay. I told him that the regs speak only to a prohibition on use of the mono-product, and he might want to check with the BOP on the status of the compounding pharmacy. (I saw a previous email re: a flyer that was posted in a dr's office about a compounding pharmacy with a lozenge, and I believe BOP had concerns about that flyer—not sure if this is something that should/could be addressed in the FAQs. I'm not knowledgeable on whether such compounding offers are acceptable).

Dr. Greene stated that one great side effect of the regs is the number of pts who are now interested in weaning and are in the process of doing so (I guess the price difference in the mono-product/$2 pill compared to the bi-product/ $5 pill is pushing this result).

Re: Narcan. He said that he noticed the day the regs issued he had called a local pharmacy and was given a price of $90 for narcan, and then one week later it was $325. He said he has since been in touch with a helpful pharmacist who advised that his pts get a 2mg narcan for $2-5 co-pay. Several of his pts have reported back that Humana is covering the cost of the Narcan.

From: Rothrock, Laura (DHP)
Sent: Friday, April 07, 2017 5:24 PM
To: Deschenes, Jennifer (DHP)
Cc: Morton, Colanthia D. (DHP)
Subject: RE: Returning your call

Hi Jennifer,

Apparently he hasn't seen your email because I had two voice mails from him this afternoon while I was in meetings. He said he would be in the office until 9pm if someone is able to call him. ☺

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, May 09, 2017 12:11 PM
To: Morton, Colanthia D. (DHP)
Subject: RE: buprenorphine mono product guidance

Dear Mr. Counts:

Thank you for your question.

Here is the answer found in the Frequently Asked Questions that were just sent to the waivered physicians in Virginia listed on the SAMHSA website.

6. Are buprenorphine and naloxone safe for mothers and their breastfeeding infants?
The American Society of Addiction Medicine National Practice Guideline adopted June 2015 stated, "It was shown that the amount of buprenorphine metabolites secreted in breastmilk are so low that they pose little risk to breastfeeding infants." In the May 11, 2016 issue of the ASAM Magazine, a question about breastfeeding was addressed by a Providers' Clinical Support System expert, "While buprenorphine levels transfer to breastmilk in very low levels, naloxone is even much less detectable, if at all." An August 2016 article from the Journal of Human Lactation confirmed that infant plasma levels were low or undetectable. A consultant to the Board, an OB-GYN who provides MAT, opines that naloxone-containing products prescribed to the mother can be considered safe for breastfeeding infants.

A regulatory advisory panel will be meeting on Monday the 15th.

If anything changes with this answer, it will be published on the Board of Medicine's website.

I hope this is helpful.

From: Board of Medicine
Sent: Tuesday, May 09, 2017 11:46 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: buprenorphine mono product guidance

From: Gavin Counts [mailto:highlandsrx@gmail.com]
Sent: Tuesday, May 09, 2017 10:17 AM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: buprenorphine mono product guidance

Hello, my name is Gavin. I am a pharmacist and I am emailing in regards to guidance on the appropriateness of a prescribed drug. I am trying to see if, after the new guidance was issued in march, if it is appropriate to give buprenorphine mono product to a breast feeding mother whose child is being weaned down on morphine from being born addicted. The baby was born two weeks ago and I have made an exception the last two weeks but I am concerned for my own sake if I am myself in compliance of the law as it states that breastfeeding is not a consideration. I am not here to call them out but rather get clarity for myself. Any help would be greatly appreciated

Harp, William L. (DHP)

From: CLAAD Policy <policy@claad.org>
Sent: Wednesday, May 03, 2017 4:56 PM
To: Harp, William L. (DHP)
Subject: Comment Letter Re: Regulations Governing Prescribing of Opioids and Buprenorphine [18 VAC 85 – 21]
Attachments: VA BOM Comment Letter 170501.pdf

Dear Dr. Harp and Board of Medicine Members:

Please see attached comment letter from the Center for Lawful Access and Abuse Deterrence.

Thank you for the opportunity to comment on this topic.

Sincerely,
Kate

Katherine McClaskey, J.D. Policy Advisor
Center for Lawful Access and Abuse Deterrence
202.599.8435 • www.CLAAD.org • @CLAAD_Coalition

CLAAD Center for Lawful Access and Abuse Deterrence

May 3, 2017

William L. Harp, M.D.
Executive Director
9960 Mayland Drive, Suite 300
Richmond, VA 23233
Via email: william.harp@dhp.virginia.gov

Dear Dr. Harp and Board of Medicine Members:

Thank you for the opportunity to provide input on the regulations set forth regarding the prescribing of opioids for acute or chronic pain management and for prescribing of buprenorphine for addiction treatment.

Background

The Center for Lawful Access and Abuse Deterrence (CLAAD) is a tax-exempt, not-for-profit organization that works to reduce prescription drug abuse and other substance use while advancing consumer access to high-quality care for pain, addiction, HIV, hepatitis C, and other health conditions. CLAAD's *National Prescription Drug Abuse Prevention Strategy*, now in its fourth iteration, has been vetted and endorsed by over 30 not-for-profit public health and safety organizations.

An estimated 25.3 million Americans experience persistent pain and have a legitimate need for treatment, including access to U.S. Food and Drug Administration (FDA) approved medications for pain.[1] At the same time, opioid overdose is a public health epidemic in the United States.[2] With such alarming rates of overdose, regulators and policymakers are tasked with determining the most effective methods for preventing and treating opioid use disorder (OUD), all while ensuring access to appropriate treatment for people with pain. Effective methods include encouraging the development, use, and coverage of non-pharmacologic, non-controlled, and lower scheduled treatments, as well as novel molecules, formulations, and delivery systems.

Opioid Therapy for Chronic Pain

Buprenorphine is a partial opioid-agonist that fills opioid receptors in the brain, thereby effectively treating pain without increasing opioid sensitivity and the risk of overdose.[3] When an appropriate dose is reached, buprenorphine has a "ceiling effect," which increases its safety profile by lowering the risk of respiratory depression and overdose.[4]

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[1] *Americans Are in Pain: Analysis of Data on the Prevalence and Severity of Pain from National Survey*, NATIONAL INSTITUTES OF HEALTH, (August 2015), https://nccih.nih.gov/research/results/spotlight/081515.

[2] *The U.S. Opioid Epidemic*, U.S. DEP'T OF HEALTH & HUMAN SERVS, (Apr. 8, 2016), http://www.hhs.gov/opioids/about-the-epidemic/#us-epidemic.

[3] Laura McNicholas, M.D., Ph.D. Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, (Treatment Improvement Protocol (TIP) Series, No. 40. 2 Pharmacology, (2004), https://www.ncbi.nlm.nih.gov/books/NBK64245/pdf/Bookshelf_NBK64245.pdf; The Facts about Buprenorphine for Treatment of Opioid Addiction, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, (2011), http://store.samhsa.gov/shin/content/SMA09-4442/SMA09-4442.pdf.

[4] Laura McNicholas, M.D., Ph.D., Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES

Buprenorphine is a Schedule III controlled substance, and therefore, by definition, has a lower potential for abuse than Schedule II medications, which include most opioid pain relievers currently prescribed for chronic pain.[5]

Yet, as written, the regulation for treatment of chronic pain with opioids[6] singles out buprenorphine by restricting the prescribing and administration of the medication to its FDA-approved indication, with no exceptions. However, the regulation does not impose such a requirement on all other prescription opioid medications, most of which are riskier, Schedule II medications. Rather, the regulation allows health care practitioners to prescribe opioid medications other than buprenorphine, so long as there is proper documentation and rationale in the medical record.

Restricting access to buprenorphine, a medication with lower potential for abuse than most commonly prescribed opioid pain relievers, fails to address the underlying causes of prescription drug abuse and also impedes broader efforts to reduce the opioid overdose and heroin epidemic.

Instead, we recommend regulating treatment with buprenorphine for chronic pain as you have with all other opioids in Part III of the regulations, with one exception. Specifically, we recommend excluding 18VAC85-21-70(C), which states "[b]uprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose."[7]

Such an amendment would keep the comprehensive evaluation and treatment protocols of Part III, such as performing an evaluation prior to prescribing a controlled prescription medication, the development of a treatment plan, and proper documentation in the medical record, among other things. However, the amendment would allow health care providers to otherwise prescribe or administer buprenorphine for the treatment of chronic pain when, in their professional judgment, they deem it medically necessary to do so.

Prescribing Buprenorphine for Addiction Treatment

As you are aware, a practitioner-administered buprenorphine implant has now been FDA-approved for treatment for individuals with OUD. Additionally, multiple buprenorphine mono-products with novel delivery systems, such as depot injectables, are currently in the pipeline for approval for treatment for OUD.[8]

While the regulation pertaining to treatment with buprenorphine for addiction treatment[9] is written to ensure appropriate treatment with oral buprenorphine for patients with OUD, it unintentionally prevents

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ADMINISTRATION, (Treatment Improvement Protocol (TIP) Series, No. 40. 2 Pharmacology, (2004), http://www.ncbi.nlm.nih.gov/books/NBK64236/.

[5] Medication-Assisted Treatment, Partnership for Drug Free Kids, (2017), http://drugfree.org/wp-content/uploads/2017/02/Medication-Assisted-Treatment-ebook.pdf; The Facts about Buprenorphine for Treatment of Opioid Addiction, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, (2011), http://store.samhsa.gov/shin/content/SMA09-4442/SMA09-4442.pdf.

[6] 18 V.A.C. 85-21-70(C).

[7] 18 V.A.C. 85-21-70(C).

[8] http://www.medscape.com/viewarticle/853244; John Kent, *Camurus AB: Braeburn Pharmaceuticals and Camurus Announce Positive Top-line Phase 3 Results for Long-Acting Buprenorphine for Treatment of Opioid Addiction*, Phillypurge.com, (December 12, 2016), http://www.phillypurge.com/2016/12/12/camurus-ab-braeburn-pharmaceuticals-and-camurus-announce-positive-top-line-phase-3-results-for-long-acting-buprenorphine-for-treatment-of-opioid-addiction/.

[9] 18 V.A.C. 85-21-150.

health care practitioners from using their professional training and judgement to treat patients with practitioner-administered medications that inherently enhance treatment plan adherence and reduce diversion, when they deem it medically necessary.

Medical necessity with a specific medication may be established for reasons other than those stated in the product's label based on the health care provider's clinical experience, medical judgment, and the available options for treatment. The FDA supports this position, having stated that "[g]ood medical practice and the best interests of the patient require that physicians use legally available drugs . . . and devices according to their best knowledge and judgement."[10]

Additionally, the FDA further advises that, at times, "off-label uses or treatment regimens may be important therapeutic options and may even constitute a medically recognized standard of care."[11] Practitioner-administered medications inherently ensure treatment adherence and reduce diversion unlike any oral medication. Therefore, it may be medically necessary for health care practitioners to prescribe practitioner-administered buprenorphine products for an individual not expressly addressed in the product's labeling.[12]

Therefore, we respectfully request that the Virginia Board of Medicine amend the regulation to permit health care professionals to use their medical training and judgment, along with proper documentation and rationale, when prescribing (1) buprenorphine for the treatment of pain, and (2) practitioner-administered mono buprenorphine for the treatment of opioid use disorder.

Thank you for considering our recommendation on this matter.

Sincerely,

Shruti R. Kulkarni
Outside Counsel

[10] "Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices – Information Sheet, U.S. FOOD & DRUG ADMINISTRATION, (Last updated January 25, 2016), http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm.

[11] Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, U.S. FOOD & DRUG ADMINISTRATION (December 2011), http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm285145.pdf.

[12] Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, U.S. FOOD & DRUG ADMINISTRATION (December 2011), http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm285145.pdf.

Buprenorphine Dispensing Problems in Virginia: Coal Country Rules

April 13, 2017

By Alison Knopf

The Virginia Board of Medicine, backed by the state, has banned the use of buprenorphine with the exception of treating pregnant patients in both office based opioid treatment (OBOT) programs and in opioid treatment programs (OTPs). OTPs may use the mono-product for on-site administration but no longer may use it for take-homes. Part of a broad set of regulations aimed at opioid prescribing in general, including for pain, this was a surprising turn of events in a state where OTPs have been dispensing take-home buprenorphine mono-product for years.

The reasoning for the decision by the Board of Medicine was that the mono-product would be diverted.

"Approximately 1,100 Virginians died of an opioid overdose in 2016, a 30% increase over 2015," said Maria Reppas, communications director for the Richmond Department of Behavioral Health and Developmental Services (DBHDS). "DBHDS has worked closely with the Board of Medicine and other state agencies, state and local organizations, and concerned citizens to address this epidemic," she added. "DBHDS supports the actions of the Board of Medicine to improve patient health and safety in the treatment of the deadly epidemic disease of opioid addiction."

In Virginia, there "continues to be concern about diversion of buprenorphine products, which contributes to opioid abuse," she said, noting that the sublingual combination product containing naloxone was developed to curtail this risk. The governor's task force therefore recommended that the Virginia Board of Medicine, in collaboration with DBHDS, convene a workgroup of physicians experienced with utilizing

buprenorphine to review standards of care from a variety of sources. The result was a guidance document, which then became the regulations.

Buprenorphine with naloxone cannot be melted down and injected, as the naloxone would render the buprenorphine inactive. However, the generic mono-product is much less expensive than the combination buprenorphine-naloxone product.

OTPs Respond

Mark Parrino

Mark Parrino, MPA, president of the American Association for the Treatment of Opioid Dependence (AATOD), wrote to William L. Harp, MD, executive director of the Virginia Board of Medicine, in February, describing the regulations governing take-home medication from OTPs. The OTPs are also conservative in providing the patient with any take-home medication. From the letter:

"Generally speaking, most patients are being medicated at the OTP five days per week," the letter continued. When take home medication is provided to the patient through the OTP, the patient must meet eight clinical standards, which have been enforced since the regulatory authority of the Food and Drug Administration that continued under the regulatory oversight of the Substance Abuse and Mental Health Services Administration (SAMHSA).

"These criteria include absence of recent drug abuse, which is determined through toxicology reports in addition to established regularity of clinic attendance, absence of serious behavioral problems, absence of known recent criminal activity, stability in the patients' home environment, length of time in comprehensive maintenance treatment, ensuring that take home medication can be safely stored within the patient's home and whether the rehabilitative benefit the patient derives from decreasing the frequency of clinic attendance outweighs potential risk. Compliance with the regulations is mandatory.

"The Virginia Department of Behavioral Health and Developmental Services gave approval to OTPs to begin using the mono-formula of buprenorphine in OTPs under the rules and regulations that are in place or all methadone maintained patients," Mr. Parrino's letter noted.

Coal Country

Mr. Parrino also noted that in Virginia, the coal mining industry is biased against treatment using methadone. Despite the fact that it would be a violation of the Americans with Disabilities Act, employers would likely terminate someone even for the therapeutic use of methadone. The same bias does not exist for buprenorphine, which is why some patients in Virginia prefer it.

There were about 600 patients in Virginia being treated in OTPs with the mono-buprenorphine product at the time the ban went into effect.

About 300 patients were being treated using the mono-buprenorphine at the four Acadia Healthcare treatment centers in Virginia. The same criteria used for take-home privileges for patients being treated with methadone were used for take-home buprenorphine, said Ed Ohlinger, Acadia Healthcare's Regional Director for Virginia and North Carolina.

The history is this: 10 years ago, the Virginia State Opioid Treatment Authority (SOTA) gave OTPs permission to give take-home buprenorphine-naloxone–at the time, the only available product was the Suboxone tablet. About 5 years ago, when the tablet was replaced with film, the price became

unaffordable for patients. But the generic mono-product was affordable, and that's what the OTPs were dispensing.

"We know the mono-product brings to treatment people who wouldn't come if the only medication available was methadone," said Mr. Ohlinger. "The coal mining industry has a zero tolerance for methadone," he said. "This is a longstanding Appalachian phenomenon."

Absorbing Costs of the Combination Product

So when the new rules were announced, Acadia switched all of its mono-buprenorphine patients in Virginia to the combination product, and—at least for now—is absorbing the added costs. "We have not increased their rates to stay in treatment, as we continue to work closely with the medical board," said Mr. Ohlinger, who was in the process of appealing the regulations to get a special exemption for OTPs. "We're incurring significantly higher medication costs at the present time. We're not passing that on until we get through an appeal and see where we go—it is what it is, and Acadia has chosen to do the right thing."

Of the 300 patients being treated by Acadia at the time of the ban, nine have transferred to treatment programs in North Carolina either because of an allergy to naloxone or because they have not done well on the combination product in the past, said Mr. Ohlinger.

Possible Appeal

But things are looking up. At the end of March, representatives of the Virginia Board of Medicine attended part of the Virginia Provider Association's 10-year anniversary conference. "We had a very frank, very open, positive 45-minute conversation where we clearly delineated for them why we are different from OBOTs [office-based opioid treatment]," said Mr. Ohlinger.

There is a problem with diverted mono-buprenorphine, as found in recent arrests and other criminal activities. "But this is mono-product that was coming out of OBOTs in North Carolina, Tennessee, and Kentucky," he said. "I know that some OBOT practices do a really good job, but we know that some don't provide any services" other than induction and prescribing of buprenorphine.

The situation is reminiscent of what happened a decade ago, when methadone diverted from pain clinics was blamed on OTPs. "This is history repeating itself," said Mr. Ohlinger.

The Board of Medicine officials "walked us through the process for filing an appeal, or through a process that could exempt us from the regulations," said Mr. Ohlinger. "They were very open-minded to our explanation about what we do."

A decision from the Board of Medicine was expected in early April.

For more information, see:

http://leg1.state.va.us/cgi-bin/legp504.exe?171+ful+HB2167ER.

https://www.dhp.virginia.gov/medicine/newsletters/OpioidPrescribingBuprenorphine03142017.pdf.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Wednesday, March 15, 2017 4:28 PM
To: Morton, Colanthia D. (DHP)
Cc: Deschenes, Jennifer (DHP); Wood, Jennie (DHP)
Subject: RE: HB 2163 needs work done to it

Dear BupeAdvocacy:

The Board of Medicine debated the issue of including an exception for intolerance to naloxone, but in the final analysis, it did not do so.

Patients will need to work with their physicians to address how to address this change in the law and regulations.

With kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Wednesday, March 15, 2017 12:28 PM
To: Harp, William L. (DHP)
Subject: FW: HB 2163 needs work done to it

From: Steve M [mailto:bupeadvocacy@outlook.com]
Sent: Sunday, March 12, 2017 8:34 AM
To: Board of Medicine
Subject: HB 2163 needs work done to it

Dear Board of Medicine,

HB 2163 will do harm to patients that cannot have suboxone or the generic. What is going to happen to patients that have a documented allergy on file? Do these people deserve to lose treatment due to an allergy? Every other state that passed a similar law includes people with a documented allergy to Naloxone on file to also receive prescriptions. As far as I know none of them have taken take homes from patients that go to OTP's either. These OTP's operate under strict federal guide lines. You need to prevent pain doctors from writing prescriptions for tablets as there are patches that are much more effective treatment for pain. Patients with an allergy should get to keep their prescriptions as, and OTP's should be able to continue to dispense it. I have yet to meet any doctors in Virginia that would prescribe mono buprernorphine over the generic suboxone unless he felt their was a reason. This will affect thousands of patients, so what are these patients supposed to do? The ones that have a documented allergy what should they do?

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Friday, March 17, 2017 3:16 PM
To: 'bupeadvocacy@outlook.com'
Subject: RE: HB 2163

Dear BupeAdvocacy:

Thank you for your message.

Here are the regulations that address the use of buprenorphine for opioid addiction.

Note section 18VAC85-21-150 http://townhall.virginia.gov/L/ViewXML.cfm?textid=11462

I hope this is helpful to you.

William L. Harp, MD
Executive Director
Virginian Board of Medicine

From: Board of Medicine
Sent: Friday, March 17, 2017 12:00 PM
To: Harp, William L. (DHP)
Subject: FW: HB 2163

From: Steve M [mailto:bupeadvocacy@outlook.com]
Sent: Friday, March 17, 2017 5:41 AM
To: Board of Medicine
Subject: HB 2163

From what I see that bill hasn't been signed HB 2163 and I was told it wasn't signed just yesterday by the Governors Office. I know of a few excellent patients are being treated with it because he had a documented allergy on file. I have yet to see a doctor prescribe it unless their was a reason. Sometimes it was an allergy sometimes it was just the cost of one is lower than the other. If they have for physicians, except for that 5000.00$ dollar implant. That isn't a cure all, and Suboxone can be abused just as much. They give the same effects when abused, and the problem with abuse is it does. It needs to include people that have it documented as now they are cut off from their medication. That PDF that was released on the streets said you all were concerned and patients shouldn't be put back on the streets. This is what that has done, I can understand the restrictions to a point but some people are allergic and these people will pay the price of whos mess ups. I would almost bet that most of the diverted medications came from pain clinics and not otp clinics that have doctors that write prescriptions. Are there shady doctors that do things they shouldn't out there? Sure, but I bet if we could look at the statistical data we would see most the that diverted medication came from pain clinics. Id almost bet on it. What are their other options, go to a clinic everyday to earn methadone take homes which is more abusable, deadlier, and more potent full agonist? The didnt have a medical detox or anything, I dont understand the reasoning behind it. I heard there was a consultant to

consult on the matter. Can you tell me the other options these patients that have a documented allergy have right now? Theres patients all over the state crying for help so if there is any more immediate options they have please inform me, as I have spoke with doctors and they dont know what to do.

Thank You For Your Time
Steve

Harp, William L. (DHP)

From: Morton, Colanthia D. (DHP)
Sent: Friday, March 17, 2017 11:43 AM
To: Harp, William L. (DHP)
Subject: FW: Michael Dowdy

From: Bowen, Calvette (DHP)
Sent: Friday, March 17, 2017 10:30 AM
To: Morton, Colanthia D. (DHP)
Subject: Michael Dowdy

He wants to know why they are taking his Suboxone away. 276-979-6115

Thank you,

DEPRESSED + HA's

Calvette M. Bowen
Virginia Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
(Direct) 804-786-0245 (Fax) 804-527-4426

Harp, William L. (DHP)

From: Morton, Colanthia D. (DHP)
Sent: Friday, March 17, 2017 11:43 AM
To: Harp, William L. (DHP)
Subject: FW: Dr. Brown

From: Bowen, Calvette (DHP)
Sent: Friday, March 17, 2017 10:19 AM
To: Morton, Colanthia D. (DHP)
Subject: Dr. Brown

Question regarding Opioid Law - 757-567-6890

INDUCTION WITH THE MONO - PRODUCT.

Thank you,

Calvette M. Bowen
Virginia Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
(Direct) 804-786-0245 (Fax) 804-527-4426

Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Tuesday, March 21, 2017 5:27 PM
To: pwalker@nrvcs.org
Cc: Harp, William L. (DHP); Wood, Jennie (DHP); Morton, Colanthia D. (DHP)
Subject: RE: clarification of new emergency regulations re: buprenorphine

Dear Ms. Walker:

The regulations state "shall" be seen by the "prescriber", so a registered nurse would not appear to meet the criteria of a "prescriber." Thank you.

F. During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on no more than eight milligrams of buprenorphine per day. The patient shall be seen by the prescriber at least once a week.

Jennifer L. Deschenes, JD, MS
Deputy Executive Director, Discipline
Virginia Board of Medicine

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463
Phone: 804.367.4462
Fax: 804.527.4429
Email: jennifer.deschenes@dhp.virginia.gov

From: Board of Medicine
Sent: Tuesday, March 21, 2017 4:19 PM
To: Deschenes, Jennifer (DHP)
Subject: FW: clarification of new emergency regulations re: buprenorphine

From: Patricia Walker [mailto:pwalker@nrvcs.org]
Sent: Friday, March 17, 2017 2:09 PM
To: Board of Medicine
Subject: clarification of new emergency regulations re: buprenorphine

I work in a Suboxone MAT program at a CSB in the New River Valley. I would like some clarification about the regulation for induction with buprenorphine or buprenorphine with naloxone that requires the patient to be seen by the prescriber at least once a week. Must this be a face to face with the prescriber herself, or could it be a registered nurse that works with the prescriber?

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Wednesday, March 15, 2017 3:12 PM
To: Morton, Colanthia D. (DHP)
Cc: Deschenes, Jennifer (DHP); Wood, Jennie (DHP)
Subject: RE: clarification on a regulation to start on March 15,2017

Dear Ms. Walker:

Thank you for your question.

The Board discussed intolerance to naloxone, but in the final analysis it decided to write the regulations as they appear.

The regulations became effective today, and they carry the weight of law.

I can't say much more than that.

I hope this is of some help to you.

With kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Wednesday, March 15, 2017 12:34 PM
To: Harp, William L. (DHP)
Subject: FW: clarification on a regulation to start on March 15,2017

From: Patricia Walker [mailto:pwalker@nrvcs.org]
Sent: Wednesday, March 15, 2017 9:26 AM
To: Board of Medicine
Subject: clarification on a regulation to start on March 15,2017

I am a registered nurse managing a Suboxone MAT program with a community services board in the New River Valley. I would like some clarification to the new regulation concerning treatment of addiction with buprenorphine. One portion of the new regulation states that buprenorphine without naloxone (the mono-product) shall only be prescribed when a patient is pregnant, when converting a patient from methadone, or in forms other than the tablet form.

My question is whether or not there is an allowance for when a patient has a documented intolerance to the naloxone in the buprenorphine combination products? We have several patients in our program who are unable to tolerate the naloxone in Suboxone due to physical side effects that are intolerable. We have been treating them with buprenorphine mono-product, and would like to continue doing so, but do not want to violate the law. Would our prescribers be in violation of the law if they prescribed buprenorphine mono-product to a patient who did not meet the above criteria of pregnancy, or converting from methadone, but DID have a documented intolerance to naloxone?

Harp, William L. (DHP)

From: Scott Johnson <sjohnson@hdjn.com>
Sent: Thursday, March 30, 2017 4:50 PM
To: Kim Gilliam
Cc: Lauren Bates-Rowe; Harp, William L. (DHP)
Subject: Re: Buprenorphine law

Good afternoon

Have copied Lauren at the medical society so she can refer you to the assistance program for consideration.

Best,

Scott

W. Scott Johnson, Esquire
804-402-6279
Sent from my iPhone

> On Mar 30, 2017, at 4:45 PM, Kim Gilliam <gilliamkd2@gmail.com> wrote:
>
> Hello. I just recently learned about the new law passed in SouthWest Virginia regarding buprenorphine. I am allergic to the ingredient naloxone in suboxone therefore i have to take subutex. I find the new law should have put that into perspective also for i cannot afford to pay for my medication. There should be a exception for those that are allergic to the ingredient in suboxone

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Monday, April 10, 2017 9:05 AM
To: 'Dexter Gravley'
Subject: RE: 18VAC85-21-150. Treatment with buprenorphine for addiction.

Dear Mr. Gravley:

The regulations were pursuant to the Commissioner of Health's declaration of an emergency.

As mentioned below, the issue of having an exception for naloxone intolerance was discussed, but it was not included in the emergency regulations.

Now the Board of Medicine is re-establishing the Regulatory Advisory Panel to consider this issue and several others.

I will forward your e-mail to the Secretary of Health and Human Resources.

I hope this is helpful.

Kindest regards,

WLH

From: Dexter Gravley [mailto:dgravley70@gmail.com]
Sent: Friday, April 07, 2017 9:57 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: RE: 18VAC85-21-150. Treatment with buprenorphine for addiction.

Could you please explain to me where you saw the governor's signature on HB 2163. I have looked everywhere and I see nothing of the sort. I have seen where he made recommendations but no signature. I is my opinion that the Virginia Board of Medicine stepped out of its bounds by enacting such regulations before it was signed into law. Why not put naloxone in everything then, hell let's put it in the water, make sure everyone gets a dose, it won't hurt anyone. You have put alot of innocent people out on the streets against their will. I don't want to start on the thousands of Virginians that were going to the OTP's, there should have been a little warning. I could go on and on but I'm not. After you get this I want you to sign back and think what is hb2163 going to do, I'm speechless, if someone is going to abuse buprenorphine they are going to abuse it. A doctor is supposed to use rationale and weigh the risk verses the benefits I think this puts far more people at risk and the only ones this is going to benefit is big pharma to make them BIGGER. Please forward to the governor because I can't. We won't be heard. It's all political. I hope you are not like the rest of them don't take it personal I just want to be heard this is not right. I emailed the "governor's office" like it will make it to him. We are all addicts seeking the next high, to them. I think everyone that voted yes should have to take naloxone for just 1 week, since it has no affect. Maybe I'm wrong.

On Apr 7, 2017 12:08 PM, "Harp, William L. (DHP)" <William.Harp@dhp.virginia.gov> wrote:

Dear Mr. Gravley:

Thank you for your comments.

When the Board of Medicine was developing regulations, an exception for naloxone intolerance was discussed, but at the end of the day, the Board decided not to include it. Since the regulations were signed by the Governor on March 15th and disseminated to physicians around the state, the Board has received many comments similar to yours from a number of physicians and a few patients. This morning, the Executive Committee of the Board voted to re-establish a Regulatory Advisory Panel comprised of physicians that treat opioid addiction with buprenorphine products to look at this issue.

I hope this is of some help/hope to you.

With kindest regards,

William L. Harp, MD

Executive Director

Virginia Board of Medicine

From: Dexter Gravley [mailto:dgravley70@gmail.com]
Sent: Thursday, April 06, 2017 9:48 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: 18VAC85-21-150. Treatment with buprenorphine for addiction.

I don't understand why you think everyone on buprenorphine monotherapy should pay the price for the mistakes of others. I am currently bedridden because I can't tolerate naloxone. I hurt from my head to my toes including my nuts. It feels like somebody is sticking a knife in my side and twisting it. I was doing perfectly fine for 16 months on Subutex and now because of the actions of a few idiots u think it best to put unnecessary regulations on my Dr that in your opinion doesn't know what he is doing. I have had to quit my job of 1 year because I can't leave my bed because I can't stand up because of the pain the naloxone is causing. Yes naloxone is good for some things but use some common sense about it. It's been glorified in the media for the past year so let's put it in everything is what you idiots think. Believe it or not there are people that actually can't take it and not just because they don't want to. I have been an addict for 20 years which is half my life because I'm 40 now and I have a wife and 3 teenage boys that I would like to be around for them to graduate high school, but if idiots like u keep imposing stupid regulations as these I won't be. Believe it or not we were

in a drug epidemic around 2000 I don't know where the hell all of you all were then, but the addicts have been made you need to work on not putting restrictions on things that are actually helping. The naloxone is just a political measure because buprenorphine can be abused with or without it, most people that has been on prescription meds long as I have don't get high off of anything anyway it's been 4 or 5 years since i did morphine and felt it, I just take my daily buprenorphine dose just to maintain and function no high at all. I just can't get high off of anything. All I want to do is go about my life without having to worry about what everyone else has gone and screwed up. I've been through rehab 2 times it never works I guess my brain is broken. I don't wish this on anyone but please leave the ones of us that have worked so hard to have a functionable life alone. Back to the regulations you do realize all you are doing is setting up to be the biggest illicit drug crisises (heroin) putting all of these regulations on the pain management and the addiction doctors. Please all of you get your head out of each others asses like the governor's and state health commissioner and all the senators and legislators that voted yes on hb2163. Thanks alot

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, April 11, 2017 8:56 AM
To: 'concernedforvaaddicts@gmail.com'
Subject: RE: HB 2163

Dear Ms. Walker:

Thank you for your message.

The Board has received many similar comments and will be reconvening the Regulatory Advisory Panel (RAP) to review this issue and amend the regulations if warranted.

We hope to have it pulled together in early May.

Your message will be shared with the RAP.

Kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Tuesday, April 11, 2017 7:54 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: HB 2163

From: Ashley Walker [mailto:concernedforvaaddicts@gmail.com]
Sent: Monday, April 10, 2017 4:37 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: HB 2163

Doctor Harp,
I am urging you to reconsider adding a documented naloxone allergy to this bill. Make it stricter, make pill counts happen, more drug testing, inspecting the body of IV use. Anything but please do not take away medication from us. There are some people who CAN NOT have naloxone. And there's so people who can't possible live with these allergies everyday. I for one cant, I can't have naloxone, I can't go everyday to the doctor to get my medication, and I can't possibly be pregnant everyday. The samhsa guidelines for a naloxone allergy is to take subutex. Would you tell me if I was allergic to Penicillin to just go ahead and take it, I really don't think you would. So why tell me to take suboxone when I'm allergic to it? I'm afraid I'm running out of options here, I don't want to relapse. But if this bill doesn't change I will have no other option.

The person who takes buprenorphine feels normal, not high. However, the brain thinks it is receiving the problem opioid, so withdrawal symptoms stay away. Buprenorphine also reduces cravings. If cravings continue to be a problem, your doctor will adjust your medication or help you find other ways to reduce them.

You take buprenorphine as a pill that dissolves under the tongue. You do NOT chew or swallow it. There are two forms. **Suboxone®** contains buprenorphine plus another medication called **naloxone**. The naloxone is added to prevent abuse—it brings on withdrawal in people who abuse buprenorphine by injecting it. **Subutex®** contains only buprenorphine. This form is prescribed if you should not take naloxone for any reason, such as if you are allergic to it or are pregnant.

The pill is taken once a day. Over time, the dose interval may stay at once a day or change to every other day.

The main advantages of buprenorphine are:

- You are unlikely to overdose on buprenorphine if you take it properly.
- Buprenorphine is long acting. This means that after an initial period, your doctor may have you take the pill every other day rather than once a day.
- Doctors can prescribe buprenorphine so that you can take doses at home. **Important:** Not all doctors have approval to prescribe this medication, and not all doctors provide counseling for addiction. Also, daily check-in at a treatment center can be helpful to

combination product is injected, the naloxone produces significant attenuation of buprenorphine's effects and may precipitate acute withdrawal.[14] The combination product is designed to be less subject to diversion and injection misuse than the mono-product. For this reason, the combination product is the preferred formulation for all patients, with the exception of pregnant women[15] and those with a demonstrated allergy to naloxone.

Buprenorphine, both as a mono- and as a combination product, has long been available in sublingual tablet form. Newer formulations include a soluble buprenorphine/naloxone film for sublingual or buccal use. The films dissolve more quickly than tablets, an advantage when monitored dose ingestion is indicated.[16]

Two new formulations (Zubsolv sublingual tablets and Bunavail buccal film) provide higher bioavailability of buprenorphine than other formulations. Higher bioavailability means that more buprenorphine enters the bloodstream, allowing for lower doses. For example, one Bunavail 4.2 mg/0.7 mg buccal film provides buprenorphine exposure equivalent to one Suboxone 8 mg/2 mg sublingual tablet;[17] one Zubsolv 5.7 mg/1.4 mg sublingual tablet provides buprenorphine exposure equivalent to one

Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Wednesday, April 05, 2017 9:19 AM
To: Harp, William L. (DHP); Brown, David (DHP)
Subject: FW: Buprenorphine regulations are hurting people that cannot have the combination drug

FYI.

From: Kyle Miles [mailto:Unryl@live.com]
Sent: Tuesday, April 04, 2017 8:40 PM
To: Deschenes, Jennifer (DHP)
Subject: Re: Buprenorphine regulations are hurting people that cannot have the combination drug

Thank you for getting back to me, and I understand regulations but hurting patients for something they cannot control isn't the right way to do things. Ill comment on it via the internet, if I could comment in a public meeting I would but unfortunately Richmond is 5 hours away and I have a hard enough time getting transportation as is. Thank you so much.

From: Deschenes, Jennifer (DHP) <Jennifer.Deschenes@DHP.VIRGINIA.GOV>
Sent: Tuesday, April 4, 2017 7:48 PM
To: Unryl@live.com
Cc: Harp, William L. (DHP); Brown, David (DHP)
Subject: RE: Buprenorphine regulations are hurting people that cannot have the combination drug

Dear Mr. Myles:

Thank you for your email, explaining that you have a documented hypersensitivity/allergy to naloxone. I appreciate your concerns regarding the Board's Emergency Regulations on Buprenorphine Prescribing and the effect the regulations have had on your ability to access the buprenorphine mono-product in tablet form. The Board did consider including an exception to the limitations on prescribing the mono-product for those with a documented allergy or intolerance, but ultimately decided not to include such an exception in the Emergency Regulations. The regulations do allow for prescribing of the mono-product in FDA approved formulations other than tablet form, but I understand your concerns related to the potential costs of such alternate formulations.

The Board is hearing from patients and practitioners on this issue and will carefully consider all comments, as it moves forward on finalizing regulations in this area. I am including a link to the Regulatory Townhall: http://townhall.virginia.gov/L/viewchapter.cfm?chapterid=2929 (look under "Current Actions" and select "Emergency/NOIRA" for links to the regulations and an opportunity to comment by selecting "In Progress" under the "Comment Period" section), so that you can follow the Board's progress as it works on the regulations. You are

encouraged to make public comments on the regulations through Townhall, or by attending any public meetings the Board holds in the future on this issue. Thank you for sharing your concerns.

Virginia Regulatory Town Hall View Chapter

townhall.virginia.gov

Description: Regulations set out provisions for prescribing of opioids for acute or chronic pain management and for prescribing of buprenorphine for addiction treatment.

Kindest regards,

Jennifer L. Deschenes, JD, MS
Deputy Executive Director, Discipline
Virginia Board of Medicine

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463
Phone: 804.367.4462
Fax: 804.527.4429
Email: jennifer.deschenes@dhp.virginia.gov

From: Board of Medicine
Sent: Tuesday, April 04, 2017 10:46 AM

To: Deschenes, Jennifer (DHP)
Subject: FW: Buprenorphine regulations are hurting people that cannot have the combination drug

From: Kyle Miles [mailto:Unryl@live.com]
Sent: Monday, April 03, 2017 9:47 AM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Buprenorphine regulations are hurting people that cannot have the combination drug

Hello,

My name is Kyle, I am a patient that has a documented hypersensitivity/allergy to Naloxone. I cannot have it and have been receiving treatment with Buprenorphine. I can understand where restrictions and such need to be in place but patients with documentation need to be allowed to stay in treatment. Luckly I was seen right before these new regulations were put into effect and I thought at the least I had one more month. I don't understand why patients such as myself will lose treatment pretty much overnight. This is going to hurt some of the patients in your state, and all this does is tie the doctors hands to where he cannot treat said patient anymore. I urge you all to take these patients such as myself into consideration. Patients that have done all the counseling and followed the guidelines, have documentation, and have never failed a urine screen shouldn't lose access to a medication that has helped save their lives. If taken from the abruptly like it will have a drastic effect on their lives. Right now the only alternative I know of Is Probuphine but that treatment costs arount 5 thousand dollars. It is also a restricted program, and most insurance companies will not cover it. I know some of the restrictions have been in the making for a couple years but to outright ban people that cannot have the combination drug wasn't seen coming from anyone. If it was doctors wouldn't have remained treating patients up until the regulations, they were sure that Virginia would do what every other state has done and allow people with a documented hypersensitivity/allergy to remain in treatment. Thank you for your time and consideration, and I hope you all allow these patients to stay in treatment. We have a bad enough problem with street drugs as it is and with patients losing treatment that's where they will turn, and with since they cannot have Naloxone if they were to overdose it would probably end up in them dying.

Yours Sincerely
Kyle

Harp, William L. (DHP)

From: Kyle Miles <unryl@live.com>
Sent: Tuesday, April 11, 2017 11:57 AM
To: Harp, William L. (DHP)
Subject: RE: Lost Buprenorphine Treatment all together

Please do good people are suffering right now. Maybe some of them have found treatment already and the ones that could convert have. Maybe you all can let the pharmacies know its legal for at least a 1 week taper to be filled. Ill ask my doctor to get into contact with you all. No pharmacies will as of this moment though I mean that would at least give these people a little breathing room until you all come to a decision. I know you all mean well and there is an epidemic going on but cutting people out of treatment will only make it worse. Thank you for your time and efforts.

Get Outlook for Android

From: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Sent: Tuesday, April 11, 2017 9:52:30 AM
To: Kyle Miles
Cc: Deschenes, Jennifer (DHP); Oehl, Diane (DBHDS)
Subject: RE: Lost Buprenorphine Treatment all together

Dear Mr. Myles:

You have pointed out at least 2 important issues that the Board's regulations do not address--tapering and intolerance to naloxone.

Your comments will be presented to the Regulatory Advisory Panel.

Thanks,

WLH

From: Kyle Miles [mailto:Unryl@live.com]
Sent: Tuesday, April 11, 2017 1:38 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Re: Lost Buprenorphine Treatment all together

Dear Dr. Harp,

I never thought in a million years the board would make such a bad decision. I am not saying it's all your fault, but when this bill was first proposed and then was amended to give the board of medicine power I thought surely they know some people cannot have it like some of the other states. Restrictions and regulations to help protect the public are one thing but some things hurt people. I was all for the restrictions on prescriptions as long as the people that that cannot have naloxone for whatever reason are included. Some people do have allergies/hypersensitivities to Naloxone. While maybe 5 out of 100 patients an addiction

Harp, William L. (DHP)

From: Kyle Miles <unryl@live.com>
Sent: Wednesday, April 12, 2017 8:41 AM
To: Harp, William L. (DHP)
Subject: RE: Lost Buprenorphine Treatment all together

Can you all at least please inform these doctors and clinics that patients are allowed at least the 1 week taper prescriptipn you mentioned. The pharmacies wont fill them even if a doctor writes it. If you put out an announcement informing people the 1 more week would buy people 1 more week to try and seek treatment else where. Its not an option for me but the one more week would greatly help as i feel like crap and hopefully you all figure this out. Thank you for your time.

Get Outlook for Android

From: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Sent: Tuesday, April 11, 2017 9:52:30 AM
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Cc: Deschenes, Jennifer (DHP); Oehl, Diane (DBHDS)
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Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, April 11, 2017 9:52 AM
To: 'Kyle Miles'
Cc: Deschenes, Jennifer (DHP); Oehl, Diane (DBHDS)
Subject: RE: Lost Buprenorphine Treatment all together

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Your comments will be presented to the Regulatory Advisory Panel.

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From: Kyle Miles [mailto:Unryl@live.com]
Sent: Tuesday, April 11, 2017 1:38 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
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From: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Sent: Monday, April 10, 2017 10:14 AM
To: Kyle Miles; Oehl, Diane (DBHDS); Deschenes, Jennifer (DHP)
Subject: RE: Lost Buprenorphine Treatment all together

Dear Mr. Miles:

Thank you for your message.

It was not the Board's intention to harm any patients participating in medication-assisted treatment for opioid addiction. The Board wants all patients to get good care. The regulations do require that the treating physician use a naloxone-containing product instead of the mono-product of buprenorphine.

For those patients that do not wish to switch to a naloxone-containing product for whatever reason, the regulations appear to allow a week of mono-product for the process of tapering.

The Board of Medicine has received many comments on the issue of intolerance to naloxone and has voted to reactivate the Regulatory Advisory Panel to review the comments and consider revisions to the regulations.

I hope this is helpful to you.

With kindest regards,

William L. Harp, D

Executive Director

Virginia Board of Medicine

From: Kyle Miles [mailto:Unryl@live.com]
Sent: Sunday, April 09, 2017 12:47 AM
To: Oehl, Diane (DBHDS) <Diane.Oehl@dbhds.virginia.gov>; Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Lost Buprenorphine Treatment all together

Hello,

Hey guys, I wanted to write the both of you. I am a patient in Virginia that has a bad reaction to Naloxone. I had my doctors appointment today for the first time since the ban. I went in there only to find out I cannot be switched to suboxone because my reaction is to bad. My doctor is literally scared to administer it to me because of the tongue and throat swelling so now as of today I have to go without. I have no clue as what to do because the board of medicine tied my doctors hands. So what happens to patients like me, I guess I have to be kicked off overnight? Please guys I'm not making this up. I was getting my life together now I will be forced back into teh streets if I cant find an alternative in a couple days. The patients that were doing great, and actually cannot have it shouldn't lose treatment. I cant afford to go to NC for treatment, I have no transportation and I shouldn't have to. How is it fair Methadone and Suboxone patients get to stay in treatment but because I have something god gave me I'm all of a sudden not worth treating.

Kyle Miles

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Wednesday, April 12, 2017 8:55 AM
To: 'Pamela Sickal'
Subject: RE: Hb 2163 and naloxone allergy

Dear Ms. Sickal:

Thank you for your message.

The Board is going to revisit the issue of naloxone, hopefully in early May.

Your message will be presented to the regulatory panel that will be reviewing this matter.

However, I cannot tell you what the will of the Board will be.

With kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Pamela Sickal [mailto:psickal09@gmail.com]
Sent: Tuesday, April 11, 2017 10:53 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Hb 2163 and naloxone allergy

Dr. Harp,
I emailed the board of medicine last week to express my concern over the newly passed house bill 2163 but I wanted to make sure my email got you personally.
My name is Pamela Sickal and I have been successful in MAT, my doctor even considers me his model patient. I go to my appointments, I go to counseling, I go to meetings, my drug screens are negative I am a stable recovering addict. When I first took suboxone, I broke out in hives, had severe itching and then debilating migraines. My doctor switched me to subutex and all of those adverse reactions went away. Since then I have been on subutex, well until I went to my last appointment and learned that my doctor couldn't legally write me my prescription. So now I have to take benadryl 30 mins before I dose so my reactions aren't so severe. But the benadryl knocks me on my feet and I feel like a zombie. I can't possibly take care of my children and work like that. I've had to call out of work this week for a debilating migraine that would not go away with OTC medications. I can't possibly go to a clinic everyday as the closest to me is over an hour away and I can't switch to methadone because I use to abuse that. I'm at a loss of options on what I can do.
Please reconsider adding naloxone allergies/sensitivity to this bill. I agree we need to stop the Drug epidemic but this bill is only going to make it worse. I saw today that the vets got permission to have buprenorphine back for animals so why can't us humans get it back. Our lives have to be just as important.
Thank you for taking the time to read this.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, April 11, 2017 8:56 AM
To: 'concernedforvaaddicts@gmail.com'
Subject: RE: HB 2163

Dear Ms. Walker:

Thank you for your message.

The Board has received many similar comments and will be reconvening the Regulatory Advisory Panel (RAP) to review this issue and amend the regulations if warranted.

We hope to have it pulled together in early May.

Your message will be shared with the RAP.

Kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Tuesday, April 11, 2017 7:54 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: HB 2163

From: Ashley Walker [mailto:concernedforvaaddicts@gmail.com]
Sent: Monday, April 10, 2017 4:37 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: HB 2163

Doctor Harp,
I am urging you to reconsider adding a documented naloxone allergy to this bill. Make it stricter, make pill counts happen, more drug testing, inspecting the body of IV use. Anything but please do not take away medication from us. There are some people who CAN NOT have naloxone. And there's so people who can't possible live with these allergies everyday. I for one cant, I can't have naloxone, I can't go everyday to the doctor to get my medication, and I can't possibly be pregnant everyday. The samhsa guidelines for a naloxone allergy is to take subutex. Would you tell me if I was allergic to Penicillin to just go ahead and take it, I really don't think you would. So why tell me to take suboxone when I'm allergic to it? I'm afraid I'm running out of options here, I don't want to relapse. But if this bill doesn't change I will have no other option.

Harp, William L. (DHP)

From: Victor Lewis <vtroller@aol.com>
Sent: Saturday, March 18, 2017 12:24 AM
To: Harp, William L. (DHP)
Subject: Allergy to suboxin

Dear Sir,

My 37 year old son has been on Subutex for over a year. He is a recovering addict from a 15+ year heroin addiction. He does not abuse Subutex. He is allergic to naloxin that is in Suboxin. He gets violently ill, vomiting and pain. He has recently been diagnosed with EDS and has been prescribed a beta-blocker (Metoprolol). He has only taken his first dose last night. We don't know if his heart can stand withdrawals from Subutex and he can't take Suboxin. What can he do considering the new regulations in Virginia on opiate prescriptions. Given his circumstances, will he still be able to receive Subutex? This is the longest he has been heroin free. He lives with us. Thank you for your consideration in this matter.

Sincerely,
Karen Lewis

Sent from my iPad

Harp, William L. (DHP)

From: Carrie Pearson <tjsmom7112@icloud.com>
Sent: Saturday, April 15, 2017 2:36 PM
To: Board of Medicine; Harp, William L. (DHP)
Subject: Symptoms

This is awful I am suffering VERY BAD from rashes, pulsating in my ears as well as ringing, my limbs are jerking, I feel "confused" in ways and in 9-10 days I've dropped 8 pounds. This is dangerous! Our bodies are having an allergy to naloxone regardless of how much or less we take, our bodies are giving these symptoms to warn us something isn't right and we need to "help" it. We aren't asking for much other than our allergies to be accepted and sympathized with! I have been shivering cold in 80 degree weather while taking suboxone. I've been to the hospital since this happened because well when I take naloxone that's what happens! Please don't force us out of treatment that worked because of the small few abusing it. All states with this law (which IS GOOD) have allergy exceptions! I've never been ashamed of Virginia which is my home state born and raised until now. It truly hurts me as I feel we are being discriminated against. Most of our addictions started from emotional pain from things many couldn't even imagine to endure and with subutex (even ones that CAN tolerate suboxone) we have done very well. Methadone is a harsh route we DONT want to go down, it works for some great however not everyone is the same and buprenorphine works for us! We are willing to have stricter rules as far as pill counts or random drug screens. Take the Abusers prescriptions away, not us doing well on it. This is only going to cause a HUGE heroin epidemic and sadly, death. I never knew why I felt so sick to the point myself and my dying mother believed I was dying as well until it was documented and proven that I DO have a allergy everything changed and I gained weight and completely normal again. Not everyone is the same, not everyone can take the same medications! The FDA even has proof of that (in another email I sent that information) but I am begging you please allow allergy/hypersensitive I am terrified of this allergy.. I am a momma of two, my babies need me and need me to be healthy and there for them! I've been so sick that my almost 5 year old has memorized how to call 911 and explain what is happening if I have a worse reaction.. THAT is sad and shouldn't have to happen! My son was taken to the park daily and for walks, I cannot do that being as sick and weak as I am right now from this allergy I nearly pass out after 5 minutes outside.. I have never had a dirty urine and never did wrong in my program, in fact I am basically a model patient and tapering off because I don't want on this for life however I shouldn't have to suffer in the meantime.. Why will it take weeks of suffering for us because were addicts and admitted that years ago?! Don't you know majority of pain management patients are abusing medication but just because WE admitted openly we had an issue we are to blame?! It's not fair.. I'm not saying ANY of you intentionally caused this but it defiantly wasn't fully thought through.. I am more than willing to have my fiancé drive me to Richmond even and have a meeting with you guys if you'd like! I really just want you, the board and others to understand we are normal people living life and doing normal people things finally but now we have a major set back!! This allergy CAN kill people let alone the ones having to drop out of treatment or doesn't have a doctor on call -- suicide, relapse and overdose CAN AND WILL happen.. This is addiction being dealt with here and it's a very scary but important thing to keep in mind!! All I am asking is some acknowledgement of the information I have given, it's proven by FDA.. This is killing people and pushing them to the streets, which we DONT want that!! Also please research there's been NO proven deaths on buprenorphine alone as far as overdose because it "blocks" others however methadone it has helped many but failed many too in the "euphoric feeling" so giving that as a "alternative" is almost like handing an addict a prescription of Vicodin! Methadone does get some patients high which some do need methadone as subutex/suboxone isn't strong enough but the ones on buprenorphine DONT want to even risk that!! I know of at least 5 people relapsed so this isn't the way to go.. No one can fake a allergy, it's there or it's not! I've taken pictures of mine 20 minutes after dosing.. Again my number is 571-358-7105 if someone would like to discuss ANYTHING PLEASE CALL!! I am willing at this point to do anything to prove we are normal people that deserve to be treated as such.. Yes we used and are "addicts" but we aren't in ACTIVE addiction, we don't get high or abuse it.. The ones abusing is ones not even in the program and just buying from the ridiculous ones who needs to lose treatment not us!! I feel if you sell your meds in anyway you should be cut.. Why can't that happen right? PLEASE I am begging you to allow allergy exception even just for my babies and the other babies watching their parents suffer allergy or worse dropping out of treatment. My kids are almost 5 and the other is 10 months old, I don't

want them to see their momma sick!! If you're allergic to penicillin there's another one that can help in this case subutex is needed.. Subutex was MADE FOR ADDICTION not for pain management or animals sure it helps them too but why take it away from the people it was created for??

iPhone - Carrie Pearson

Harp, William L. (DHP)

From: Board of Medicine
Sent: Monday, April 17, 2017 10:01 AM
To: Harp, William L. (DHP)
Subject: FW: Side effects of naloxone
Attachments: photo 1.JPG; ATT00001.txt; photo 2.PNG; ATT00002.txt

-----Original Message-----
From: Carrie Pearson [mailto:tjsmom7112@icloud.com]
Sent: Tuesday, April 11, 2017 7:39 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Side effects of naloxone

Here's proof from a government website and side effects of naloxone, just SOME of what we are dealing with. It also says "this medicine is not right for everyone DO NOT use if you have had a allergic reaction to naloxone" I'm trying to find all the info I can here to help others understand the suffering and what is at stake here! Sure having regulations is great but not to accept allergies? That's very unsafe with ANY medication. It's okay for pain and animals but not addicts? That's discriminating. We are people too and shouldn't suffer because of our past that we've worked so hard to change and now we have to prove ourselves after already proving hard enough starting treatment! Thank you have a good day.

https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0011328/?report=details

Micromedex Consumer Medication Information.

Published: March 1, 2017

Naloxone (By injection)

nal-OX-one

Treats narcotic overdose in an emergency situation.

Drug classes

Antidote (About this - PubMed Health)

Uses

Uses of This Medicine

Naloxone injection is used to treat an opioid emergency such as an overdose or a possible overdose of a narcotic medicine. Some signs and symptoms of an opioid emergency are breathing problems (which can range from slow or shallow breathing to no breathing), extreme sleepiness, slow heartbeat, or not being able to respond.

This medicine is available only with your doctor's prescription.

Other uses (PubMed Health)

How To Use

Injectable

This medicine is given as a shot under your skin or into a muscle.

This medicine comes with patient instructions and a training device. You, your home health caregiver, and family members should read the instructions carefully. Ask your doctor if you have any questions.

Do not use the medicine if it is cloudy, discolored, or has large particles in it.

The autoinjector can be used only on time. Do not remove the red safety guard until you are ready to use it.

This medicine is available in 2 dosage strengths: 0.4 milligram (mg)/0.4 milliliter (mL) autoinjector and 2 mg/0.4mL autoinjector.

To use:

- Inject the medicine into the outer thigh, through clothing, if needed. If you are giving this medicine to a child younger than 1 year of age, pinch the thigh while you give the medicine.
- After you give the first dose to the patient, **get emergency medical help right away.**
- Closely watch the patient after the injection for signs and symptoms of an opioid emergency.
- Give a new injection every 2 to 3 minutes if symptoms return.

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light.

Drugs and Foods to Avoid

Ask your doctor or pharmacist before using any other medicine, including over-the-counter medicines, vitamins, and herbal products.

When Not To Use

Contents

Uses

Warnings

Possible side effects

Brand names

This medicine is not right for everyone. Do not use it if you had an allergic reaction to naloxone.

Warnings

Tell your doctor if you are pregnant or breastfeeding, or if you have kidney disease, liver disease, or heart disease.

Keep all medicine out of the reach of children. Never share your medicine with anyone.

Possible side effects

Summary More details

Call your doctor right away if you notice any of these side effects:

Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing

Crying more than the usual (in babies)

Diarrhea, nausea, vomiting, stomach cramps

Fast, pounding, or uneven heartbeat, trouble breathing

Fever, runny nose, sneezing, sweating, yawning

Seizures, tremors, feeling restless, nervous, or irritable

If you notice other side effects that you think are caused by this medicine, tell your doctor.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

More side effects of this drug

Brand names include

Evzio, Naloxone HCl Novaplus, Narcan, PremierPro Rx naloxone HCl

There may be other brand names for this medicine.

More detailed version of this drug page

TRUVEN HEALTH ANALYTICS

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Recent Activity

Turn Off Clear

Naloxone (By injection) PubMed Health

Transfer of buprenorphine into breast milk and calculation of PubMed

Mast cell activation syndrome: a review. PubMed

The differential diagnosis of bigeminal rhythms. PubMed

See more...

Drugs and Foods to Avoid

Ask your doctor or pharmacist before using any other medicine, including over-the-counter medicines, vitamins, and herbal products.

When Not To Use

This medicine is not right for everyone. Do not use it if you had an allergic reaction to naloxone.

Warnings

Tell your doctor if you are pregnant or breastfeeding, or if you have kidney disease, liver disease, or heart disease.

Keep all medicine out of the reach of children. Never share your medicine with anyone.

Possible side effects

any of these side effects:

Allergic reaction: itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing

Crying more than the usual (in babies)

Diarrhea, nausea, vomiting, stomach cramps

Fast, pounding, or uneven heartbeat, trouble breathing

Fever, runny nose, sneezing, sweating, yawning

Seizures, tremors, feeling restless, nervous, or irritable

If you notice other side effects that you think are caused by this medicine, tell your doctor.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

More side effects of this drug

Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Monday, April 24, 2017 2:31 PM
To: Harp, William L. (DHP)
Subject: FW: FW: [EXTERNAL] asking for guidance regarding HB2163

FYI.

From: Shar444561@aol.com [mailto:Shar444561@aol.com]
Sent: Monday, April 24, 2017 2:25 PM
To: Deschenes, Jennifer (DHP)
Subject: Re: FW: [EXTERNAL] asking for guidance regarding HB2163

Jennifer,
Thank you so much for keeping us in mind. I have commented in the town hall discussion online and will see what I can do about attending the panel board on May 15. Was just thinking of writing you yesterday. My daughter is now on a compound with the least amount of Naloxone allowed which was developed by her doctor in conjunction with a pharmacy. Its been a few weeks and she still has nausea, extreme fatigue and the face rash has developed. In addition, the compound is not covered by insurance so she is using her college fund to pay the $300.00 out of pocket on top of paying for her clinic fees which are out of network.
The mandate has certainly made our lives more difficult and I worry about her staying power in terms of tolerating the side effects vs relapsing.
Sharon Thomas

In a message dated 4/24/2017 1:51:21 P.M. US Eastern Daylight Time, Jennifer.Deschenes@DHP.VIRGINIA.GOV writes:

> Dear Ms. Thomas:
>
> I wanted to let you know that a regulatory advisory panel of the Board will meet on May 15, 2017 at 9 AM at the Department of Health Professions in the west end of Richmond to consider possible revisions to the buprenorphine regulations (eg, the lack of an exception for illness or allergy).
>
> The address is 9960 Mayland Drive, Henrico, VA 23233. The meeting will be in the 2nd floor conference room. You are welcome to attend the meeting and the Board will accept comments from the public at this meeting. Also, if you are unable to attend, but would still like to have your comments considered, you may send an email or letter to my attention and I will ensure that it is reviewed at the meeting on May 15. Thank you.
>
> Kindest regards,
>
> Jennifer

Jennifer L. Deschenes, JD, MS
Deputy Executive Director, Discipline
Virginia Board of Medicine

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463
Phone: 804.367.4462
Fax: 804.527.4429
Email: jennifer.deschenes@dhp.virginia.gov

From: Shar444561@aol.com [mailto:Shar444561@aol.com]
Sent: Monday, March 20, 2017 11:53 AM
To: Deschenes, Jennifer (DHP)
Subject: Re: FW: [EXTERNAL] asking for guidance regarding HB2163

Dear Jennifer,

Thank you for your reply, I also received another email from Dr. Terplan which I have attached at the end of this note. Bottom line is it looks like she cannot continue on her prescribed Buprenorphine once the legislation is active. In looking at the SAMSHA guidelines Bupe mono is recommended for patients who are pregnant or have an allergy to Naloxone, however it appears that according to HB2163 and the Virginia Medical Board that allergy or adverse medical complications are not considered legitimate reason to use the mono product. Cori has an appointment at her clinic today (Foundation Medical Group) and I suppose we will just have to see what the outcome is, am hoping she gets one more month of her Rx. After that I see a few possibilities if the Governor does not modify the Bill: she tries a product with the lowest possible amount of Naloxone and is able to manage the side effects (respiratory, GI, depression and unsightly rash) or she takes the Naloxone/Bupe product and ends up in the ER again. Second scenario is terrifying to me as I am in Fairfax and she is in Richmond and I cannot eyeball her as in the past.

Do you have any indication as to whether the Governor is considering amending the bill to enable current patients with documented success to continue their course?

Again I thank you for your time and investment in helping me

Sharon Thomas

Dear Ms Thomas

My apologies but I was completely backwards about film versus tablet. The law does apply to mono-product tablets. It does not apply to film – however the mono-product (buprenorphine only) film is no longer available.

We looked into different formulations of the combination product (buprenorphine plus naloxone) to see which has the lowest amount of naloxone – which appears to be the bunavail film (0.3 mg naloxone for a 2.1mg film).

Your daughter may not have the adverse reactions with the lower dose of naloxone.

Another option is the implant. You said she has a phobia of needles, but I think that this is something that your daughter should explore with her physician. I remain available to answer other questions and to talk to her provider as well if you wish. The Board of Medicine can also assist with other questions.

Again my apologies for the confusion.

Sincerely,

Mt

Mishka Terplan MD MPH FACOG FASAM

Professor Departments Obstetrics and Gynecology and Psychiatry

Associate Director Addiction Medicine

Virginia Commonwealth University

In a message dated 3/15/2017 3:42:29 P.M. US Eastern Daylight Time, Jennifer.Deschenes@DHP.VIRGINIA.GOV writes:

Dear Ms. Thomas:

I completely see why you are confused (and I was a bit also, when reading this chain). However we may be talking about the same thing, just using different names for it. Perhaps your daughter is already on one of the FDA approved formulations. I notice you mention it being a "mono-dissolvable" tablet, so perhaps Dr. Terplan is familiar with this formulation and it is a dissolvable product that is not subject to abuse in the tablet form referenced in the Board's Regs. I have pasted below the section of the Regs that are applicable to your question, and highlighted in green the areas that should be considered. It may also be that your daughter falls under subsection (B), or as I mentioned the

formulation she received has some dissolvable feature that prevents it from being crushed or abused. The Regs do read the mono-product shall not be prescribed except "in formulations other than tablet form".

Part. IV. Prescribing of Buprenorphine for Addiction Treatment.

18VAC85-21-150. Treatment with buprenorphine for addiction .

A. Buprenorphine without naloxone (buprenorphine mono-product) shall not be prescribed except:

1. When a patient is pregnant;

2. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days; or

3. In formulations other than tablet form for indications approved by the FDA.

B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed opioid treatment programs (OTPs). With the exception of those conditions listed in subsection A, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use offsite from the program.

C. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

Jennifer L. Deschenes, JD, MS
Deputy Executive Director, Discipline
Virginia Board of Medicine

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463
Phone: 804.367.4462
Fax: 804.527.4429
Email: jennifer.deschenes@dhp.virginia.gov

attorney regarding any legal questions related to state and federal laws and regulations, including the interpretation and application of the laws and regulations of VBOM.

UNDER NO CIRCUMSTANCES SHALL VBOM, ITS MEMBERS, OFFICERS, AGENTS, OR EMPLOYEES BE LIABLE FOR ANY ACTIONS TAKEN OR OMISSIONS MADE IN RELIANCE ON ANY INFORMATION CONTAINED IN THIS EMAIL.

From: Shar444561@aol.com [mailto:Shar444561@aol.com]
Sent: Thursday, March 09, 2017 12:27 PM
To: Deschenes, Jennifer (DHP)
Subject: Fwd: [EXTERNAL] asking for guidance regarding HB2163

Jennifer,

Here is the email exchange I had with Dr. Terplan. I think it will explain why I am still in a state of confusion LOL

Sharon Thomas

From: Mishka.Terplan@vcuhealth.org
To: Shar444561@aol.com
Sent: 3/8/2017 12:34:23 P.M. US Eastern Standard Time
Subj: RE: [EXTERNAL] asking for guidance regarding HB2163

Yes

Tablets are exempted from the new law. At least that is what I was told from leadership at the Board and DMAS. I will look for language for you. My understanding is that she could continue to take what she is taking now.

Allergy is not a legitimate cause in VA for the mono-product.

MT

From: Shar444561@aol.com [mailto:Shar444561@aol.com]
Sent: Wednesday, March 08, 2017 12:32 PM
To: Mishka Terplan <Mishka.Terplan@vcuhealth.org>
Subject: Re: [EXTERNAL] asking for guidance regarding HB2163

Thank you for your prompt reply.

I am a bit confused by your response. My daughter is currently taking generic Buprenorphine HCL 8mg twice daily: tablets, not the films. A representative from the Virginia Board of Medicine told me that the law applies to tablets yet you stated it applies to the films. Are you saying that continuing with mono dissolvable tablets is permitted under the new legislation? And if so, who manufactures these and are they available?

I also want to clarify if what you are saying is that documented allergy and adverse reaction to products containing Naloxone is not considered legitimate cause for continuation with the tablet form dissolvable mono product.

Thank you for your offer to consult with her prescribing physician in Richmond. I will pass your contact information along to him.

Sharon Thomas

In a message dated 3/8/2017 8:05:27 A.M. US Eastern Standard Time, Mishka.Terplan@vcuhealth.org writes:

> Good morning – and thank you for writing me
>
> I can't imagine the stress you and your daughter are going through right now regarding these legislative changes
>
> Under the new law buprenorphine mono-product film will only be prescribed to pregnant women (and people for the first few days of switching from methadone to bupe). Allergies or adverse event related to the naloxone are not an indication for continuation of the mono-therapy (Subutex).
>
> Do note this law applies only to the films – and not to tablets. There are several different buprenorphine mono-product tablets (which dissolve as does the film under the tongue) – these are still available. Some are generic formulations, other (such as Zubsolv) are not. Patches are approved for pain only and should not be used for the treatment of addiction.

I am happy to talk to your daughter's physician – and would suggest that she transition from the film to a tablet.

Best

MT

Mishka Terplan MD MPH FACOG FASAM

Professor Departments Obstetrics and Gynecology and Psychiatry

Associate Director Addiction Medicine

Virginia Commonwealth University

From: Shar444561@aol.com [mailto:Shar444561@aol.com]
Sent: Tuesday, March 07, 2017 8:14 PM
To: Mishka Terplan <Mishka.Terplan@vcuhealth.org>
Subject: [EXTERNAL] asking for guidance regarding HB2163

Dear Dr. Mishka,

I was given your name by my Delegate Eileen Filler-Corn who said you may be able to assist me in navigating the new laws regarding Buprenorphine as they relate to my daughter Corinna.

My 19 year old daughter Cori transferred to VCU in January is currently being seen at Foundation Medical Group (Dr. Gregory Condie) for MAT. He informed her at her last visit about the new legislation and she now has only a two week supply left of Subutex. She was switched from Suboxone to Subutex by her provider here in Fairfax in 2016 . Subutex ended up being the best and most successful treatment for her based on a few factors: hives, rash, nausea and depression from Naloxone as well an asthma attack requiring an ER visit during rehab resulting from Naloxone

when she was already compromised from environmental allergies. (History of asthma and reactive airway disease).

Cori has no history of abusing the Subutex and was not an IV user of heroin due to her phobia of needles. The phobia presents a problem in terms of the sub dermal or injection options for Buprenorphine Mono products.

Can you tell me if there are transdermal or mucosal adhesive options available as a Buprenorphine Mono product or if her documented history of success with Subutex and poor outcomes with Suboxone would be sufficient to allow her doctor to continue to prescribe the mono product tablet? And finally, if her doctor would like to consult with you regarding viable naloxone -free options, are you open to that?

I really appreciate your taking the time to read and respond to this, as you can imagine I do not want to see this two year fight against Heroin go awry just as Cori is finally living a "normal" life opiate free.

Sincerely,

Sharon Thomas

703-786-4568

Harp, William L. (DHP)

From: Board of Medicine
Sent: Wednesday, April 26, 2017 3:14 PM
To: Harp, William L. (DHP)
Subject: FW: STOPPING DRS FROM PRESCIBING A LIFE CHANGING MEDICINE (buprenorphine)

From: Mitchell Dunlow [mailto:mitchelldunlow@gmail.com]
Sent: Tuesday, April 25, 2017 8:51 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: STOPPING DRS FROM PRESCIBING A LIFE CHANGING MEDICINE (buprenorphine)

I could not believe my ears when my DR told he could no longer prescribe me (buprenorphine) for my opiod addiction, I have been taking this medicine for 2 yrs and was down to one 8mg tablet a day.
I have been clean now for 3 yrs, and now thats all over , I do not have insurance (400 month med insutance) and I guess you people really do not care about this problem , allot of legitmet patiets was taking that med . I can not afford 700.00 month to see dr go to 2 groups a month and fill a prescipt of suboxone strips. Know I will have to go back to taking pececent, I will have to go back to that life again, because some assholes setting behind a desk just helped ruin my life and i am sure allot more have been affected fron your disission to remove this cheap and better drug for addiction..

30 day supply of bupre cost 50.00 dollars and 30 day supply of suboxone strips 8 mg cost 470.00 ,if you want to help get that greedy pharm Co to lower the price of this suboxone strips

Harp, William L. (DHP)

From: Board of Medicine
Sent: Tuesday, May 02, 2017 4:01 PM
To: Harp, William L. (DHP)
Subject: FW: What gives you the right?

From: Stephanie Godwin-Brown [mailto:stephanie.godwin.brown@gmail.com]
Sent: Thursday, April 27, 2017 9:08 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Re: What gives you the right?

I'm not sure if I will be able to make it to the 5/15/2017 meeting, but I would like you to know I have been forced to buy Subutex off the street to keep from being sick. So now, I am right back to square one. And just to let you know, all this law did was increase the street value of Subutex. They are now selling for $50 a piece in my area. There is no war on drugs. A war is a struggle between two opposing forces. Unfortunately, the side that claims to be fighting the war is actually contributing to it. I will try to make it to the meeting, if I can, but in all honesty, I don't think it will make a difference. Our government would have to actually care about the welfare of ALL people, not just the ones they deem worthy, in order to see any kind of head way. Addiction does not discriminate. It's not just affecting the poor and lower class. It affects everyone! It's just that people who have money, and power, and status can hide it better. They can also afford the price tags. I am not willing to jeopardize my sobriety, therefore, I will continue to put money into the street subutex. No one is going to make sure I'm ok, except me! If I have learned anything during my active years of addiction, it is that no one is going to fight to save my life, except me.

Thanks again,
Stephanie Brown

On Apr 12, 2017 9:40 AM, "Stephanie Godwin-Brown" <stephanie.godwin.brown@gmail.com> wrote:

I went to my doctor appointment yesterday, only to be told I can no longer receive the meds I have been on for a while because the state of VA thinks they know what is best? I was switched to a medication I have a KNOWN and DOCUMENTED allergy to because I'm not pregnant! So my physician, knowing all the symptoms and side effects I suffer from when I take Suboxone, still wrote me a prescription for it. My only other option was METHADONE! METHADONE? Are you serious? Have ANY of you people ever actually SEEN what methadone does to the body? It stores in the bone marrow and the person taking it becomes highly dependent on it. Better yet, have you ever seen anyone come off of methadone? No, because if you had, you would be ASHAMED of what you are doing! The funniest part is, instead of bringing you down off of it slowly, they gradually increase your dose until you are hooked for life. Now my physician, who knows I have severe allergic reactions to Suboxone, has to write me a medication that will make me even sicker and cause me to be on OTHER meds to control the side effects. Doctors go to school for 8+ years only for politicians to tell him they know better? Why? Because you sit in your nice houses, with all your nice things, and you have no clue what it's like to go through an addiction. Well I am in the loop! You think you are HELPING? What a JOKE! You think someone in the midst of their addiction won't find a way around this law? They will. And guess who will suffer? The unwanted babies that are going to be born to people who are good at getting

pregnant, but not good at being mothers, and the people who are actually trying to stay sober! I was on Suboxone and I stayed sick all the time! Constant migraines (that require migraine meds), swelling in my legs and feet (that requires Lasix for me to be able to walk and take care of my family), rashes on my body and sores on my tongue. There was a reason my doctor switched me to the Subutex. I now realize this is a money racket. Subutex are a third of the cost of Suboxone and they contain naloxone (narcan) which is used to being people back from overdoses! So I haven't took a pain pill or ANY OTHER drug since I was prescribed Subutex but you think I should put another medication in my body that I don't need? That makes sense! Now I have 3 choices, take the Suboxone and deal with an allergic reaction DAILY, withdrawal from the subutex, or go back to looking for opiates. Only time will tell what will happen. I know one thing, if it was up to our government, they would prefer all the addicts just die in the street. When your little scheme blows up in your face, you still won't care, because it doesn't affect you! Funny how that works? The government was the one that allowed all these drugs in, with corrupt politicians, and police officers, and all their ties to the drug mafia years ago when crack and cocaine infiltrated all the lower income cities. That was decades ago, yet I see no dent in the war on drugs. You people set up their on your high horses, preaching about things you have no clue about. If you want to stop people from doing things they shouldn't then require drug screenings at every appointment, require pill counts weekly, so things that will keep people straight. That is what a government that CARES about fixing the issues would do! What you people are doing is unconscionable. What gives you the right to tell people their MD can only write them a prescription for something that will make them sick (Suboxone) or something that will pull them so far into an addictive Hell that they want to die(Methadone)? Because that is the goal, right? Kill off all the addicts and then your war on drugs just disappears? You people have NO CLUE what you have done and it's so obvious that you do not care! Are any of you going to take responsibility for people who have a severe allergic reaction if they don't make it to the Hospital in time, after taking a Suboxone? Or should they tell their families to sue the doctors for malpractice after they are forced to prescribe them something that is less beneficial than what they were on? I have finally got my life back on track just for you people to come along and tell me I was doing TOO good? You will reap what you sow. I am an educated woman, so I know that this email will probably not even be read, and if by chance it is, I'm sure it won't affect you in any way. But? What if I was one of your children? I bet if I was, I would get the medication I need, not something I'm allergic to!

Thanks you for reading (if you did) and for pretending this will email will even matter,
Stephanie Brown

Harp, William L. (DHP)

From: Morton, Colanthia D. (DHP)
Sent: Monday, April 24, 2017 3:49 PM
To: Harp, William L. (DHP)
Subject: FW: New submission from Website Feedback

From: Ly, Mylam (VDH)
Sent: Friday, April 21, 2017 4:30 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: FW: New submission from Website Feedback

Hello,

We received the following message on our website feedback form. Would you be able to assist Tyler Moody?

Mylam Ly

Virginia Department of Health
Work: (804) 864-7263
Mobile: (804) 441-0922

From: Website Feedback
Sent: Friday, April 21, 2017 11:53 AM
To: Ly, Mylam (VDH)
Subject: New submission from Website Feedback

Type of Feedback

General Question or Comment

Name (Optional)

Tyler Moody

Email

wireghostx@gmail.com

Feedback

Dear Virgina Department of Health:

I am writing concerning House Bill 2163, in which the prescription drug Subutex is not to be prescribed without Naloxone. I was surprised that this bill passed and was signed into law. It seems it was bundled with other Bills regarding the epidemic. These other Bills make perfect sense, and will do a lot of good, but this one (HB2163) is terribly detrimental! I have been on Subutex for Chronic pain , RLS & Fibromyalgia for a long time originally from Reckitt and Benckiser's trials. From the age of 16, this drug has saved my life, allowing me to accomplish quite a lot, from playing concert violin with the Richmond Philharmonic, to becoming the world's youngest professional Philatelist, to a career in Information Security deploying cutting edge security defenses.
I certainly realize we are in the midst of an opioid epidemic of epic proportion, however; this Bill does nothing to gain ground in resolving this crisis. It has a great potential to make matters much worse, especially for those like myself. Collateral ramifications to chronic pain and illness sufferers will resort in any multitude of reactions, from some having to go on addictive tolerance enhancing painkillers, to drugs on the streets or dark-markets quite possibly and probably resulting in death.
The open distribution of Naloxone for opioid addicts is certainly a great thing (I keep it with me myself & everyone should), however the drug Naloxone can have severely adverse affects on those suffering from chronic pain. House Bill 2163 is going to

have devastating affects on both chronic pain patients and their physicians. I
In the past, when fighting these attempts from legislators, I've received back text book replies stating, that they are committed to fighting the opioid epidemic, or diversion crisis. Each time I cringe at the the response, as I know the full facts have not been presented in regard to representation of chronic pain sufferers, and Virginia edges ever closer to draconian laws.
As a sufferer of chronic pain, I would like the opportunity to discuss this, in depth, in front of the VA Senate or House of Delegates, before it begins to wreak havoc on those like me. This Bill must be repealed or amended. It does nothing but harm good people, and will make our epidemic worse. I absolutely do not want to end up on stronger more strictly scheduled, higher tolerance producing and more addictive painkillers
This is the first letter I am writing regarding this Bill, and I intend to contact everyone who voted on it. I can not cease to fight this matter, as it's repercussions could end my life. You are the Virginia Department of Health. Please, I implore you to look into this Bill and Amend it.

Regards,

Tyler Moody
CISO
CEHv9, MS, MCP,
Network Architect & Engineer

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, May 09, 2017 12:05 PM
To: Morton, Colanthia D. (DHP)
Subject: RE: Va board of medicine. Dr Harp

Dear Mr. Price:

Thank you for your comments.

I will make sure the Regulatory Advisory Panel that is meeting on Monday the 15th sees your message.

Kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of MEdicine

From: Board of Medicine
Sent: Tuesday, May 09, 2017 11:50 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: Va board of medicine. Dr Harp

From: Oren Price [mailto:olpamv@gmail.com]
Sent: Monday, May 08, 2017 9:54 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Va board of medicine. Dr Harp

Va board of medicine. Dr Harp I'm an patient at the tassel Clinic. I'm father of 4 the only worker in the hVa board of medicine. Dr Harp I'm an patient at the tassel Clinic. I'm father of 4 the only worker in the home. I've complied with all classes home. I've complied with all classes drug screening and everything and was on Subutex which was half price and tell March and was switch and now I'm paying 600 and some dollars to go to this I can't afford it and I'm asking to please be able to go back to my subutext. Because it's only half the costed I've got no insurance so I'm having lots trouble to be able to support and provide for my family.. I was switch to Subutex originally from Jake go because Suboxone films and tablets give me bad headaches and I could not function right and started the subutex and was doing well I've been in the program and you can ask Miss Holloway I've complied a hundred percent so I'm asking please do what you can for the ones that can afford this and be able to still maintain without going back to the illegal drugs and using thanks in advance

Oren Price

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Wednesday, May 10, 2017 10:32 AM
To: 'molovesd@gmail.com'
Cc: Morton, Colanthia D. (DHP)
Subject: RE: Hey

Dear Morgan Brown:

Thank you for your comments.

WLH

From: Board of Medicine
Sent: Wednesday, May 10, 2017 10:24 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: Hey

From: Morgan Brown [mailto:molovesd@gmail.com]
Sent: Tuesday, May 09, 2017 4:01 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Hey

I'm a patient of Dr Lawrence Conell and I have been on the plain buprenorphine tablets for almost 2 years. I really need this medicine and when I was on the suboxone strips that had the naloxone in it.. It made me really sick with head aches and sweats. Please don't take the plain buprenorphine tablets away from the people who really need it.

OPIOID QUESTIONS AND COMMENTS

Harp, William L. (DHP)

From: PETER Boling <peter.boling@vcuhealth.org>
Sent: Wednesday, March 15, 2017 11:55 AM
To: Harp, William L. (DHP)
Subject: Re: [EXTERNAL] RE: opiate regs

Yes, helpful and thanks for the quick response Bill

Grateful as always for your hard work

Peter

Sent from my iPhone

On Mar 15, 2017, at 11:51 AM, Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV> wrote:

> Peter:
>
> Thanks for your question.
>
> Surely that is not the intent of these regs.
>
> I think the section you are referring to in the regs is "2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist."
>
> This language is in the acute pain and the chronic pain sections.
>
> The Board addressed the concern that it might not be possible to have a patient evaluated by a pain management specialist by including the language "shall document in the medical record the reasonable justification for such doses".
>
> That provides an alternative for the physician.
>
> Hope this helps,
>
> Bill
>
> **From:** PETER Boling [mailto:peter.boling@vcuhealth.org]
> **Sent:** Wednesday, March 15, 2017 10:37 AM
> **To:** Harp, William L. (DHP)
> **Subject:** Re: [EXTERNAL] RE: opiate regs
>
> Following up
>
> Reviewed the regs

We have Q question about the requirement for a "pain management" consult for chronic opiate pts on more than 120 MME

There are not sufficient available resources to comply with this rule and docs are therefore gearing up to take legitimate chronic opiate patients off some or all of their pain meds which will cause increased pain. Surely this is not the intent?

Peter

Sent from my iPhone

On Feb 15, 2017, at 9:59 AM, Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV> wrote:

> Peter:
>
> Thanks for your comments.
>
> The Board heard the same comment from one of its members.
>
> His take was that primary care docs, in general, would begin to shy away from dealing with opioids if the regs prove to be too burdensome.
>
> I am OK these days, thanks for asking.
>
> Kindest regards,
>
> Bill
>
> **From:** Board of Medicine
> **Sent:** Wednesday, February 15, 2017 9:52 AM
> **To:** Harp, William L. (DHP)
> **Subject:** FW: opiate regs
>
> **From:** PETER Boling [mailto:peter.boling@vcuhealth.org]
> **Sent:** Tuesday, February 14, 2017 10:14 AM
> **To:** Board of Medicine
> **Subject:** opiate regs
>
> Bill
>
> throwing in an uninvited 2 cents
>
> I heard about new regs in the works related to opiate prescribing, think
> I understand the politics and optics to some extent
>
> truth: there is already a major deficit of providers who will manage patients' oral pain meds. most self-described and sometimes accredited pain management

specialists prefer to give injections. when it comes to giving advice and overseeing other forms of pain management, they overtly indicate that PCPs must handle oral pain meds, and they give helpful advice by recommending the usual things we all know about and have usually already tried... some PT, gabapentin or lyrica, some antidepressants, other non-medication pain abatement strategies, which sometimes work but often do not.

the business of prescribing opiates for chronic pain in older patients with deforming and painful conditions is already burdensome and miserable, and is in most cases is not responsible for the epidemic of opiate-related adverse events that are in the news.

Since this work domain is already challenging, our older patients and their doctors may get crushed by the new burdens that I fear we will soon be facing. many PCPs are now posting signs saying that their practice will not fill chronic pain meds, to deflect patients with these needs

hope you are well, and that the needs of primary care providers and their patients are being heard around this table

Peter

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Wednesday, March 15, 2017 2:00 PM
To: 'PETER Boling'
Cc: Deschenes, Jennifer (DHP); Wood, Jennie (DHP)
Subject: RE: one more inquiry, re chronic pain regs

Peter:

Good catch by your colleague.

The intent of the Board was to have the same language for acute pain and chronic pain, and the AND just got by us.

It should read OR in the chronic pain section, and the Senior Policy Analyst is seeing if she can get that changed.

Bill

From: PETER Boling [mailto:peter.boling@vcuhealth.org]
Sent: Wednesday, March 15, 2017 12:44 PM
To: Harp, William L. (DHP)
Subject: one more inquiry, re chronic pain regs

Bill, a generalist colleague of mine responded that the regs under opiates for chronic pain posted on the website are as follows, focusing on the word "and" which seems not to allow much wiggle room

18VAC85-21-70. Treatment of chronic pain with opioids.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses **and** refer to or consult with a pain management specialist.

Peter

1405 Early Street
Charlottesville, VA 22902-6330
March 29, 2017

Virginia Board of Medicine
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

To Whom It May Concern:

This concerns the recent requirement for opioid drug screening. I am copying my various state and federal representatives because I see this as a political matter.

I am a 77-year-old woman dealing with fibromyalgia, osteoarthritis, and psoriatic arthritis among other conditions. Using hydrocodone as well as OTC pain relievers as needed helps me to manage, despite the fact that OTC painkillers are being described more and more as probable causes of heart problems. There are days when I can barely get up in the morning; some days I can manage with acetominophen or naproxen sodium. When it's really bad I use the hydrocodone. Sometimes I take a whole pill, sometimes half. Sometimes I can go several days without it. I also have to put up with occasional mild nausea and gastric side effects (ironically, another new drug is out now to resolve the latter problem). What I find incredibly stupid is that the test looks for a positive outcome; I don't know long the opiate stays in the body but given that I don't always have to take it this means that on my test day I HAVE to take it so that it comes out positive!! Talk about enabling people!

In addition to watching prices rise and drug companies play around with tiers so they can make more money I have to put up with the hassles of calling my doctor's office when I need a new prescription, waiting for the call back, going to pick up the script, going to the pharmacy, and waiting for the medicine. It's also a trial for my doctor as well as the office staff. What'll I do when I can no longer drive? It's bad enough I can't rely on JAUNT anymore because of another stupid regulation at both local hospitals that require one to be picked up by someone one "knows" after being sedated for whatever. The last time I had to undergo this the situation was such a disaster I filed a complaint against UVA Hospital as well as the idiot doctor, so-called, who performed the incomplete procedure. I don't have anyone here except for a couple of friends/acquaintances. I was brought down here in 1995 because of a job change and then I bought a house because I was sent a nephew to take care of. He has since died and I'm stuck with the house which I can't sell because I can't afford to fix it up. I would LOVE to move back to Vermont, a more civilized state, but I find it very hard to do so and will probably end up dying here.

I bet I dare say it's easier to buy a gun!

The cost for hydrocodone (though a generic and yet marked as a tier 3) has sextupled for me this year; I live on +/-$22K per year. Though I get some tax relief from the City I'm still not poor enough for SNAP, and despite the minute COLA rise this year I am actually getting less in social security than last year because of the price increases for Medicare A, B, and C, with a good chunk of most of my yearly expenses being medically related. Adding insult to injury I now have to pay my doctor $45 for the test though I'm going to try and recoup that from Medicare but I doubt it'll do any good. This is unneeded additional stress for me. If I'm lucky I have another ten or so years left and I'd like to live them with less stress and a little more peacefulness.

Over the years I've watched the originally noble profession of medicine (though admittedly biased toward arrogance, perhaps because it deals with life and death) deteriorate into just another corporatized and politicized business. It's one thing to watch the police get militarized, the law increasingly corrupted, politics descending further into more sleaze, life in general becoming so impossible, that one wonders perhaps the reason that so many people are doing drugs and dying young is precisely because they CAN'T deal with anything anymore. The problem is with society itself and all this fearmongering only makes it worse. What did Prohibition do except create another layer of criminality and several generations of alcoholics? And look at us here proselytizing for "craft" beers and whiskeys, selling alcohol the way we used to sell cigarettes. And nicotine is harder to overcome than any opiate; I know as I finally quit after 55 years and now seven and a half years later I wish I could smoke again just to deal with the sheer stupidities going on. You only fix a problem like this by going to the source and creating positive ways to solve the problems not only of the addiction but of the society itself. You don't make people in trouble feel like criminals; you HELP them.

Well, we're watching the demise of the American empire and thank heaven I won't be around to see it but the least your organization...AND the politicians....could do is to allow doctors a bit more discretion in their ability to control their prescriptions.

Thank you for your attention.

Doris Safie

Cc: Gov. Terry McAuliffe, Patrick Henry Bldg., 3rd Floor, Richmond, VA 23219
Lt. Gov. Ralph S. Northam, 102 Governor Street, Richmond, VA 23219 ✓
Atty. Gen. Mark Herring, 900 East Main Street, Richmond, VA 23219
Sen. Mark Warner,475 Russell Senate Office Building, Washington, DC 20510
The Hon. Tom Garrett, 415 Cannon HOB, Washington, DC 20515
The Hon. Tim Kaine, B40C Dirksen Senate Office Building, Washington, DC 20510
The Hon. Creigh Deeds, POB 5462, Charlottesville, VA 22905
The Hon. David Toscano, 211 E. High St., Charlottesville, VA 22902

PS And you pols: work toward decriminalizing all drugs + tax and regulate their recreational use (while allowing ATF the real pros, i.e. doctors, regulate their patients and without taxation.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Thursday, April 06, 2017 5:50 PM
To: 'lauraburijon@yahoo.com'
Subject: RE: questions about new opiate regulations

Dear Dr. Burijon:

The regulations do not specifically speak to the intermittent administration of opioids,

The regulations address acute pain, which is usually one episode of treatment, and chronic pain which anticipates daily medication.

I cannot further interpret the regulations for you, but were there to be a complaint about your "intermittent" care, the Board would look at the regulations and the facts in the case to decide if there was a violation.

I hope this is helpful.

With kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Thursday, March 30, 2017 5:17 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: questions about new opiate regulations

From: Laura Burijon [mailto:lauraburijon@yahoo.com]
Sent: Wednesday, March 22, 2017 2:16 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: questions about new opiate regulations

Hi there! I have 2 questions regarding the new opiate prescribing regulations:

1. How do we reasonably screen the urines of patients who only take controlled substances sporadically? Many patients receive tramadol #30 for 6 months, for example. Is there agreement for monitoring those patients?

2. What is our obligation if we are prescribing only the benzodiazepine, but another doctor is prescribing the narcotic? Would I then be expected to prescribe narcan?

I'd love some literature I can give to patients explaining the proper storage, indications, and efficacy of narcan. I've been asking my patients to bring a family member to appointments as the patient himself would clearly not be the one administering narcan. This part of the new guidelines requires more time and counseling than I expected.

Thank you for your time and consideration,

Laura Burijon MD

"Where sin abounds, Grace much more abounds." Romans 5:20

Harp, William L. (DHP)

From: Wells, Jim <jwells@valleyhealthlink.com>
Sent: Thursday, April 06, 2017 12:20 PM
To: Harp, William L. (DHP)
Subject: RE: [secure]

Absolutely does. Thank you. jim

Jim Wells, R.Ph.
Pharmacy Administrative Director
Director of Cardiopulmonary Services
Warren Memorial Hospital
1000 Shenandoah Avenue
Front Royal, VA 22630
(540) 636-0256

Pharmacy Administrative Director
Page Memorial Hospital
200 Memorial Drive
Luray, Virginia 22835
(540) 743-8029

Mobile: (540) 533-9002

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From: Harp, William L. (DHP) [mailto:William.Harp@DHP.VIRGINIA.GOV]
Sent: Thursday, April 06, 2017 12:17 PM
To: Wells, Jim
Cc: Yeatts, Elaine J. (DHP); Deschenes, Jennifer (DHP)
Subject: RE: [secure]

Dear Mr. Wells:

Thank you for your question.

Tramadol is an opioid, so it is subject to these regulations.

For your question on drug testing and chronic pain, below is what I believe to be the relevant section of the regulation (bolding and underlining added).

I hope this is helpful to you and your patient and family.

Kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

18VAC85-21-100. Opioid therapy for chronic pain.

A. The practitioner shall review the course of pain treatment and any new information about the etiology of the pain and the patient's state of health at least every three months.

B. Continuation of treatment with opioids shall be supported by documentation of continued benefit from such prescribing. If the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

C. Practitioners shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

D. Practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter.

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate healthcare provider, or refer the patient for evaluation for treatment if indicated.

From: Wells, Jim [mailto:jwells@valleyhealthlink.com]
Sent: Thursday, April 06, 2017 11:48 AM
To: Yeatts, Elaine J. (DHP) <Elaine.Yeatts@DHP.VIRGINIA.GOV>
Subject: [secure]

Ms. Yeatts, received a question from a patient's family.....is there any new regulation you are aware of which requires a general Physician/prescriber to urine test a patient on long term Tramadol? Is it possibly that the urine screen is one feature of "certifying the patient has a need for long term prescriptions" or is it possibly one of the elements required to write a long term prescription for a substance? Thank you. NOT EMERGENT. Jim wells

Jim Wells, R.Ph.
Pharmacy Administrative Director
Director of Cardiopulmonary Services
Warren Memorial Hospital
1000 Shenandoah Avenue
Front Royal, VA 22630
(540) 636-0256

Pharmacy Administrative Director
Page Memorial Hospital
200 Memorial Drive
Luray, Virginia 22835
(540) 743-8029

Mobile: (540) 533-9002

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Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Tuesday, March 28, 2017 7:32 PM
To: GJM3H@hscmail.mcc.virginia.edu
Cc: Harp, William L. (DHP); Brown, David (DHP)
Subject: RE: Question on new regulations of prescribing opioids

Thank you for your question. There is no additional language defining "extenuating circumstances", as that would be determined by the practitioner on a case by case basis in light of the medical issue and presenting patient. I have pasted in the complete sentence from the regulations and note that the regulations require clear documentation in the record of the extenuating circumstances that lead the practitioner to prescribe beyond 14 days. If a complaint were filed against the practitioner, the Board would look to see that the extenuating circumstances were clearly documented, as you have done in the example you provided below.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

I hope this information is helpful.

Kindest regards,

Jennifer Deschenes
Board of Medicine
804-367-4462

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From: MacCleery, Gavin J *HS [mailto:GJM3H@hscmail.mcc.virginia.edu]
Sent: Friday, March 24, 2017 4:30 PM
To: Board of Medicine
Cc: Molnar, Marcia A *HS
Subject: Question on new regulations of prescribing opioids

To whom it may concern,
I have a few questions pertaining to the recent regulations "Governing Prescribing Opioids and Buprenorphine – 18 VAC 85-21-10 et seq." I work in a busy Neurosurgical Department and we are operating on patients with major spine deformities that require extensive thoracolumbar realignment and major surgery. The patients having this surgery are in a significant amount of pain afterwards for up to 6 weeks. In reviewing your recent regulations I had a few questions:

1. In "18VAC85-21-40 Treatment of acute pain with opioids" there is reference to being able to prescribe opioids for longer than 14 days in extenuating circumstances. Would the following be considered extenuating circumstances:

a. Extensive thoracolumbar surgery causing extreme pain for up to at least 6 weeks.
b. Patients needing pain control to allow them to ambulate/get out of bed thereby facilitating healing and preventing complications.
c. Patient unable to take NSAID's due to interference in fusion process.
d. Tylenol unable to control pain of this level.
e. Many patient's come from long distance 2-6 hours away. Transportation for appointments not always feasible every 14 days due to significant pain, difficulty in transporting, and potential stress/damage to surgery with multiple car trips.

Thank you for your consideration,

Gavin MacCleery, M.S., PA-C
University of Virginia
Department of Neurosurgery
(Office) 434-924-1843
(Cell) 434-409-1324
(Hospital Pager) 6797
gjm3h@virginia.edu

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Friday, March 17, 2017 2:02 PM
To: 'Jennifer.Sargent2@va.gov'
Cc: Morton, Colanthia D. (DHP)
Subject: RE: tramadol and new opioid guidelines

Dear Dr. Sargent:

Tramadol is mentioned in the regulations.

I commend them to your reading.

http://townhall.virginia.gov/L/ViewXML.cfm?textid=11462

Kindest regards,

William L Harp, MD
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Friday, March 17, 2017 12:01 PM
To: Harp, William L. (DHP)
Subject: FW: tramadol and new opioid guidelines

From: Sargent, Jennifer E RICVAMC [mailto:Jennifer.Sargent2@va.gov]
Sent: Friday, March 17, 2017 11:53 AM
To: Board of Medicine
Subject: tramadol and new opioid guidelines

Dr Harp

I would like clarification about tramadol and the new Virginia opioid guidelines.
I work through the Richmond VAMC and in the past, tramadol was not regulated as stringently as Other opioids.

Is tramadol covered under the new guidelines?
I would like to clarify not just for myself but for my fellow colleagues at the local VA clinics.

Thank you for your time and attention.

Sincerely

Jennifer Sargent, MD

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Wednesday, March 15, 2017 4:08 PM
To: 'David Taminger'
Cc: Deschenes, Jennifer (DHP); Wood, Peggy (DHP)
Subject: RE: Questions regarding naloxone in new regulations

David:

The Board didn't put any "give" in that section, so I don't think you or I can explain it any further than the language itself.

The discussion by the Board was that it would be the enforcer of these regs and would apply its analysis to the evidence in each case.

I think that's all we can say.

Sorry not to be of more help,

WLH

-----Original Message-----
From: David Taminger [mailto:dtaminger@yahoo.com]
Sent: Wednesday, March 15, 2017 12:01 PM
To: Harp, William L. (DHP)
Subject: Questions regarding naloxone in new regulations

Good morning Dr. Harp.
I'm trying to clarify some questions from colleagues regarding the new regulations.

Specific question is ....
Must Naloxone be prescribed even for lower doses of opioids with concurrent use of benzodiazepines?
Especially in cases where one or both may be for PRN use only

Thanks and talk to you soon.

Dave Taminger

Harp, William L. (DHP)

From: Greenawald, Mark H. <mhgreenawald@carilionclinic.org>
Sent: Wednesday, March 15, 2017 3:44 PM
To: Harp, William L. (DHP)
Cc: Mertes, Christopher P. (Chris); Jeremiah, Michael P.; Deschenes, Jennifer (DHP); Wood, Jennie (DHP)
Subject: RE: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

Thanks Bill. Very helpful. Appreciate your taking the time to respond and for your leadership on this and so many other things.

From: Harp, William L. (DHP) [William.Harp@DHP.VIRGINIA.GOV]
Sent: Wednesday, March 15, 2017 3:41 PM
To: Greenawald, Mark H.
Cc: Mertes, Christopher P. (Chris); Jeremiah, Michael P.; Deschenes, Jennifer (DHP); Wood, Jennie (DHP)
Subject: RE: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

Mark:

I was not privy to all the discussion at the General Assembly, but perhaps you are referring to the 120 MME that ended up in the regulations.

We had a regulatory advisory panel with pain management experts on it.

They were presented with the CDC guidelines, which in addition to its discussion of 90 MME, included the following language regarding the State of Washington guidelines/regulations – "before increasing long-term opioid therapy dosage to >120 MME/day, clinicians in Washington must obtain consultation from a pain specialist who agrees that this is indicated and appropriate."

I think this might be the answer to your question.

Kindest regards,

Bill
William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Greenawald, Mark H. [mailto:mhgreenawald@carilionclinic.org]
Sent: Wednesday, March 15, 2017 2:59 PM
To: Harp, William L. (DHP)
Cc: Mertes, Christopher P. (Chris); Jeremiah, Michael P.
Subject: RE: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

Hi Bill,

Warm greetings to you with hopes you are well. Suspect you've a bit overwhelmed after this announcement.

Quick question for you. Do you know why the legislature chose a MME of 120 rather than 90 for an "upper limit" number, particularly given that this differs from the CDC guidelines.

Appreciate any insight you can provide.

Warm regards,

Mark

Mark H. Greenawald, MD, FAAFP
Vice Chair, Academic Affairs and Professional Development
Carilion Clinic Department of Family and Community Medicine
Professor and Vice Chair of Family and Community Medicine
Virginia Tech Carilion School of Medicine
Medical Director of Physician Leadership and Professional Development
Carilion Clinic

CARILION CLINIC

Make encouragement and gratitude a way of life ...

From: Virginia Board of Medicine [medbd@dhp.virginia.gov]
Sent: Tuesday, March 14, 2017 7:22 PM
To: Greenawald, Mark H.
Subject: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

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Virginia Department of Health Professions

Virginia Board of Medicine

Virginia Board of Medicine

Dear Prescriber,

In response to the escalating opioid crisis in Virginia – and recently passed legislation – the Board of Medicine has promulgated regulations on the prescribing of opioids for pain. These regulations, which take effect March 15th, will:

- Provide clear, evidence-based guidance on the proper prescribing for acute and chronic pain.
- Decrease the number of patients who abuse or develop an addiction to opioids.
- Rein in intentional and indiscriminate overprescribing by practitioners who treat pain.

The Board worked diligently with pain experts, addiction experts and stakeholders to

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Wednesday, March 15, 2017 2:21 PM
To: 'Lisa Barr'
Cc: Morton, Colanthia D. (DHP); Deschenes, Jennifer (DHP); Wood, Jennie (DHP)
Subject: RE: Questions re: recent Opioid regs

Lisa:

Thanks for asking, but you would know the answer better than I.

WLH

From: Lisa Barr [mailto:bullseyebarr@gmail.com]
Sent: Wednesday, March 15, 2017 2:14 PM
To: Harp, William L. (DHP)
Cc: Morton, Colanthia D. (DHP); Deschenes, Jennifer (DHP); Wood, Jennie (DHP)
Subject: Re: Questions re: recent Opioid regs

Dr. Harp, what dose of the Naloxone (dosage and number of tabs) should we be prescribing to patients who would fall under scenario number 2 in my earlier email.
Thanks!
Lisa

On Wed, Mar 15, 2017 at 1:35 PM, Harp, William L. (DHP) <William.Harp@dhp.virginia.gov> wrote:

Lisa:

Thanks for your questions.

I have tried to answer the best I can for the Board, and I hope they are somewhat helpful.

WLH

From: Lisa Barr [mailto:bullseyebarr@gmail.com]
Sent: Wednesday, March 15, 2017 11:42 AM
To: Morton, Colanthia D. (DHP); Angel Bingman; Lisa Barr; Bonnie Nock; Rob Spear; David Levi; Scott Horn
Subject: Questions re: recent Opioid regs

Hi Coco, I called your office this am to inquire about several questions we have about the new opioid regs. Sine I placed the call we came up w a few more questions...

At this point we are mostly compliant with the new regs as stated and have been for several years. There are five questions we have based on the most recent correspondence that have currently given us cause for pause.

Questions:

1. If a patient admits to occasional **marijuana use** or their urine drug screen pops + for marijuana then what action should we take? Fortunately, it very rarely comes up for us that our patients are taking more serious street drugs.

The Board of Medicine expects physicians to use good judgement in their care of patients. Obviously you need to speak with the patient about the marijuana, make your treatment decision to continue your treatment, refer for a substance abuse eval, or discontinue treatment, etc. The Board doesn't have a pat answer for this, just that what you do and why you do it should be fully documented in the chart.

2. If we are seeing a patient who is **receiving benzodiazepines from another provider** or is on a benzo for sleep (Ambien for example)- do we need to prescribe Naloxone at the same time we prescribe any opioid for acute or chronic pain?

I believe the answer is yes. These regs are meant to save lives. There would need to be coordination with the other practitioner so that you are on the same page. Controlled substances from more than one doc could lead to an inadvertent OD. There is a provision for "extenuating circumstances" in the regs, in case the benzo is absolutely essential for the patient's well-being.

3. Typically, in the past, because we work hard to pre-screen out drug seeking people from our practice- when we saw **new patients** we **did not routinely urine drug screened them**, especially if they present w clear cause of acute musculo-skeletal pain- like an acute herniated disc. We have been and will continue to PMP each patient who gets any controlled RX. If I read them correctly, the new regs indicate that **we need to urine drug screen these patients as well.** Is this true? If performing a urine drug screen prior to prescribing any opioid is a board requirement then will the board close to loop with the Insurance companies so that they will cover this mandated test or will this be at the expense of the patient? P.S. this can get expensive...

All I can say is-that is what's in the regs. The Board of Medicine has no plans to speak with insurers regarding the regs.

3. Is it true that for **acute pain** we can only prescribe 1 weeks worth of pain meds for **acute pain** patients? If so then would we have to see then weekly if they continue to require opioid RX.

Seven days is in the regs, and it is intended to reduce the total amount of medication prescribed. Again, you see that "extenuating circumstances" appears in this section.

4. What is the board policy on **prn use of pain meds**. For example, we have patients with severely degenerated spines who play golf and want to be able to stay active they may use one short acting opioid three times a week. How do we address the needs of these patients? Especially the ones who can't take NSAIDS and Tylenol doesn't cut it...

Since the Board does not address these situations in these regulations, it would have to make the determination about the standard of care in such a case, based upon the documentation of the treatment.

Our practice has tried to stay ahead of the cure on all of this and we want to make sure we continue to be part of the solution and not part of the problem.

We welcome the input and suggestions of the board and will appreciate a prompt response to these questions.

Thanks so much!

Feel free to call me directly, 757-572-4967 (cell) or 757-422-2967 (office)

Lisa Barr, M.D.

APM Spine and Sports

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Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, April 04, 2017 11:05 AM
To: 'mkuo@lmgdoctors.com'
Cc: Morton, Colanthia D. (DHP); Deschenes, Jennifer (DHP)
Subject: RE: Question regarding naloxone with the new opioid regulations

Dear Dr. Kuo:

The regulations say that naloxone is to be prescribed to patients in certain circumstances.

How far you go beyond writing the prescription and educating the patient is at your discretion.

I hope this is helpful.

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Tuesday, April 04, 2017 10:36 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: Question regarding naloxone with the new opioid regulations

From: Michael Kuo, MD [mailto:mkuo@lmgdoctors.com]
Sent: Friday, March 31, 2017 9:28 AM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Question regarding naloxone with the new opioid regulations

Good morning,

I had a question about the VA Board of Medicine new opioid regulations. We are prescribing Narcan (naloxone) in specific circumstances to patients as outlined by the new regulations. I've noticed that some insurance companies are not covering the medication. How far does our office need to go to help the patient obtain the medication?

Thank you for your help!

Michael

Michael Kuo, MD
Loudoun Spine and Rehabilitation
224D Cornwall Street, NW
Suite 202
Leesburg, VA 20176
Office 703-443-8110

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Thursday, April 06, 2017 5:32 PM
To: 'David Allingham, M. D.'
Subject: RE: Opiate medicated chronic pain question

Dear Dr. Allingham:

Buprenorphine mono-product formulations that are FDA approved for the treatment of pain can be used for chronic pain.

Examples include Belbuca buccal film and Butrans transdermal patch.

D. Buprenorphine is not indicated for acute pain in the outpatient setting, except when a prescriber who has obtained a SAMHSA waiver is treating pain in a patient whose primary diagnosis is the disease of addiction.

C. Buprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose.

I hope this is helpful to you.

WLH

From: David Allingham, M. D. [mailto:annasikoria@aol.com]
Sent: Friday, March 31, 2017 6:40 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Re: Opiate medicated chronic pain question

Hi Dr. Harp,

So, to make it perfectly clear, can buprenorphine without naloxone be prescribed for chronic pain in an extended fashion without tapering?

Warm regards,

David Allingham, M. D.
Mobile 703-963-8422

-----Original Message-----
From: Harp, William L. (DHP) (DHP) <William.Harp@DHP.VIRGINIA.GOV>
To: annasikoria <annasikoria@aol.com>
Cc: Morton, Colanthia D. (DHP) (DHP) <CoCo.Morton@dhp.virginia.gov>
Sent: Fri, Mar 31, 2017 1:44 pm
Subject: RE: Opiate medicated chronic pain question

Dear Dr. Allingham:

The regulations are for the prescribing of buprenorphine products for addiction.

I hope this is helpful.

Kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

-----Original Message-----
From: Board of Medicine
Sent: Thursday, March 30, 2017 5:23 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: Opiate medicated chronic pain question

-----Original Message-----
From: David Allingham MD [mailto:annasikoria@aol.com]
Sent: Wednesday, March 29, 2017 4:53 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Re: Opiate medicated chronic pain question

Another question. What about chronic pain patients receiving Suboxone for off label treatment of chronic pain that have no substance abuse history. Do THEY need monthly counseling by a licensed counselor? Or are they required to get annual counseling like other opiate chronic pain patients?

Thanks!

Sent from my iPhone

> On Mar 27, 2017, at 5:50 PM, Board of Medicine <medbd@DHP.VIRGINIA.GOV> wrote:
>
> You ask about counseling for patients on oxycodone presumably for chronic pain. Please carefully review the regulations below. There does not appear to be a requirement for counseling of chronic pain patients, you may be confusing the regulations that apply to prescribing buprenorphine for addiction treatment.
>
> Part III. Management of Chronic Pain.
> 18VAC85-21-60. Evaluation of the chronic pain patient.
> A. Prior to initiating management of chronic pain with a controlled substance containing an opioid, a medical history and physical examination, to include a mental status examination, shall be performed and documented in the medical record, including:
> 1. The nature and intensity of the pain; 2. Current and past
> treatments for pain; 3. Underlying or coexisting diseases or
> conditions; 4. The effect of the pain on physical and psychological
> function, quality of life and activities of daily living; 5.
> Psychiatric, addiction and substance abuse history of the patient and
> any family history of addiction or substance abuse; 6. A urine drug
> screen or serum medication level; 7. A query the Prescription
> Monitoring Program as set forth in § 54.1-2522.1 of the Code of
> Virginia; 8. An assessment of the patient's history and risk of substance abuse; and 9. A request for prior applicable records.
> B. Prior to initiating opioid treatment for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment to include securely storing the drug and properly disposing of any unwanted or unused drugs. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective.
> 18VAC85-21-70. Treatment of chronic pain with opioids.
> A. Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.
> B. In initiating and treating with an opioid, the practitioner shall:
> 1. Carefully consider and document in the medical record the reasons

> to exceed 50 MME/day; 2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.
> 3. Prescribe naloxone for any patient when risk factors of prior
> overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present; and 4. Document the rationale to continue opioid therapy every three months.
> C. Buprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose.
> D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medications if prescribed.
> E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate healthcare provider, or refer the patient for evaluation and treatment if indicated.
> 18VAC85-21-80. Treatment plan for chronic pain.
> A. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including but not limited to pain relief and improved physical and psychosocial function, quality of life, and daily activities.
> B. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.
> C. The prescriber shall document in the medical records the presence or absence of any indicators for medication misuse, abuse or diversion and shall take appropriate action.
> 18VAC85-21-90. Informed consent and agreement for treatment for chronic pain.
> A. The practitioner shall document in the medical record informed consent, to include risks, benefits and alternative approaches, prior to the initiation of opioids for chronic pain.
> B. There shall be a written treatment agreement, signed by the patient, in the medical record that addresses the parameters of treatment, including those behaviors which will result in referral to a higher level of care, cessation of treatment, or dismissal from care.
> C. The treatment agreement shall include, but not be limited to, notice that the practitioner will query and receive reports from the Prescription Monitoring Program and permission for the practitioner to:
> 1. Obtain urine drug screens or serum medication levels, when
> requested; and 2. Consult with other prescribers or dispensing pharmacists for the patient.
> D. Expected outcomes shall be documented in the medical record including improvement in pain relief and function or simply in pain relief. Limitations and side effects of chronic opioid therapy shall be documented in the medical record.
> 18VAC85-21-100. Opioid therapy for chronic pain.
> A. The practitioner shall review the course of pain treatment and any new information about the etiology of the pain and the patient's state of health at least every three months.
> B. Continuation of treatment with opioids shall be supported by documentation of continued benefit from such prescribing. If the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.
> C. Practitioners shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.
> D. Practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter.
> E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate healthcare provider, or refer the patient for evaluation for treatment if indicated.
> 18VAC85-21-110. Additional consultations.
> A. When necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment.
> B. When a prescriber makes the diagnosis of opioid use disorder, treatment for opioid use disorder shall be initiated or the patient shall be referred for evaluation and treatment.
> 18VAC85-21-120. Medical records for chronic pain.
> The prescriber shall keep current, accurate and complete records in an accessible manner readily available for review to include:
> 1. The medical history and physical examination; 2. Past medical
> history; 3. Applicable records from prior treatment providers and/or
> any documentation of attempts to obtain; 4. Diagnostic, therapeutic
> and laboratory results; 5. Evaluations and consultations; 6. Treatment
> goals; 7. Discussion of risks and benefits; 8. Informed consent and
> agreement for treatment; 9. Treatments; 10. Medications (including
> date, type, dosage and quantity prescribed and refills).

> 11. Patient instructions; and
> 12. Periodic reviews.
>
>
> Any and all statements provided herein shall not be construed as an official policy, position, opinion, or statement of the Virginia Board of Medicine (VBOM). VBOM staff cannot and do not provide legal advice. VBOM staff provides assistance to the public by providing reference to VBOM statutes and regulations; however, any such assistance provided by VBOM staff shall not be construed as legal advice for any particular situation, nor shall any such assistance be construed to communicate all applicable laws and regulations governing any particular situation or occupation. Please consult an attorney regarding any legal questions related to state and federal laws and regulations, including the interpretation and application of the laws and regulations of VBOM.
>
> UNDER NO CIRCUMSTANCES SHALL VBOM, ITS MEMBERS, OFFICERS, AGENTS, OR EMPLOYEES BE LIABLE FOR ANY ACTIONS TAKEN OR OMISSIONS MADE IN RELIANCE ON ANY INFORMATION CONTAINED IN THIS EMAIL.
>
>
> -----Original Message-----
> From: David Allingham MD [mailto:annasikoria@aol.com]
> Sent: Monday, March 27, 2017 1:25 PM
> To: Board of Medicine
> Subject: Opiate medicated chronic pain question
>
> Do Chronic Pain Patients medicated with oxycodone with no history of abuse need to have counseling every month while on this medication?
>
> Thanks!
> DAVID ALLINGHAM, M.D.
>
> Sent from my iPhone

Harp, William L. (DHP)

From: Morton, Colanthia D. (DHP)
Sent: Wednesday, April 12, 2017 5:27 PM
To: Harp, William L. (DHP)
Subject: Voicemail message - Schleicher

1- 3/31 at 3:26pm
Richard ~~Schleicher~~ (SP?) SCHUSHEN
Needs clarification on the new regs
540-986-6153

Colanthia Morton Opher
Operations Manager
Virginia Board of Medicine
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
☎ 804.367.4558
804.527.4463
coco.morton@dhp.virginia.gov

SUBUTEX FOR CHRONIC PAIN

The Virginia Board of Medicine currently licenses: Acupuncturists, Athletic Trainers, Behavior Analysts, Assistant Behavior Analysts, Doctors of Chiropractic, Doctors of Medicine and Surgery, Doctors of Osteopathic Medicine and Surgery, Doctors of Podiatry, Genetic Counselors, Interns & Residents, Midwives, Nurse Practitioners*, Occupational Therapists, Occupational Therapy Assistants, Physician Assistants, Polysomnographic Technologists, Radiological Technologists, Radiological Technologists-Limited, Radiologist Assistants, Respiratory Therapists, Surgical Assistants & Surgical Technologists (*Jointly with the Board of Nursing)

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, May 09, 2017 12:23 PM
To: 'seadoc@aol.com'
Subject: RE: Opiate prescribing

Dear Dr. Clarke:

Thank you for your comments.

I will make sure that the Regulatory Advisory Panel sees your message at its meeting on Monday the 15th.

Kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Monday, May 08, 2017 5:15 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: Opiate prescribing

From: SeaDoc [mailto:seadoc@aol.com]
Sent: Wednesday, May 03, 2017 8:00 AM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Opiate prescribing

Dear Dr. William Harp, i am a retired Boarded Surgeon in general and thoracic surgery , practiced non cardiac thoracic & vascular surgery for nearly 40 years.
In regards to the following attached paragraphs
of the new Opiate regs, I would like to make a comment.

18VAC85-21-40. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

1. A prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record. This shall also apply to prescriptions of a controlled substance containing an opioid upon discharge from an emergency department.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

My comment is this. The commonly used opioids used for post op pain relief are rapidly addicting. These drugs even for post surgical pain management should be allowed to be prescribed for only 7 days, and if an extension is needed, the physician (himself or herself) should be required to sign the refill (not a practice extender).

Would this prove onerous. Yes. But the problem created by these rapidly addicting drugs warrants such measures. Often after 7 days one can successfully shift to non-opioid drugs and other measures.

Thanks for all you do.

John P Clarke, MD, Past President, Virginia Surgical Society
Sent from my iPhone

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, May 09, 2017 2:43 PM
To: 'randssiddiquii@msn.com'
Cc: Morton, Colanthia D. (DHP)
Subject: RE: Question on your and drug screens

Dear Dr. Siddiqui:

Thanks for your questions.

Question 1 is a clinical judgment call. The results of a drug screen should be interpreted in light of all the facts in a case.

Gabapentin has been placed in a category called "drug of concern" because it apparently has been used by drug abusers to augment the high they get from other drugs of abuse.

Good luck with your CME presentation.

WLH

From: Board of Medicine
Sent: Monday, May 08, 2017 4:44 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: Question on your and drug screens

From: Rasheed Siddiqui [mailto:randssiddiqui@msn.com]
Sent: Saturday, May 06, 2017 5:26 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Question on your and drug screens

Dear Dr. Harp

I am a physician board certified by the American Board of anesthesiology with the sub specialty certification in pain medicine. I practice in Charlottesville. My partner and I are giving a lecture/ CME on addiction,opioids and the new regulations concerning prescribing.

Please feel free to forward my question and comment to the state commissioner Dr. Levine if appropriate.

Question 1)If a patient is on long-term opioids for chronic pain but the medication is PRN (short acting opioid) and I obtain a urine drug screen, it is sometimes negative for the opioid. I often get asked by fellow physicians if this is OK and I have been informing them that since the medication is PRN it is OK to have a urine negative for the opioid. Obviously long acting opioids would have to be present in the urine as these are scheduled medications and taken daily.

Question 2) I have noticed gabapentin now is listed on the PMP. Is this considered a sedative/hypnotic? If not I don't understand the rationale for gabapentin on the PMP. Also I realize Lyrica/pre-Gabalin is a scheduled drug. Does the same hold for Lyrica? I tend to use these drugs interchangeably.

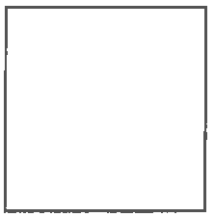
Comment : I believe it is important to inform physicians of opioid induced hyperalgesia (OIH). At times it may be difficult to distinguish from tolerance but physicians should be aware, especially if the physician is considering dose escalation.

I greatly appreciate your time on this matter.

Thank you,

Rasheed Siddiqui MD

On May 2, 2017, at 7:31 PM, Virginia Board of Medicine <medbd@dhp.virginia.gov> wrote:



Virginia Board of Medicine

Virginia Board of Medicine

Dear Colleague:

Here is the Board Briefs newsletter for the Spring of 2017. It has the usual item including the calendar for meetings, recent meeting minutes of the Board and th Advisory Boards, disciplinary actions taken by the Board since the last issue, ar specific items of interest to a number of professions. Since the declaration of a public health emergency by the Virginia Commissioner of Health, Marissa Levin MD, there has been considerable activity by the General Assembly and the Boa of Medicine to address the opioid crisis. You can click on the links below to be taken directly to the items about what the Board has done and how its actions affect your practice and your patients.

- New Pain Management and Buprenorphine Regulations
- Frequently Asked Questions about the Prescribing of Opioids for Pain
- Frequently Asked Questions about the Prescribing of Buprenorphine for Addiction
- Type 1 Continuing Education Courses on Opioids

I hope this issue is informative to you.

Kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

May 9, 2017

William L. Harp, MD
Executive Director
Virginia Board of Medicine
Department of health Professions
Perimeter Center
9960 Mayland Dr, Henrico, VA 23233

Dear Dr. Harp,

Thank you for the opportunity to express support for the Virginia Board of Medicine and the new Opioid Prescribing Regulations. My name is Stephanie Galica – I am the Senior Director of Government Affairs for Adapt Pharma. I have been working in the Substance Use Disorder Treatment Space for over 10 years. Unfortunately, despite increases in physicians prescribing medications to assist treatment, there continues to be an even higher demand for those trying to reach it. I have seen the devastation occurring to the nations communities due to the dramatic increase in opioid overdose deaths. Per the CDC, 91 Americans die every day from an opioid overdose.

This epidemic continues to grow, with the number of overdose deaths increasing again in 2015 to over 33,000, of which nearly half involved a prescription opioid. Virginia, per recently published CDC data, had an over 14% increase in mortality rates over the reporting period of 2014-2015.

For more than 40 years, the opioid antagonist, naloxone, has been used to reverse the effects of an opioid overdose. This is only the first step to helping someone access treatment and creating a pathway to recovery. Expanded access to naloxone in the community has demonstrated, that an adequate dose of naloxone administered in time saves many lives; from 1996 through June 2014, organizations that provide community-based overdose prevention services, including those with in the state of Virginia, recorded more than 26,000 opioid overdose reversals in the United States.

Yet, these rates continue to increase despite the efforts being made. Clinician prescribing of naloxone is a critical next step to increasing the probability that this potentially life-saving medication will be in the right place at the right time. Most opioid overdoses are witnessed, and factors that increase risk have been identified. The Center for Disease Control, American Medical Association, Substance Abuse and Mental Health Services Administration and the American Board of Addiction Medicine are among many organizations, who encourage providers to prescribe naloxone – an opioid antagonist used to reverse opioid overdose.

The Governors announcement of the state of emergency along with legislative action in Virginia has allowed the Board of Medicine and the Board of Pharmacy to address this issue specifically. Opioid prescribing regulations and providing guidelines to those that are at risk of overdosing, is the next step to impact the controllable mortality rates within the state.

Please consider when re-evaluating the details of the recent regulations, that not only effective opioid guidelines be supported but also clearer guidance on prescribing the antidote naloxone in both chronic pain and substance use disorder diagnosed patients. These risks have been outlined in the CDC, AMA and SAMHSA documents. Prescribers should know and be provided the exact definition of those that are at risk to overdose but also those that are at risk to witness an overdose. To ensure an increase in access to naloxone for these patients and caregivers and for the reasons stated above, we support enhancements to the Opioid Guidelines being discussed.

Sincerely,

Stephanie Galica

Senior Director of Government Affairs

Adapt Pharma

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, May 09, 2017 3:24 PM
To: 'Cynthia.williams2@rivhs.com'
Subject: RE: clarification on BOM emergency regulations on opioid prescribing

Dear Ms. Williams:

Yes to #1.

Regarding #2, I will ensure that the Regulatory Advisory Panel sees your question for its meeting on Monday the 15th.

Kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Board of Medicine
Sent: Monday, May 08, 2017 4:48 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: clarification on BOM emergency regulations on opioid prescribing

From: Williams, Cindy [mailto:Cynthia.Williams2@rivhs.com]
Sent: Friday, May 05, 2017 12:00 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: RE: clarification on BOM emergency regulations on opioid prescribing

I am following up on my request below, as well as several additional questions that have come up as I travel throughout the health system and work with our providers to ensure compliance

1. Is Tramadol considered an opioid for the purpose of this regulation and the regulatory requirements?
2. Riverside operates 3 Program of All Inclusive Care of the Elderly (PACE) programs. These patients qualify for assisted living, but receive services in our center so that they can remain at home. They are serviced by a single source pharmacy. Would these patients be exempt from the regulations, or if not, what would be the process to request regulatory change for this category of patient. The largest concern is the dispensing of naloxone for any patient that is co-prescribed an opioid at any dose and a benzodiazepine.

If it would be beneficial to talk via phone, I am happy to call, but have rolled to voice mail each time I have attempted.

Thank you.

Cindy Williams, B.S.Pharm, FASHP
Vice President/Chief Pharmacy Officer
Riverside Health System
856 J Clyde Morris Blvd, Suite C
Newport News, VA

*** NOTE NEW PHONE CONTACT***757-316-5707

From: Williams, Cindy
Sent: Tuesday, April 25, 2017 6:58 AM
To: 'medbd@dhp.virginia.gov' <medbd@dhp.virginia.gov>
Subject: clarification on BOM emergency regulations on opioid prescribing

Good morning,

I am working with our medical group on educating all providers on the emergency regulation on opioid prescribing. In rolling out the regulation, some questions have come up. If you can provide guidance, I will incorporate into future educational efforts.

1. For surgical patients that need acute pain management for more than 14 days after the immediate perioperative period, is the provider then limited to a maximum of 7 days per prescription.
2. For patients needing acute pain management (both surgical and non-surgical) past the specified maximum day supply (7 or 14 day), does the patient need to be seen in person, or can the reassessment be via a structured process via phone.

Thank you

Cindy Williams, B.S.Pharm, FASHP
Vice President/Chief Pharmacy Officer
Riverside Health System
856 J Clyde Morris Blvd, Suite C
Newport News, VA
*** NOTE NEW PHONE CONTACT***757-316-5707

Harp, William L. (DHP)

From: Deschenes, Jennifer (DHP)
Sent: Monday, April 10, 2017 5:30 PM
To: Harp, William L. (DHP)
Subject: FW: Questions regarding directive regarding Narcan

Please double check my answers below.

From: Teresa B. Reed [mailto:treed@selmamed.com]
Sent: Friday, April 07, 2017 2:32 PM
To: Board of Medicine
Subject: Questions regarding directive regarding Narcan

I'm from Selma Medical Associates in Winchester Va. I spoke with someone last week who recommended that any questions regarding Narcan be forwarded for an information sheet that is being created.

-If a patient is taking PRN opiates and benzo's does Narcan need to be prescribed (patient does not use prn meds consistently?

YES, see below excerpt from the Regs.

18VAC85-21-40. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

… 3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

-We have found that the Narcan being dispensed sometimes is syringes and a vial of medication other times it is an auto injector of Narcan. It depends on what the insurance company pays for. What form of Narcan do you recommend?

The Board has not taken a position on the form of Narcan that should be prescribed. The Regs simply state that "Naloxone shall be prescribed."

-What is our responsibility if the patient is self pay or their insurance will not cover the Narcan?

The Regs require that Naloxone be prescribed. It is the patient's decision as to whether he will fill the prescription.

-Should Tramadol be included even though it is a schedule 3?

Tramadol is an opioid.

-What do we do if the patient does not choose to fill the Narcan prescription not refill narcotics?

The Regs require that the Narcan be prescribed. When prescribing the Narcan, the practitioner has an opportunity to educate the patient on the dangers of taking narcotics (dangers to the patient, and to potential family members who may accidentally ingest the narcotics), and the potential life-saving benefit of having Narcan on hand in the case of an accidental overdose. The Regs do not require that the practitioner refuse to refill the patient's narcotics if the patient

elects not to fill the Narcan. Again, if the patient refuses to fill the prescription, the practitioner might want to discuss the risks and benefits of Narcan and document that such a discussion occurred in the patient's medical record, but note that the patient refused and indicate the patient's reason for refusal.

-How often should the Narcan be refilled?

There is no requirement for refills. It is expected that the Narcan would have an expiration date, and so the practitioner might wish to issue a refill on or around the date of expiration.

-Is the prescribing of Narcan for any patient on benzo's and opiates or a patient on benzo's and opiates and exceeds 120 MME/day?

Please see above excerpt from Regs. Any patient who is receiving benzos and opiates concomitantly should be prescribed Narcan. Any patient who is only receiving opioids, but in a dosage that exceeds 120MME/day, should be prescribed Narcan.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Thursday, April 13, 2017 4:16 PM
To: 'Stephen Heretick'
Subject: RE: Prescribing Narcan Outpatient

Steve:

Essentially the same language is found in both sections—ACUTE PAIN and again in CHRONIC PAIN.

Bolding and highlighting added below.

Hope this helps.

WLH

18VAC85-21-40. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

1. A prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record. This shall also apply to prescriptions of a controlled substance containing an opioid upon discharge from an emergency department.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

18VAC85-21-70. Treatment of chronic pain with opioids.

A. Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.

B. In initiating and treating with an opioid, the practitioner shall:

1. Carefully consider and document in the medical record the reasons to exceed 50 MME/day;

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Prescribe naloxone for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present; and

From: Stephen Heretick [mailto:steve@hereticklaw.com]
Sent: Thursday, April 13, 2017 4:02 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: Prescribing Narcan Outpatient

Dr. H—

A follow up question, if you can offer a little further assistance or guidance. Please see below.

It would seem to me that a side prescription for Narcan is a sound practice anytime an opiate is ordered in conjunction with a benzo, regardless of whether the pain to be addressed is acute or chronic. Frankly, it would seem to me that the danger is more pronounced in cases of chronic pain, where a patient may have less ongoing experience with the drug combination and may be more prone to over-medicate in response.

Thanks!

Steve

Stephen E. Heretick, Esquire
715 Loudoun Avenue
Portsmouth, Virginia 23707
(757) 397-9923
(757) 397-9925 (facsimile)
Steve@Hereticklaw.com

From: Obermeyer, Robert MD [mailto:robert.obermeyer@chkd.org]
Sent: Thursday, April 13, 2017 3:50 PM
To: Stephen Heretick <steve@hereticklaw.com>
Subject: Re: Prescribing Narcan Outpatient

Steve
Thank you for the rapid response!
I am sure you have been right more than once today!

There has been a debate in our practice about this because the regs didn't seem to specify that narcan was required by law if the narcotic was for acute postop pain when combined with benzo's. Some of us are reading this regulation to mean Narcan is required by law only if the narcotic is being prescribed for chronic pain and combined with benzo's.

Can you please ask Dr. Harp about this minor but important distinction?

I know the easy answer seems to be to just prescribe Narcan but there other factors that play into this - extra work, drug cost, confusion for the family, drug availability, etc.

Of course, we want all of our patients to be safe, prevent addiction, and we want to be law abiding providers.

Thank you again. I promise to let it go after this.

Bob

Robert J. Obermeyer, MD, FACS, FAAP
Pediatric Surgery
CHKD

On Apr 13, 2017, at 2:46 PM, Stephen Heretick <steve@hereticklaw.com> wrote:

> Dr. Obermeyer—
>
> It appears that, for the first time today, I was actually right. Please see the comments below from Dr. Harp. I hope this helps!
>
> As always, if I can assist you in any possible way, please don't hesitate to let me know.
>
> Steve
>
> Stephen E. Heretick, Esquire
> 715 Loudoun Avenue
> Portsmouth, Virginia 23707
> (757) 397-9923
> (757) 397-9925 (facsimile)
> Steve@Hereticklaw.com
>
> **From:** Harp, William L. (DHP) [mailto:William.Harp@DHP.VIRGINIA.GOV]
> **Sent:** Thursday, April 13, 2017 2:39 PM
> **To:** Stephen Heretick <steve@hereticklaw.com>
> **Subject:** RE: Prescribing Narcan Outpatient
>
> Steve:
>
> Well, you're right.
>
> That's what the regulations say; presence of a benzodiazepine requires a prescription for naloxone.
>
> And Board staff cannot advise anyone differently than what the regs say.
>
> However, we are keenly aware that these regs do not fit everyone's style of practice.
>
> We've had many more comments about the buprenorphine regs than the pain regs.
>
> We're going to reconvene the Regulatory Advisory Panel in May to review the regs and make revisions if deemed necessary.
>
> Hope this helps.
>
> Glad to hear your son is doing well!

WLH

From: Stephen Heretick [mailto:steve@hereticklaw.com]
Sent: Thursday, April 13, 2017 2:27 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: Prescribing Narcan Outpatient

Dr. H—

I received this inquiry from Dr. Robert Obermeyer, the surgeon who saved my son's life last year. I think the answer to his question is yes, but I wanted to run it past the pros for certainty.

Thanks!

Steve

Stephen E. Heretick, Esquire
715 Loudoun Avenue
Portsmouth, Virginia 23707
(757) 397-9923
(757) 397-9925 (facsimile)
Steve@Hereticklaw.com

From: Obermeyer, Robert MD [mailto:robert.obermeyer@chkd.org]
Sent: Thursday, April 13, 2017 1:54 PM
To: Stephen Heretick <steve@hereticklaw.com>
Subject: Fwd: Prescribing Narcan Outpatient

I hope all is well with you and your family! I hear Stephenson is doing great which makes me really happy.

I was hoping you could provide me with some guidance on whether we need to legally send our postop surgery patients home with Narcan if we give them a 2 week course of narcotics (<50MME/d) along with a prescription for Ativan (benzodiazepine) and Robaxin (muscle relaxant). This combo has worked great for pain control after Nuss chest wall reconstruction (which is painful) for over 10 years without a single overdose in over 1000 patients. Also, I don't know of any drug seeking behavior in our patients.

I sent this question to the board via the email link and I am waiting for a response.

I would really appreciate any guidance here at CHKD

My best,
Bob

Robert J. Obermeyer, MD, FACS, FAAP
Pediatric Surgery
CHKD

Begin forwarded message:

From: "Obermeyer, Robert MD" <robert.obermeyer@chkd.org>
Date: April 12, 2017 at 7:35:24 PM EDT
To: "Chicella, Michael" <Michael.Chicella@CHKD.ORG>
Cc: "Robinson, Jim" <James.Robinson@CHKD.ORG>, "Frantz, Frazier W" <Frazier.Frantz@chkd.org>
Subject: FW: Prescribing Narcan Outpatient

We typically only send patients home with a 2 week course... but since we send patients home with **Hydrocodone, Ativan, and Robaxin**
I have two questions

1) Mike: Do you think it would be safer for us to send them home with Narcan?
2) Jim: The VA law as published on the website (not the attached limited brochure) is not clear to me and I wonder if it is stating that we MUST send them home with Narcan.

Please help us with this medico-legal question.
Thank you,
Bob

From: Stout, Samantha
Sent: Wednesday, April 12, 2017 11:07 AM
To: Wiltshire, Amanda (Mandi); Soroka, Amanda P; Fike, Callan M; Kern, Stepfanie; Obermeyer, Robert MD
Subject: FW: Prescribing Narcan Outpatient

Here is an update from Mike in the PICU and his thoughts on sending kids home with narcan.

Samantha R Stout, MSN, CPNP
Pediatric Surgery and Trauma
Children's Hospital of the King's Daughters
601 Children's Ln
Norfolk, VA 23507
Phone: 757-668-9526
Email: Samantha.Stout@chkd.org

From: Chicella, Michael
Sent: Tuesday, April 11, 2017 1:06 PM
To: Stout, Samantha
Subject: RE: Prescribing Narcan Outpatient

Sorry forgot the attachments!

Mike Chicella, Pharm.D., BCPPS, FPPAG
Children's Hospital of The King's Daughters
Department of Pharmacy
Norfolk, VA

From: Chicella, Michael
Sent: Tuesday, April 11, 2017 1:05 PM
To: Stout, Samantha
Subject: RE: Prescribing Narcan Outpatient

A couple of thoughts:

1) I would think the pectus patients fall under the "acute pain" guidelines. The benzodiazepine combination only comes into play if it is for "chronic pain." I attached a copy of the letter to this.
2) You only need to prescribe naloxone if the amount of opioid exceeds 120mg of morphine (similar to 120mg of hydrocodone a day or 80mg of oxycodone a day). If you prescribe hydrocodone 10mg every 6 hours, that is only 40mg morphine equivalents and should not require naloxone. I attached a copy of the CDC calculator info to this.
3) There is a program called the REVIVE program. This includes a brochure for the patients. I have attached a copy. The guidelines lead me to believe the brochure and the education is being done by the outpatient pharmacies. Having said that, when I pick up prescriptions the pharmacist never talks to me, so I don't know how much education is being done...

Hope it helps.... Let me know if you need anything else.
Mike

Mike Chicella, Pharm.D., BCPPS, FPPAG
Children's Hospital of The King's Daughters
Department of Pharmacy
Norfolk, VA

From: Stout, Samantha
Sent: Thursday, April 06, 2017 2:10 PM
To: Chicella, Michael
Subject: Prescribing Narcan Outpatient

Michael,

We were reviewing the new laws when it comes to prescribing narcotics and we had a couple of questions regarding prescribing narcan for outpatient use that I was wondering if you could possibly help us with. The requirements now state that we are required to prescribe narcan if we send home a patient with both a benzo and a narcotic which typically only relates to our pectus patients and the occasional trauma patient if they had an ortho procedure. When it comes to writing the prescription I am reading from UptoDate that it would be 2 or 4mg intranasal, 1 spray and can be repeated every 2-3 min until medical assistance arrives.

Based on what UptoDate states it sounds like there will need to be a lot of teaching about the drug and I would assume this would be done by pharmacy, but outpatient when they fill the script? The other thing is with our pectus patients they typically have their medications filled out here at the farm fresh pharmacy. So am I right to assume they would do teaching down there? Also do you know how easily accessible this drug is to get at pharmacies?

None of us are familiar with prescribing this med either so we wanted to make sure that we're prescribing what is appropriate, providing the appropriate teaching and whether or not this drug will be easy to get when filled.

Any insight would help!
Thanks,

Samantha R Stout, MSN, CPNP
Pediatric Surgery and Trauma
Children's Hospital of the King's Daughters

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Monday, April 24, 2017 1:19 PM
To: 'robert.obermeyer@ckhd.org'
Cc: Morton, Colanthia D. (DHP)
Subject: RE: question

Dear Dr. Obermeyer:

Thank you for your question.

As the regulations currently stand, the answer to your question is YES.

#3 below does not read AND, but rather reads OR for the scenarios listed in #3.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

I hope this is helpful.

With kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: Morton, Colanthia D. (DHP)
Sent: Monday, April 24, 2017 12:51 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: question

From: Board of Medicine
Sent: Monday, April 24, 2017 12:20 PM
To: Morton, Colanthia D. (DHP) <CoCo.Morton@dhp.virginia.gov>
Subject: FW: question

From: Obermeyer, Robert MD [mailto:robert.obermeyer@chkd.org]
Sent: Wednesday, April 12, 2017 7:48 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: question

We have some patients that undergo orthopedic surgery due to trauma or elective surgery with significant pain and muscle spasms.
If I send a patient like this home from the hospital after surgery with acute pain management that includes a two week course of hydrocodone (<50 MME/day) along with Ativan (benzo) and Robxin (muscle relaxant), do I legally have to send them home with Narcan?
I know it may be safer, but I just can't seem to get a clear answer with regards to the law.

Thank you very much,
Dr. Robert J. Obermeyer
Pediatric Surgery
CHKD

Harp, William L. (DHP)

From: Morton, Colanthia D. (DHP)
Sent: Wednesday, April 12, 2017 5:04 PM
To: Harp, William L. (DHP)
Subject: Voicemail - Waxman

Otto Waxman, Stoney Creek Pharmacy
Questions about new regs
434-246-5191

SUBUTEX
OFF-LABEL FOR PAIN

Colanthia Morton Opher
Operations Manager
Virginia Board of Medicine
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
☎ 804.367.4558
804.527.4463
coco.morton@dhp.virginia.gov

Leroy Moore, Jr.
101 Jordan Drive
Hampton, VA. 23666
C: 757-508-0840, H: 757-826-7717

04/10717

Virginia Board of Medicine
Executive Director
9960 Mayland Drive, Suite 300
Henrico, VA 23233

Attn: Dr. William L. Harper, MD

Dear Sir:

I am a citizen living in the commonwealth of Virginia with a concern with the recent regulation on Opioids Prescribing and Bupenorphine.

I am a patient that suffers from acute chronic peripheral neuropathy feet pain, low-back pain, hand wrist extremities pains and leg pains. This pain is throbbing; shooting and burning a great deal of the time, and worsen its peak with changes in weather conditions and lying down.

I have lived and tolerated this condition for 17 years with the well managed and controls of medications. I have been treated with the Opioids. Fentanyl 50 mcg /hand Percocet 7.5-325 for breakthrough pains. During these years I have lived a very fulfilling and productive life and have a quality lifestyle. During this time I followed the pain management doctor's directions and have no apparent addiction problems.

My present pain management doctor advised me some time ago that this promulgated regulation day may come which is now a reality. My doctor pain management doctor (Jeremy Hoff, DO) has recently tried a procedure (Spinal Cord Stimulator Trial) to control the chronic pain and wean me off the Opioids. This neurostimulation system was a failure for me. ***The Fentanyl, 50 mcg/h seem to be the only medians that seem to control my pains.*** I have been prescribed doses of 25 mcg and 75 mcg, along with Morphine, Lyrcia and others in its class. Where I am with respect to doses is where I am comfortable with and want to remain at this level. I have been advised that my current dose will have to be reduced to approximately one-half of the current to be in compliance with the new MME regulations.

The purpose of this letter is to request that my current (MME) dose of Fentanyl 50 mcg/h and Percocet 7.5-325 be assign to me due to extenuating circumstances, 17 years of continuous use with pains that is tolerable. Please exempt me from the 120 MME/day rule. I don't want to be one of the persons looking for narcotics outside the medical system-on-line or the streets.

Thank you for this consideration.

Leroy Moore, Jr.
CC:
Jeremy Hoff, DO
730 Thimble shoals Blvd
Newport News, VA 23606

Harp, William L. (DHP)

From: Morton, Colanthia D. (DHP)
Sent: Monday, April 24, 2017 3:41 PM
To: Harp, William L. (DHP)
Subject: FW: 18 VAC 85-21-10 et seq. ... Error in "Prescriber Regulations Guidelines"

From: Board of Medicine
Sent: Monday, April 24, 2017 12:25 PM
To: Morton, Colanthia D. (DHP) <CoCo.Morton@dhp.virginia.gov>
Subject: FW: 18 VAC 85-21-10 et seq. ... Error in "Prescriber Regulations Guidelines"

From: Tom Small [mailto:njobvu007@gmail.com]
Sent: Sunday, April 23, 2017 7:17 AM
To: PMP (DHP) <PMP@DHP.VIRGINIA.GOV>; healthpolicy@msv.org; Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Re: 18 VAC 85-21-10 et seq. ... Error in "Prescriber Regulations Guidelines"

I received a response from Mr. Orr at Virginia's Prescription Monitoring Program indicating the subject regulations are owned by the Board of Medicine. The following update corrects a misstatement I made in the original email.

Information provided to me by an employee was incorrect. I have spoken directly to my doctor and he IS a pain management specialist, resolving my particular situation.

While this new information resolves my immediate issue, it does not address the discrepancy between the "Regulations" and "Guidelines". I look forward to hearing from the Board of Mecicine on this matter.

Respectfully,
Tom Small
A Severe Chronic Pain Sufferer

On Apr 19, 2017 4:38 PM, "Tom Small" <njobvu007@gmail.com> wrote:

Please note the incongruity between the REGULATIONS and the GUIDELINES. The discrepancy in the GUIDELINES makes the GUIDELINES MUCH more stringent than the REGULATIONS.

PRESCRIBER REGULATIONS GUIDELINES

New Requirements for Treating Chronic Pain

Step 3

- >120 MME/day, document reasonable justification in the medical record AND refer to or consult with a pain management specialist

REGULATIONS

Part III. Management of Chronic Pain

18VAC85-21-70 Treatment of chronic pain with opioids

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses OR refer to or consult with a pain management specialist.

I think you must agree there is a HUGE difference between these two statements.

I have had to use opioid pain medications for over a decade for severe cervical, thoracic and lumbar spine pain. My "pain management doctor" with Sheltering Arms "pain management clinic" is in the process of removing most of my pain medications because his medical degree is not as a pain management specialist. I have a fully documented history of physical therapy, scores of spinal injections, RFA, and trigger point injections. I even tried (unsuccessfully) to have a spinal stimulator installed. The only thing that has helped with pai management has been opioids medications. I have been told I must go to a pain management specialist to continue with opioids in excess of 120MME/day.

Honestly, I feel like a criminal. Nobody wishes my pain could be managed without opiods more than me but history has proven that currently it is the only method that enables me to play with me grand-children, baby sit when needed, travel toTexas to see my daughter and other grandchild. This ability to somewhat function in my life is being taken awy.

Apparently, my doctor is reading the AND and not the OR.

Respectfully,

A Chronic Severe Pain Sufferer

Harp, William L. (DHP)

From: Richard Wood <rick@solusinc.com>
Sent: Wednesday, April 26, 2017 11:08 AM
To: Board of Medicine; Harp, William L. (DHP)
Cc: Rick Wood; idnas44@cox.net
Subject: Emergency Regulations 18VAC85-21-10 through 18VAC85-21-170
Attachments: Sandra VA Board LtrApril 24.docx; Sandra VA Board LtrApril 24.pdf

Dr. Harp and Members of the Virginia Board of Medicine;

We request the Virginia Board of Medicine amend the subject regulations to further clarify and define appropriate extenuating circumstances related to the use of opioids and benzodiazepines by patients with severe chronic illnesses and health histories that require the use of both opioids and benzodiazepines to treat their chronic illnesses, improve their a quality of life, and increase their life expectancy.

Attached are word and pdf docs of a signed letter we have mailed to the Virginia Board of Medicine regarding the subject regulation. Please feel free to rwach out to us if you have any questions or would like additonal information.

Regards

Sandra and Richard Wood
754 Suffolk Lane
Virginia Beach, VA
23452
757-486-3570
richard.wood@solusinc.com
idnas44@cox.net

Sandra and Richard Wood
754 Suffolk Lane
Virginia Beach, VA 23452

April 26, 2017

Virginia Board of Medicine
Executive Director; William L. Harp, M.D.
9960 Maryland Drive
Suite 300
Richmond, VA 23233

Subject: Emergency Regulations 18VAC85-21-10 through 18VAC85-21-170

Dr. Harp and Members of the Virginia Board of Medicine;

We request the Virginia Board of Medicine amend the subject regulations to further clarify and define appropriate extenuating circumstances related to the use of opioids and benzodiazepines by patients with severe chronic illnesses and health histories that require the use of both opioids and benzodiazepines to treat their chronic illnesses, improve their a quality of life, and increase their life expectancy.

We are retired and live a quiet life in Virginia Beach, Virginia. I am affected by several chronic conditions and have been classified by the State of Virginia and the federal government as fully disabled. My husband, Richard, manages my medication to ensure its safe and proper use as directed by my treating physicians.

I am being adversely affected by the subject regulations. The negative impact is a result of actions by my treating physicians in response to the subject regulations. Their reaction may be related to the lack clarity on "appropriate extenuating circumstances" in addition it is our observation that their concern is related to their liability implied in the regulations. Below are details of my medical diagnosis, treatment history, and medication management. In closing we have provided several recommended revisions to the subject regulations.

I am a retired Virginia Beach elementary school teacher who was diagnosed with Bi-Polar and anxiety disorder in 1986, the illness progressed and in 1998 it was determined by the State of Virginia and the federal government I was 100% permanently disabled resulting in my retirement from teaching. In 2011 I was diagnosed with an auto-immune disorder that transitions in and out of remission.

When the disorder is active I am in severe pain and suffers with exhaustion. In 2012 I was diagnosed with arthritis of the spine which produces severe neck and lower back pain at random intervals. Most recently in 2015 I was diagnosed with dementia that may be the early stages of Alzheimer. The treating physicians have defined all of these illnesses as "chronic". Physicians in the appropriate field of medicine manage my treatment for each illness. All of my treating physicians are provided a full record of my illnesses and treatments. Our family doctor is at the center of my treatment regiment and directly manages the long-term care related to the chronic auto-immune and spine arthritis. Specialists in the associated fields manage my treatment for the chronic psychological illnesses.

I am prescribed Lamictal, Effexor and Xanax for the treatment of Bi-polar and Anxiety disorder. For the management of severe pain and associated symptoms related to an auto-immune illness and arthritis of the spine our family doctor prescribes Prednisone, Hydroxyzine, Norco and Cyclobenzaprine. We keep an emergency supply of these medications at home. Promethazine is also available at home to treat side effects from the other medications. An additional medication used for pain is Tylenol. I average 3 pills a week of Hydroxyzine, Norco (5/325) and Cyclobenzaprine. The need for an emergency supply is to allow immediate treatment when the pain flares. The alternative would be at least a 48-72 hour delay to; request the medication, drive to the doctors office to pick up the script, drop the Rx at the pharmacy, and pick up the Rx. This is not rationale or feasible in our case. When the need arises my I am unable to leave the house and my husband can not leave the house due to my other chronic illnesses.

The complexity of my illnesses and the proper use of medication precludes me from having direct access. To ensure all of my medications are used safely and properly my husband controls access and dispenses these in accordance with physician instructions. He takes great care is taken to ensure Xanax and Effexor are not taken within a 6-hour window in which Norco and Cyclobenzaprine were taken. Norco and Cyclobenzaprine are used only if Predisone does not control the flare-up of my auto-immune illness. Norco and Cyclobenzaprine are used only if Tylenol in combination with heat/cold compresses and analgesic ointments are ineffective in relieving my pain.

Over the years of treatment I have been diligent in working with my physicians for a replacement pain medication. I have repeatedly attempted to replace the Norco with other pain medications and treatments, such as anticonvulsant pain medications (Lyrica and Nuerontin), prescription NSAIDs (Celebrex) and I have had steroid injections. However these have not proven effective and/or have negatively affected my Bi-Polar medication.

Despite our best practices to minimize my use of pain medications my physicians are indicating they will either stop the Norco or Xanax. If either would occur I

would suffer greatly. Failing to control my pain would greatly aggravate my mental state and altering my anxiety and mood treatment regiment would aggravate my ability to manage pain. These actions would be extreme measures, especially in light of the fact of the minimal Norco dosage levels I take and the stringent procedures we follow. We believe that my situation is an extenuating circumstance and any change to my medications would negatively impact my quality of life and life expectancy. These observations are supported by published National and State data show on my quality of life and life expectancy. In contrast National and State data show no impact on my quality of life and life expectancy if I continue with my current treatment approach.

Recommended Revisions:
We urge additional clarification to the statement "extenuating circumstance" with examples and supporting evidence for real life cases such as mine. The Board should take into account the impact of mental illness and other chronic conditions that govern the lives and life expectancy of individuals. Below in *underlined italic text* are several suggested revisions.

18VAC85-21-10. Applicability.
A. This chapter shall apply to doctors of medicine, osteopathic medicine, and podiatry and to physician assistants.
B. This chapter shall not apply to:
1. The treatment of acute or chronic pain related to (i) cancer, (ii) a patient in hospice care, or (iii) a patient in palliative care; *(iv) a fully disabled patient with multiple chronic medical diagnosis where each illness has a cause of death rate 5X greater than for opioid use.*
2. The treatment of acute or chronic pain during an inpatient hospital admission or in a nursing home or an assisted living facility that uses a sole source pharmacy; or *is fully disabled and treated at home by a family member under the oversight of the prescribing physicians; or*
3. A patient enrolled in a clinical trial as authorized by state or federal law.

18VAC85-21-70. Treatment of chronic pain with opioids.
A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.
B. In initiating and treating with an opioid, the practitioner shall:
1. Carefully consider and document in the medical record the reasons to exceed 50 MME/day;
2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.
3. Prescribe naloxone for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present; and

4. Document the rationale to continue opioid therapy every three months.
C. Buprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose.
D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medications if prescribed. *Extenuating circumstances include multiple life shortening permanent chronic illnesses that require support and assistance from another person.*
E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation and treatment if indicated.

We appreciate the opportunity to assist the State in improving these regulations and welcome modifications to the subject regulations that recognize the diversity of medical challenges faced each day in an effort to improve the quality of life and extend the life of all residents.

Please feel free to contact us for additional information.

Respectfully,

Sandra Wood

Richard Wood

754 Suffolk Lane
Virginia Beach, VA 23452
(757) 486-0316
rick@solusinc.com
idnas44@cox.net

Harp, William L. (DHP)

From: Board of Medicine
Sent: Wednesday, April 26, 2017 3:14 PM
To: Harp, William L. (DHP)
Subject: FW: Narcan Prescriptions
Attachments: NaloxoneProtocolForPharmacists.pdf

From: David Jacobson [mailto:d.jacobson3@verizon.net]
Sent: Tuesday, April 25, 2017 12:26 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: Narcan Prescriptions

Pain management physician wrote a prescription for Narcan, sent it to CVS electronically and then told us about it. Physician said he's required to write the prescription now for patients taking opioids, doesn't know if we actually have to fill it. Do we have to fill it or can we treat as a standing order that's good for two years (see #3 in attachment)? Dose of opioids is low and overdose possibility minimal.

Thanks for your help.

David Jacobson for the patient and his wife Linda Vansag

Harp, William L. (DHP)

From: Yeatts, Elaine J. (DHP)
Sent: Wednesday, April 12, 2017 2:04 PM
To: Harp, William L. (DHP)
Subject: RE: constituent call- Jennifer Cornell 540-333-9390

Thanks so much

From: Harp, William L. (DHP)
Sent: Wednesday, April 12, 2017 2:04 PM
To: Yeatts, Elaine J. (DHP) <Elaine.Yeatts@DHP.VIRGINIA.GOV>
Subject: RE: constituent call- Jennifer Cornell 540-333-9390

Elaine:

I spoke with Ms. Cornell.

She provided the background that she has had 10 surgeries over the years and has other medical problems. She has taken oxycodone or some other opioid analgesic for 30 years.

At her last visit with her doctor, he told her that Gov. McAuliffe and the DEA were trying to get all patients off opioids. Her doctor said his understanding was that everyone would have to be switched to Suboxone.

I let her speak for 15 minutes or so, and then asked, "Have you read the regulations?" I suggested that she read them and take them on her next visit to her doctor so they can discuss and understand what the regulations require. They do not require everyone to stop their pain medications, and they do not require everyone to take Suboxone.

She thanked me for the call. She said she needed the regulations sent in hard copy, and they are being put in the mail as I type this.

Hope this helps,

Bill

From: Yeatts, Elaine J. (DHP)
Sent: Wednesday, April 12, 2017 12:00 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: constituent call- Jennifer Cornell 540-333-9390

Bill – can you please call her?

From: Ahern, Judith (GOV)
Sent: Wednesday, April 12, 2017 11:11 AM
To: Yeatts, Elaine J. (DHP) <Elaine.Yeatts@DHP.VIRGINIA.GOV>
Subject: constituent call- Jennifer Cornell 540-333-9390

Cover Sheet

MS. Joyce Ann Richardson
5600 Qualla Rd.
Chesterfield, VA. 23832
804-744-4565

VA. [redacted] Board of Medicine
MRS Opher
DR. HARP

These are the Records You requested. Cannot total up cost yet as have one more DR 2 see MCV Takes $300 or so.
Fact that have trouble walkings seems of no concern. 59 yr old disabled people are easy 2 beat down. A lot of us have no one 2 fight 4 us.

Edmund Burke: ALL that it takes for evil 2 succeed is good men do nothing.

Joyce Ann Richardson
5600 Qualla Rd.
Chesterfield, VA 23832

Surgerys: Both wrist carpel Tunnel
Both Knees minisicus tears.
Spine DR Steven Tieore
1st Lower Spine Fusion L-4-L5
2nd: Mid back Fractured disc Bone glue
2nd lower spine = west back L4 L5 clean
out around lower spinal cord
(upcoming sent MRI Results of ~~cervical~~ cervical
spine N Results)

Feet Family practice primary
DR Douglas Wayne Sensory test & biopsy showed
Nerve damage 2 painfull 4 needles 2 get
past ankles. Trial tens unit helped 4 a
while A bit then ~~[illegible]~~ devoked allery 2 gell
conductive pads.
DR Waskins Foot n ankle ~~[illegible]~~ no help
DR ~~Herman~~ [illegible] Cortizole - More Harm then
good 1st med Kept me awake 7DAYS, 2nd
med MADE 75% of HAIR Fall out
Took 9 months after stopped to start
2 grow back in!! Tried him
DR MacMahon described Mentax saying
therapy very expensive no results
DR MARK Jones VA orthopedic 1st DR spent
~~7~~ min in Room sent me inside. DR Jones
took the time to examine feet & structure

Joyce Ann Richardson
5800 Qualla Rd
Chesterfield, VA 23832

blood flow. Said nothing structurally wrong good circulation.
my primary Dr Decker said if it could be fixed he would BE the one. Counsler Dr Martin whin tried hypnosis several time Decided to stop wasting money n wait until somebody could come up with definate answer. Just control the pain. Have tried 2 keep my b.s. A1C almost perfect. Was doing 1 hr on exercise bike and isometric neck exercises. Eating like a health nut doing my best 2 find anything that will help. Several of us have the painfull test that worked 2gether 31 yrs. Rest dont have spinal issues. We have turned over every rock n looked 4 anything else 4 help. I also lost 40 lbs phenomenal 4 me. Then I go in 4 pain med refill and 2 my horror find the Board of medicine and Governor decided no meds 4 elderly 4 pain. Is this a cruel experiment 2 see how much pain the elderly can take? Or maybe a social experiment? Because its hard enough 2 work your entire adult life and try 2 live retired and see

your benifits and rights be taken away.
bit by bit. And dignity. To be lumped
2gether as elderly or seniors is discrimanation!
Just because some of us are no longer able
2 work dosent mean we should be treated like
bums that never worked a day in there lives.
We should at least Be able 2 try 2 enjoy
our time left. At the least!!!. I see this
all around me. Old folks in the donut hole
wondering or struggling 2 pay 4 medication.
And trying 2 find solutions for our
agey selves. Im a animal lover and I
would not treat one of my animals this way.
This letter is hand written because I know
the hearing is the 15th. I am copying and
find some one 2 hire 2 find fame it and
send it 2 all the agencys I work with.
Also sending in the report from I Spine that
wants 2 implant A pacemaker spinal stimulator
in lower spine (3RD surgery) and fuse my entire
cervical spine. Total home care Risky, was
advised 2 do when absolutly had 2. Need 2 set
up cant stock up n wing it like I do most of
mine. Next page the kicker 2 this.

I go in 4 cervical Spine MRI April 21 get disc go home call 2 schedule appt with Surgeon. He has been in a bad accident and is in hospital with cervical spine injuries. Monday 24th they told me he was holding his own. Brilliant Surgeon picked him out of 3. A little bit about myself Worked 2 Jobs in [redacted] high School, graduated Weekend went 2 work Monday till Dec 2'75. Ended that job [redacted] Fri bk 2 work Sunday night 11:00. For 30 years sometimes 2 jobs and plenty of overtime. Feel like I deserve 2 end my life trying 2 save my Surgerys and Control my pain. Not forced into Surgerys and possibly end up dead or in a nursing home because of this decision

please thank Ms Opher for giving me a chance 2 have this old workhorse's position

I Spine papers about Spinal cord stimulator couldn't find They could not [redacted] print me out anything.

Joyce Ann Richardson
5600 Qualla Rd.
Chesterfield, VA 23832
Ph. 804 744 6381

Haven't been able 2 walk enough 2 get 2 computer classes.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, May 09, 2017 3:11 PM
To: Morton, Colanthia D. (DHP)
Subject: RE: question about naloxone

The regulations apply to the prescribers of the Board of Medicine in their writing of opioids and buprenorphine.

So the answer is yes.

I hope this is helpful.

From: Board of Medicine
Sent: Monday, May 08, 2017 4:44 PM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: FW: question about naloxone

From: Pamela Somervell [mailto:pamandlogan@hotmail.com]
Sent: Monday, May 08, 2017 12:16 PM
To: Board of Medicine <medbd@DHP.VIRGINIA.GOV>
Subject: question about naloxone

Are methadone clinics required to provide naloxone prescriptions to patients?

--Pamela Somervell, MD

Agenda Item: Agenda Item: Draft regulations for Licensure by Endorsement

Included in the agenda package:

Copy of Notice of Intended Regulatory Action background document

Copies of regulations from other states

Copy of "draft elements" of licensure by endorsement

Staff note:

From the minutes of the October 20, 2016 board meeting:

Regulatory action for licensure by endorsement…
Dr. Reynolds moved to accept the Credentials Committee recommendation that a NOIRA be issued for the promulgation of rules that would allow the Board to license physicians by endorsement. The motion was seconded and carried unanimously.

There was a comment period on the NOIRA from 1/23/17 to 2/22/17 – no comment was received

Action:

Adoption of recommendation for proposed amendments for consideration by the Board at its meeting on June 22, 2017.

Form: TH-01
11/14

VIRGINIA
REGULATORY TOWN HALL

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC85-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Doctors of Medicine, Osteopathic Medicine, Podiatry, or Chiropractic
Action title	Licensure by endorsement
Date this document prepared	11/2/16

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

The Board intends to propose regulations for licensure by endorsement for physicians who hold licenses in other states and who meet certain requirements established in regulation. The goal of the planned action is establishment of an expedited process for licensure of qualified physicians who want to practice in Virginia, either in person or by telemedicine.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and(2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific

provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:

...
6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...

The Code section relating to authority to issue licenses by endorsement is:

§ 54.1-103. Additional training of regulated persons; reciprocity; endorsement.
A. The regulatory boards within the Department of Professional and Occupational Regulation and the Department of Health Professions may promulgate regulations specifying additional training or conditions for individuals seeking certification or licensure, or for the renewal of certificates or licenses.
B. The regulatory boards may enter into agreements with other jurisdictions for the recognition of certificates and licenses issued by other jurisdictions.
C. The regulatory boards are authorized to promulgate regulations recognizing licenses or certificates issued by other states, the District of Columbia, or any territory or possession of the United States as full or partial fulfillment of qualifications for licensure or certification in the Commonwealth.

Purpose

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.

The Board has reviewed elements of licensure by endorsement that would provide assurance of competency to practice but also discussed potential disqualifiers including disciplinary actions by another state board, malpractice claims, and/or certain criminal convictions. While the Board may be able to license physicians who have had discipline, malpractice claims, or criminal convictions, it may determine that such an applicant requires a full review and would not qualify for an expedited license by endorsement. The intent is to facilitate licensure for physicians who have a demonstrated history of competent, safe practice in order to protect the health and safety of citizens of the Commonwealth who may become their patients.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

The Credentials Committee reviewed some elements of licensure by endorsement, which may include requirements such as: 1) Current, unrestricted license to practice in another U. S. jurisdiction and in good standing in each jurisdiction in which a license is currently held or has been held; 2) Continuous, clinical practice in another U. S. jurisdiction or in federal civil or military service for a period of time immediately preceding application for licensure in Virginia; 3) Current certification by the American Board of Medical Specialties or the Bureau of Osteopathic Specialists or is a diplomate of the American Board of Podiatric Surgery; and 4) Current report from the U.S. Department of Health and Human Services National Practitioner Data Bank (NPDB). Neither the Committee nor the full board has determined which requirements will be included in the proposal, but intends to facilitate licensure for physicians who have an unrestricted license and strong evidence of competency to practice.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no viable alternatives to the selection of the least burdensome and intrusive regulation, since the intent of this action is to expedite licensure for some applicants.

Public participation

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Townhall website , www.townhall.virginia.gov, or by mail, email or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Richmond, VA 23233 or **elaine.yeatts@dhp.virginia.gov** or by fax to (804) 527-4434. Written comments must include the name and address of the

commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

The Credentials Committee of the Board, consisting of six licensed physicians and three citizen members will serve as the Regulatory Advisory Panel to develop proposed regulations resulting from the NOIRA and any comment on the NOIRA.

NC

EXPEDITED LICENSURE ELIGIBILITY REQUIREMENTS

You are eligible for an expedited application if you meet the following four qualifications:

Please check each box that applies to you.

- ☐ completion of specialty board-certification within the past 10 years by (either initial certification or recertification by one of the following:
  - ABMS (American Board of Medical Specialities)
  - AOA (American Osteopathic Association)
  - FRCP (Fellowship of Royal College of Physicians of Canada)
  - FRCS (Fellowship of the Royal College of Surgeons of Canada)
  - CFPC (College of Family Physicians of Canada)
- ☐ currently holds a full unrestricted active license in at least one other state, the District of Columbia, U.S. Territory or Canadian province for the previous five years immediately preceding the application;
- ☐ been active in clinical practice providing patient care for an average of 20 hours or more per week for at least the last two years (you may be required to show proof);
- ☐ and have a clean license application, as defined below.

A clean license application means the following:

1) no professional liability claim(s) or payment(s); (Having never been named in a malpractice lawsuit or had a malpractice lawsuit filed again you-regardless of whether the judgment award, payment or settlement was made in your name or a malpractice settlement or payment was made, affecting or involving you, where no lawsuit was file).
2) no criminal record; (This means that you have never been (1) charged with, (2) arrested for, or (3) convicted of a misdemeanor or felony. This does not include minor traffic offenses such as speeding tickets, but does include being charged with or being arrested for any alcohol related crime);
3) no medical condition(s) which could affect the physician's ability to practice safely;
4) no regulatory board complaint(s), investigation(s), or action(s) (including applicant's withdrawal of a license application);
5) no adverse action taken by a health care institution;
6) no investigation(s) or action(s) taken by a federal agency, the U.S. military, medical societies or associations;
7) no suspension or expulsion from any school, including medical school;

8) if you graduated from a US or Canadian medical school, the school must have been approved by Liaison Commission on Medical Education (LCME) or the Committee for the Accreditation of Canadian Medical Schools (CACMS) or the American Osteopathic Association (AOA) at the time of graduation;
9) you must not have submitted the Puerto Rico Written Examination/Revalida to satisfy the requirements for medical licensure in another jurisdiction.

If you do not meet **all four** requirements, you are not eligible for an expedited license and will need to complete the full license application.

KY

201 KAR 9:023. Endorsement.

RELATES TO: KRS 311.530-311.620, 311.990
STATUTORY AUTHORITY: KRS 311.565
NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565 empowers the State Board of Medical Licensure to exercise all the administrative functions of the state in the prevention of empiricism and in the administrative regulation of the practice of medicine and osteopathy and authorizes the board to establish requirements and standards relating thereto. The purpose of this administrative regulation is to establish standards for the endorsement of a physician by the licensing authority of another jurisdiction to the board.

Section 1. "Endorsement" means the written certification of an authorized officer of a recognized entity that:
(1) An applicant is in good standing, and has successfully completed an examination recognized by the board; and
(2) The endorsing state standards are substantially equivalent to those of the Commonwealth of Kentucky.

Section 2. Endorsement shall result in the fulfillment of examination requirement for licensure if the requirements established by 201 KAR 9:031 have been met.

Section 3. Licensure by Reciprocity. Licensure by reciprocity shall be granted if it is established to the satisfaction of the board that the standards for licensure of the endorsing entity are equivalent to the standards established in the Commonwealth of Kentucky.

Section 4. Endorsing Bodies Recognized by the Board. An applicant may fulfill the examination requirement for licensure without further testing in this state upon certified written endorsement that the applicant has successfully completed an examination approved by the board in accordance with the requirements of 201 KAR 9:031 from any of the following entities:
(1) Licensure authority of another state, United States territory or Canadian province;
(2) National Board of Medical Examiners;
(3) National Board of Osteopathic Medical Examiners, Inc.;
(4) Federation of State Medical Boards of the United States, Inc.; or
(5) United States Medical Licensing Examination administered by the National Board of Medical Examiners and the Federation of State Medical Boards.

Section 5. Endorsement by the Board. The board shall not endorse any physician to the licensure authority of another state, United States territory or Canadian province unless the physician holds a valid, current and effective license to practice medicine or osteopathy in the Commonwealth. (11 Ky.R. 311; eff. 10-9-84; Am. 20 Ky.R. 1652; 2612; eff. 3-14-94.)

Official Website of the
Board of Medicine

BOARD OF MEDICINE

Licensure by Endorsement

What is licensure by endorsement?

Licensure by endorsement is an expedited permanent license for those physicians who qualify. Endorsement is NOT a temporary license issue process nor is it reciprocity.

What are the criteria for licensure by endorsement?

In brief, simple language, for license by endorsement you must:

1. Hold a current license to practice medicine in another US state or Canada that has no disciplinary action, suspension, or restrictions.
2. Be currently ABMS or AOA board certified.
3. Have held an unrestricted license for five years in any US state or Canada.
4. Disclose on the application form any physical or mental impairment that impacts your ability to practice.
5. Disclose any significant (over $50,000) malpractice settlements or judgments in the past 10 years.
6. Complete an affidavit affirming your eligibility and complete a criminal background (fingerprint) check.

Anyone seeking to be licensed to practice medicine in Idaho who is licensed to practice medicine in another state must submit a completed application and documentation that meets the following requirements:

How do I apply for licensure by endorsement?

1. Complete **on-line application** (http://www.fsmb.org/licensure/uniform-application/) as soon as possible.
2. DO NOT request any verifications or certifications.
3. Complete the addendum material and affidavit and mail to the Idaho Board of Medicine.

For a complete copy of the rules for licensure, **click here** (http://adminrules.idaho.gov/rules/current/22/0101.pdf).

04. Five Years Unrestricted Practice. Evidence of five (5) years of unrestricted practice as a licensee of any United States or Canadian jurisdiction. (3-26-08)

053. LICENSURE BY ENDORSEMENT.
An applicant, in good standing with no restrictions upon or actions taken against his license to practice medicine and surgery in a state, territory or district of the United States or Canada is eligible for licensure by endorsement to practice medicine in Idaho. An applicant with any disciplinary action, whether past, pending, public or confidential, by any board of medicine, licensing authority, medical society, professional society, hospital, medical school or institution staff in any state, territory, district or country is not eligible for licensure by endorsement. An applicant ineligible for licensure by endorsement may make a full and complete application pursuant to the requirements of Sections 050, 051 or 052. (5-8-09)

01. Character. An applicant is not eligible for licensure by endorsement if the Board finds the applicant has engaged in conduct prohibited by Section 54-1814, Idaho Code. (5-8-09)

02. Residence. No period of residence in Idaho shall be required of any applicant, however, each applicant for licensure must be legally able to work and live in the United States. Original documentation of lawful presence in the United States must be provided upon request only. The Board shall refuse licensure or renew a license if the applicant is not lawfully present in the United States. (5-8-09)

03 English Language. Each applicant shall speak, write, read, understand and be understood in the English language. Evidence of proficiency in the English language must be provided upon request only. (5-8-09)

04. Application. The applicant shall submit a completed written application to the Board on forms furnished by the Board with the necessary nonrefundable application fee. Any certificate or document required to be submitted to the Board which is not in the English language must be accompanied by a certified translation thereof into English. The application form shall be verified and shall require the original document itself or a certified copy thereof issued by the agency or institution and mailed or delivered directly from the source to the Board or a Board approved credential verification service of the following: (5-8-09)

a. Current, valid, unrevoked, unsuspended, undisciplined license to practice medicine and surgery in a state, territory or district of the United States or Canada shall constitute prima facie evidence of graduation from an acceptable school of medicine, successful completion of the United States Medical Licensing Exam (USMLE) and completion of one (1) year of postgraduate training approved by the ACGME, AOA or Royal College of Physicians and Surgeons of Canada; (5-8-09)

b. Current board certification by a specialty board approved by the American Board of Medical Specialties or AOA; (5-8-09)

c. Five (5) years of contemporaneous active, unrestricted, clinical practice of medicine and surgery as a licensee of a state, territory or district of the United States or Canada; (5-8-09)

d. Disclosure of any past or current mental and physical condition of the applicant, together with disclosure of any previous physical or mental illness which may impact the applicant's ability to practice medicine; (5-8-09)

e. Disclosure of past or pending medical malpractice actions against the applicant within the last ten (10) years and the judgments or settlements, if any, of such claims which exceed fifty thousand dollars ($50,000); (5-8-09)

f. An unmounted photograph of the applicant, of adequate size and clarity to identify the applicant and no larger than four inches tall by three inches wide (4" x 3"), taken not more than one (1) year prior to the date of the application; and (5-8-09)

g. A certified copy of a full set of the applicant's fingerprints on forms supplied by the Board which shall be forwarded to the Idaho Department of Law Enforcement and to the FBI Identification Division for the purpose of a fingerprint-based criminal history check of the Idaho central criminal database and the Federal Bureau of

IOWA BOARD OF MEDICINE

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Permanent Licensure

Eligibility for Permanent Licensure

A permanent license allows an M.D. or D.O. to practice medicine and surgery in Iowa. Eligibility requirements are found in Chapter 9.3.

- Be at least 21 years of age;
- Hold a medical degree from an educational institution accredited by the LCME or the AOA;
- If the applicant does not hold a medical degree from an institution approved by the board, the applicant shall meet one of the following requirements:
  - Hold a valid certificate issued by the ECFMG;
  - Have successfully completed a fifth pathway program established in accordance with AMA criteria;
  - Have successfully passed either a basic science examination administered by a U.S. or Canadian medical licensing authority or SPEX, and have successfully completed three years of postgraduate training in a program approved by the board, and submitted evidence of five years of active practice without restriction as a licensee of any U.S. or Canadian jurisdiction; or
  - Have successfully passed either a basic science examination administered by a U.S. or Canadian medical licensing authority or SPEX and hold board certification by a specialty board approved by ABMS or the AOA, and submit evidence of five years of active practice without restriction as a licensee of any U.S. or Canadian jurisdiction.
- Have successfully completed one year of postgraduate training in a hospital-affiliated program accredited by the ACGME, AOA, Royal College of Physicians and Surgeons of Canada, and the College of Family Physicians of Canada. A graduate of an international medical school shall have successfully completed 24 months of such training.
- Have passed one of the multi-part licensure examinations:
  - USMLE
  - NBME
  - FLEX
  - NBOME
  - COMLEX
  - LMCC

Expedited Endorsement

Expedited endorsement is a process where the board can issue a license based on the acceptance of an applicant's core credentials that have been primary source verified by another jurisdiction's licensing board. Core credentials are those documents that demonstrate the applicant's identity, medical training and practice history. This includes but is not limited to the certification of medical education, medical school diploma, medical school transcript, dean's letter, examination history, ECFMG certificate, fifth pathway certificate, and post-graduate training verification.
Applicants who meet the eligibility requirements for permanent licensure may qualify for expedited endorsement if they meet all of the following requirements:

- Hold at least one permanent U.S. state/jurisdiction or Canadian medical license
- Hold an unrestricted license in every jurisdiction in which the applicant is licensed
- Have no formal disciplinary actions or active or pending investigations by a board, licensing authority, medical society, professional society, hospital, medical school, federal agency, or institution staff sanctions in any state, country or jurisdiction
- Hold current specialty board certification by an ABMS or AOA specialty board - lifetime certification is excluded
- Have been in continuous active practice during the past five years - time spent in post-graduate training is not considered continuous active practice

Applicants who meet these criteria are not required to submit the certification of medical education, medical education transcript, copy of diploma, verification of post-graduate training or ECFMG Status Report in the application process.

Military Service & Veteran Reciprocity

Current military service or veteran applicants who do not meet the eligibility requirements for permanent licensure outlined above may request credit toward any experience or educational requirement for licensure based on military education, training, or service obtained or completed in military service. Credit for military service may not be applied to an examination requirement. Veteran applicants who hold an unrestricted professional license in another jurisdiction may be eligible for licensure through reciprocity.

To request credit of experience or educational requirement, submit the Military Service Application to the Iowa Board of Medicine for consideration.

"Military service" means honorably serving on federal active duty, state active duty, or national guard duty as defined in Iowa Code section 29A.1; in the military services of other states as provided in 10 U.S.C. section 101(c); or the organized reserves of the United States as provided in 10 U.S.C.

"Veteran" means an individual who meets the definition of "Veteran" in Iowa Code section 35.1(2)

Important Information Regarding USMLE and COMLEX

Applicants who have taken more than ten years to complete all three steps of the USMLE or COMLEX and are not specialty board certified by a member board of the American Board of Medical Specialties or American Osteopathic Specialty Boards, should contact the Director of Licensure, at 515-281-6492. Applicants in this situation do not meet the licensure requirements

New Mexico

[16.10.2.9 NMAC - N, 5/1/02; A, 1/20/03; A, 7/1/03; A, 4/3/05; A, 10/7/05; A, 7/1/06; A, 1/10/07; A, 1/3/08; A, 10/11/13; A, 01/15/14]

16.10.2.10 MEDICAL LICENSE BY ENDORSEMENT.

A. Prerequisites for licensure. Each applicant for a license to practice as a medical doctor in New Mexico by endorsement must be of good moral character, hold a full and unrestricted license to practice medicine in another state, and possess the following qualifications:

(1) have practiced medicine in the United States or Canada immediately preceding the application for at least three years;

(2) be free of disciplinary history, license restrictions, or pending investigations in all jurisdictions where a medical license is or has been held;

(3) graduated from a board approved school or hold current ECFMG certification; and

(4) current certification from a medical specialty board recognized by the ABMS.

B. Required documentation for all applicants. Each applicant for a license must submit the required fees as specified in 16.10.9.8 NMAC and the following documentation:

(1) a completed signed application with a passport-quality photo taken within the previous six months; applications are valid for one year from the date of receipt by the board;

(2) verification of licensure in all states or territories where the applicant holds or has held a license to practice medicine, or other health care profession; verification must be received directly from the other state board(s), and must attest to the status, issue date, license number, and other information requested and contained on the form;

(3) two recommendation forms from physicians, chiefs of staff or department chairs or equivalent with whom the applicant has worked and who have personal knowledge of the applicant's character and competence to practice medicine; the recommending physicians must have personally known the applicant and have had the opportunity to personally observe the applicant's ability and performance; forms must be sent directly to the board from the recommending physician; this information will be provided by HSC or another board-approved credentials verification service for applicants using that service, or directly to the New Mexico medical board;

(4) verification of all work experience and hospital affiliations in the last three years, if applicable, not to include postgraduate training; this information will be provided by HSC or another board-approved credentials verification service for applicants using that service, or directly to the New Mexico medical board;

(5) a copy of all ABMS specialty board certifications, if applicable; this information will be provided by HSC or another board-approved credentials verification service for applicants using that service, or directly to the New Mexico medical board; and

(6) the board may request that applicants be investigated by the biographical section of the AMA, the DEA, the FSMB, the national practitioner data bank, and other sources as may be deemed appropriate by the board;

(7) applicants who are not U.S. citizens must provide proof that they are in compliance with the immigration laws of the United States.

C. Licensure process. Upon receipt of a completed application, including all required documentation and fees, the applicant may be scheduled for a personal interview before the board, a board member designated by the board, or an agent of the board and must present original documents as requested by the board. The initial license will be issued following completion of any required interview, or approval by a member or agent of the board.

D. Initial license expiration. Medical licenses shall be renewed on July 1 following the date of issue. Initial licenses are valid for a period of not more than thirteen months or less than one month.

[16.10.2.10 NMAC - N, 1/20/03; A, 7/1/03; A, 4/3/05; A, 10/7/05; A, 7/1/06; A, 1/10/07; A, 10/11/13; A, 01/15/14]

16.10.2.11 TELEMEDICINE LICENSE.

A. Prerequisites for licensure. Each applicant for a telemedicine license must be of good moral character and hold a full and unrestricted license to practice medicine in another state or territory of the United States.

B. Required documentation. Each applicant for a telemedicine license must submit the required fees as specified in 16.10.9.8 NMAC and the following documentation:

(1) A completed signed application, with a passport quality photo taken within six months. Applications are valid for one year from the date of receipt.

Draft Elements for Licensure by Endorsement

1) At least one current, unrestricted license in a U. S. jurisdiction or Canada for the past 5 years.

2) License to practice in another U. S. jurisdiction or Canada is in good standing in each jurisdiction in which a license is currently held or has been held;

- Meaning of "good standing" – no history of disciplinary action; if lapsed, eligible for renewal/reinstatement? Not currently under investigation or restriction?
- U. S. jurisdiction and Canada – including territories, D.C.

3) *Continuous*, clinical practice in another U. S. jurisdiction or in Canada or in federal civil or military service for a period of time immediately preceding application for licensure in Virginia;

- What period of time –36 of the past 60 months?
- Exclude practice in residency training – fellowship?
- Require "continuous" or "active" practice – how to define?
  Average of 20 hours/week; 640 hours/year; other?

4) Current certification by the American Board of Medical Specialties or the Bureau of Osteopathic Specialists or is a diplomate of the American Board of Podiatric Surgery;

- Include Canadian board certifications?

5) Current report from the U.S. Department of Health and Human Services National Practitioner Data Bank (NPDB); and

6) No grounds for denial based on provisions of § 54.1-2915 of the Code of Virginia or regulations of the Board.

Eligibility Requirements:

•Board Certification: certification/recertification within the past 10 years by a speciality board recognized by ABMS, AOA, FRCP, FRCS or CCPC; no exceptions; no grandfathered certification
•Active full and unrestricted license for the past (5) five years immediately preceding the application in a U.S. state, or the District of Columbia or a U.S. Territory or a Canadian province
•Active in clinical practice providing patient care for an average of 20 hours or more per week for the last two years
•Clean license application

Verifications Required for Endorsement process:

•License verifications
•Fingerprints required for background check

Click to link to Application:

https://wwwapps.ncmedboard.org/Clients/NCBOM/Private/PhysicianApplication/PhysicianApplicationExpeditedEligibility.aspx

Like

Pain points Not used often as many physicians do not qualify

Eligibility Requirements:

- If a physician is currently licensed in another state and has no disciplinary action on any of his/her medical licenses.
- If a physician is from an approved medical school, or holds a valid ECFMG cert.
- If a physician is board certified.
- If a physician has practiced full time for the 3 years prior to the license application.

Verifications Required for Endorsement process:

- License verifications
- 3 years of employment (specific form)
- 2 references (specific form)
- Fingerprints required for background check

Click to link to Application:

http://www.nmmb.state.nm.us/docs/license_apps/physicians/MD%20App%20Sept%202016%20-%20BRD%20for%20Web.pdf

Like	Do not need to verify MedEd and Post-grad
Pain points	Need 3 years of employment/privs and 2 references

Eligibility Requirements:

- Successfully passed one of the following: (1) Steps one, two, and three of the USMLE; or (2) Levels one, two, and three of the COMLEX-USA.
- Unrestricted active perm license totaling 5 years. All must be currently active, can be collective amount from multiple states.
- Clinical activity in the last 2 years, NO GAPS. Had to have practiced full 2 years. Can maybe have a small gap if it was for vacation or moving.
- No more than 2 malpractice claims within a 10 year period.
- No more than a $500,000 payout on a single malpractice case.
- No criminal record.
- No suspension or expulsion from any institution of higher education or school, including a medical school.
- No medical condition that could affect medical practice.
- No adverse action taken by health care institution.
- PGY requirements for AMG: 1 year.
- PGY requirements for IMG: 2 years (US training).

Verifications Required for Endorsement process:

- NPDB (**they take this in lieu of their employee recommendation forms**)
- Fingerprints required for background check
- Exams (only if Physician not Board Certified)

Click to link to Application:

http://med.ohio.gov/Portals/0/DNN/PDF-FOLDERS/Applicant/PhysicianLicensureApplication%203_30_17.pdf

Like	Limited verifications.. Unless they are not board cert, reduces timeframe by 66%
Pain points	Needing to obtain the NPDB as it is a week turnaround

Eligibility Requirements:
•No disciplinary inqires or actions in with any State Boards
Verifications Required for Endorsement process:
•FCVS has to be submitted, but NOT complete for the endorsement to issue •License verifications
Click to link to Application: they use the UA application http://www.fsmb.org/licensure/uniform-application/

Like	Reduces timeframe by 83%
Pain points	UA application can be a bit challenging for physician

Eligibility Requirements:

*No yes answers
*Exam year/attempt limits: 7 years, 7 attempts total for all three steps (If more than 1 attempt they will not qualify for the Expedited Temp)
*PGY requirements for AMG: 2
*PGY requirements for IMG: 2
*Dr. must have another Perm state license in good standing for 3 years (training licenses do not qualify)
*Provider must be under 70 years of age

DR'S RESPONSIBILITY:
*Application –Online (UA and FCVS)– PLEASE NOTE: We do not prefill applications
*CS application - Paper
*FCVS is required-but can get expedited while it is in progress
*Personal History/Malpractice documents –

*Notarizations
--UA form
--FCVS form

Verifications Required for Endorsement process:

None

Click to link to Application:

http://www.fsmb.org/

Like	Do not require any verification, timeframe reduced by 81%
Pain points	UA application and FCVS can be a bit challenging for physician

The travel regulations require that "travelers must submit the Travel Expense Reimbursement Voucher with 30 days after completion of their trip". (CAPP Topic 20335, State Travel Regulations, p.7)

In order for the agency to be in compliance with the state travel regulations, please submit your request for today's meeting no later than

June 22, 2017