Legislative Committee Meeting

Virginia Board of Medicine

January 27, 2017
8:30 a.m.

Here you will find a **DRAFT AGENDA** and a **DRAFT PACKET OF SUPPORTING MATERIALS**.

This information is in **DRAFT** form and is subject to change. The official agenda and packet will be approved by the public body at the meeting and will be available to the public pursuant to Virginia Code Section 2.2-3708(D).

Legislative Committee

Virginia Board of Medicine
Friday, January 27, 2016, 8:30 a.m.
9960 Mayland Drive, Suite 200
Board Room 3
Henrico, VA 23233

Page

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

Roll Call

PERIMETER CENTER CONFERENCE CENTER
EMERGENCY EVACUATION OF BOARD AND TRAINING ROOMS
(Script to be read at the beginning of each meeting.)

PLEASE LISTEN TO THE FOLLOWING INSTRUCTIONS ABOUT EXITING THESE PREMISES IN THE EVENT OF AN EMERGENCY.

In the event of a fire or other emergency requiring the evacuation of the building, alarms will sound.

When the alarms sound, leave the room immediately. Follow any instructions given by Security staff.

We are currently in Board Room.

Exit the room using one of the doors at the back of the room. (**Point**) Upon exiting the room, turn **RIGHT.** Follow the corridor to the emergency exit at the end of the hall.

Upon exiting the building, proceed straight ahead through the parking lot to the fence at the end of the lot. Wait there for further instructions.

Agenda Item: **Approval of Minutes of the September 16, 2016**

Staff Note: Draft minutes that have been posted on Regulatory Townhall and the Board's website are presented. Review and revise if necessary.

Action: Motion to approve minutes.

VIRGINIA BOARD OF MEDICINE
LEGISLATIVE COMMITTEE MINUTES

Friday, September 16, 2016 | Department of Health Professions | Henrico, VA

CALL TO ORDER: The meeting convened at 8:34 a.m.

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

MEMBERS PRESENT:
Kevin O'Connor, MD, Vice-President, Chair
Syed Salman Ali, MD
Barbara Allison-Bryan, MD, President
David Giammittorio, MD
The Honorable Jasmine Gore

MEMBERS ABSENT:
Jvinder Toor, MD
Wayne Reynolds, DO

STAFF PRESENT:
William L. Harp, MD, Executive Director
Jennifer Deschenes, JD, Deputy Director, Discipline
Alan Heabrun, Deputy Director, Licensure
Barbara Matusiak, MD, Medical Review Coordinator
Colanthia Morton Opher, Operations Manager
Sherry Gibson, Administrative Assistant
Erin Barrett, JD, Assistant Attorney General

OTHERS PRESENT:
W. Scott Johnson, HDJN
Sara Heisler, VHHA

EMERGENCY EGRESS INSTRUCTIONS

Dr. O'Connor provided the emergency egress instructions.

ADOPTION OF AGENDA

The agenda packet was amended to include the draft unapproved Legislative meeting minutes of the May 20, 2016.

APPROVAL OF MINUTES OF MAY 20, 2016

Dr. Allison-Bryan moved to approve the meeting minutes of May 20, 2016 as presented. The motion was seconded and carried unanimously.

PUBLIC COMMENT

There was no public comment.

NEW BUSINESS

Board Action on Continuing Education Regulations

The Committee reviewed HB319 and draft regulations to implement the law which requires regulatory boards to provide the option of volunteer service to count for continuing education towards licensure renewal.

The Committee agreed that physicians should be encouraged to provide volunteer services. There were two determinations that needed to be made: 1) the number of service hours that would equate to 1 CE hour, and 2) how many CE hours could be earned through volunteer practice. After the discussion, Dr. Allison-Bryan moved to recommend to the full Board that 1 hour of volunteer service equate to 1 hour of Type II CE, and the number of Type II CE hours that could be obtained through service would be capped at 15. The motion was seconded and carried unanimously.

Licensure Parity

Dr. Harp reminded the members that the Executive Committee had recommended a small group be convened to look at the parity issue. It is being brought before the Legislative Committee because 2 of the 3 Board members that volunteered to address this issue are on the Legislative Committee, and any recommended changes may well involve possible statutory changes.

In preparation for this topic, it was recommended that the members read two articles from *Academic Medicine,* the publication of the Association of American Medical Colleges (AAMC): 1) "Is It Time To Rethink Postgraduate Training Requirements For Licensure?", and 2) "Yes, It Is Time To Rethink Postgraduate Training Requirements For Licensure!"

It was noted in the letter from June-Anne Gold, MD, Chair of the International Medical Graduate Section of the AMA, that 17 Boards have parity in postgraduate training for licensure of US, Canadian, and international grads. 37 boards do not have parity. Of those with parity, only 4 boards have 1 year of postgraduate training, and 13 require 2 years or more.

Dr. Ali said that the case could be made for changing to parity in Virginia or keeping the status quo. He questioned whether the difference between the medical education American and international graduates receive should be a determining factor, especially in light of their identical postgraduate training here in the US and passage of the same examinations?

Dr. Allison-Bryan brought up a few issues to consider – what does a license look like in Virginia, how many years before you can apply for a full unrestricted license, and if an

American and an international graduate can be on the same track?

Dr. Ali stated that the standard requirement should not be different as both groups are on equal footing when entering a residency program, however, the identified argument seems to be the ability to moonlight and the possibility of a greater likelihood of discipline by boards.

Dr. Ali noted that if we push the residents out to 3 years, it will cause a major shift in hospital hiring practices and lower the bar. Moonlighting opportunities will then be filled by non-physicians. Also, there is no supporting data to suggest that non-American graduates are disciplined at a higher rate than American graduates. Dr. Alison-Bryant added that there is also no evidence that suggests that 3 years produces a "good doctor".

Dr. Harp mentioned a 2004 study referenced in an article in *Academic Medicine* that indicated a higher rate of discipline for international graduates. He said that Virginia's experience does not support a higher rate of discipline for international medical graduates.

Mr. Heaberlin stated that it is not uncommon for him to receive an application in which the individual started a residency, was given a year's credit, but then asked not to return.

Dr. Harp pointed out that, even though these situations occur, any applicant whose competency to practice is in question will be required to appear before the Credentials Committee prior to being issued a license.

Dr. Harp reminded the Committee that Virginia dropped the postgraduate training requirements from 3 years to 2 years a number of years ago. If it dropped to 1 year with parity, it would be following Georgia and Wisconsin, both of which have 1 year of postgraduate training for all medical graduates.

Citing that advanced practice nurses essentially practice independently, Dr. Ali opined that an individual who has attended 4 years of medical school, completed 1 year of postgraduate training, and passed all required examinations is also capable of practicing independently.

Dr. Allison-Bryan said that perhaps the one place a "general practitioner" continues to practice is in the military. After one year, a military physician may become a General Medical Officer and provide general medical care for 3-4 years before returning to residency. In order to do, they are required to hold a valid license in some state, but would not be able to d in Virginia if more years of postgraduate training were required.

Dr. Harp stated that military physicians reported to the Board have generally not been newly licensed physicians.

Ms. Deschenes confirmed that the Board does not see many newly licensed practitioners just out of school. There have been very few issues with moonlighting residents. She stated that most are about professionalism and character rather than competency.

After discussion, Dr. Ali moved that the Board offer parity with 1-year licensure for all graduates as long as they meet all other educational requirements. The motion was seconded and carried unanimously.

Dr. Harp advised that this motion would require a statutory change and will be presented as such to the full Board in October.

Scott Johnson, General Counsel to the Medical Society of , remarked that Dr. Pandya had brought this concern to MSV for discussion and a possible resolution. Mr. Johnson advised that he would relay the Legislative Committee's recommendation to the MSV Board of Directors for its consideration prior to the 2017 General Assembly.

ANNOUNCEMENTS

There were no additional announcements.

Next meeting – January 17, 2017

Adjournment - With no other business to conduct, the meeting adjourned at 9:14 a.m.

Kevin O'Connor, MD
Vice-President, Chair

William L. Harp, MD
Executive Director

Colanthia M. Opher
Recording Secretary

Agenda Item: **Director's Report**

Staff Note: None.

Action: Informational presentation. No action required.

Agenda Item: **Executive Director's Report**

Staff Note: All items for information only

Action: None.

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Suite 300
Richmond, VA 23294

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www.msv.org

Barbara Allison-Bryan, M.D., President
William L. Harp, M.D., Executive Director
Virginia Board of Medicine
9960 Mayland Drive, Suite 300
Henrico, VA 23233

January 23, 2017

Dear Dr. Allison-Bryan and Dr. Harp,

I am pleased to write you on behalf of the Medical Society of Virginia (MSV) and our 11,000 members across the Commonwealth to support the Board of Medicine's efforts to create a *licensure by endorsement* model.

MSV supports streamlining the licensure of physicians and other health care professionals. Many physicians practice in neighboring states; this new model will reduce the regulatory burden for these physicians to practice in the Commonwealth.

MSV has concerns with an alternative proposal, the physician interstate licensure compact, as it:

- Would require duplicate licensure by physicians practicing in Virginia;
- Does not align with Virginia's disciplinary process; and
- May increase licensure fees

In addition, the Federal Bureau of Investigations (FBI) has noted concerns about the interstate licensure compact.

The *licensure by endorsement* model is an appropriate method to ensure physicians and other health care professionals may become licensed more easily, while satisfying the Commonwealth's requirements to ensure a provider is qualified to serve Virginias.

Should you have any questions or need additional information, please contact MSV's General Counsel, Scott Johnson (sjohnson@hdjn.com or 804-402-6279).

Sincerely,

Bhushan Pandya MD

Bhushan Pandya, M.D.
President

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

SENATE OF VIRGINIA

STEPHEN D. NEWMAN
PRESIDENT PRO TEMPORE
23RD SENATORIAL DISTRICT
ALL OF BOTETOURT AND CRAIG COUNTIES;
PART OF BEDFORD, CAMPBELL, AND ROANOKE
COUNTIES; AND PART OF THE CITY OF LYNCHBURG
P.O. BOX 480
FOREST, VIRGINIA 24551
E-MAIL: SNEWMAN@SENATORNEWMAN.COM
(434) 385-1065

COMMITTEE ASSIGNMENTS:
EDUCATION AND HEALTH, CHAIR
COMMERCE AND LABOR
FINANCE
TRANSPORTATION
RULES

November 16, 2016

David E. Brown, D.C., Director
Virginia Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

Dear Director Brown,

I am writing to request that the Department of Health Professions, with assistance from the Board of Medicine, undertake a study considering licensing a new class of anesthesia providers in the Commonwealth: Certified Anesthesiology Assistants (CAAs). As you know, there is a national shortage of anesthesia providers, including nurse anesthetists. Being able to employ a growing pool of CAAs would help address the present and future shortage of anesthesia providers. For this reason, I believe it would be prudent for the Department to study whether it would be beneficial to license CAAs in Virginia.

It is my understanding that seventeen jurisdictions as well as the District of Columbia currently allow CAAs to practice. Virginia is surrounded by other states that have already adopted the CAA approach (North Carolina, Washington, D.C., Kentucky and Ohio). Although some states have permitted CAAs to practice through delegatory authority, the Board of Medicine has advised that licensure would be required in Virginia.

CAAs work under the direction of licensed physician anesthesiologists to implement anesthesia care plans. CAAs work exclusively within the anesthesia care team environment and, unlike nurse anesthetists; they must be supervised by a physician anesthesiologist.

All CAAs possess a premedical background, a baccalaureate degree and also complete a comprehensive didactic and clinical program at the graduate school level. There are 10 accredited CAA educational programs in the U.S. There is interest in launching a CAA program in Virginia, as well.

There are nearly 2,000 CAAs already practicing throughout the nation. CAA students currently rotate through Virginia hospitals, but must go elsewhere to work when they finish training (i.e. there are currently 10 CAAs who are Virginia residents who have to travel to other states to work).

Because members of the Legislature are considering whether to introduce legislation on this topic, I kindly request that you let us know whether you are willing to undertake this study by December 15, 2016. If you do agree to undertake it, we would further request that you make the results of your study available no later than November 15, 2017.

With kind regards, I remain,

Sincerely yours,

Senator Stephen D. Newman

cc: William L. Harp, M.D., Executive Director of the Board of Medicine

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND

ROBERT D. "BOBBY" ORROCK
POST OFFICE BOX 458
THORNBURG, VIRGINIA 22565

FIFTY-FOURTH DISTRICT

COMMITTEE ASSIGNMENTS:
HEALTH, WELFARE AND INSTITUTIONS (VICE CHAIRMAN)
FINANCE
COUNTIES, CITIES AND TOWNS
AGRICULTURE, CHESAPEAKE AND NATURAL RESOURCES

November 16, 2016

David E. Brown, D.C., Director
Virginia Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

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There are 17 states, as well as the District of Columbia, currently allowing CAAs to practice. Virginia is surrounded by other jurisdictions that have already adopted the CAA approach (North Carolina, Washington, D.C., Kentucky and Ohio). Although some states have permitted CAAs to practice through delegated authority, the Board of Medicine has advised that licensure would be required in Virginia.

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Sincerely,

Robert D. Orrock

Delegate Robert D. Orrock

cc: William L. Harp, M.D., Executive Director, Board of Medicine

DISTRICT: (540) 891-1322 • RICHMOND: (804) 698-1054 • E-MAIL: DEL_ORROCK@HOUSE.STATE.VA.US

VANA 1934
Virginia Association of Nurse Anesthetists
CRNA

November 22, 2016

The Honorable Steve Newman
Virginia Senate
P.O. Box 480
Forest, VA 24551

The Honorable Bobby Orrock
Virginia House of Delegates
P.O. Box 458
Thornburg, VA 22565

Dear Senator Newman and Delegate Orrock,

I am writing on behalf of the Virginia Association of Nurse Anesthetists regarding your possible request to the Department of Health Professions ("DHP") to undertake a study regarding the licensing of Certified Anesthesiology Assistants ("CAA") in Virginia.

VANA represents the more than 1200 certified registered nurse anesthetists ("CRNA") who are licensed in Virginia and who serve as the primary providers of anesthesia care services in Virginia's rural surgical facilities.

As the numbers of people needing critical anesthesia care continues to grow in Virginia, it is important that we ensure a robust pipeline of anesthesia providers to meet current and future anesthesia needs. As such, we support the request for a CAA feasibility study, provided the study is comprehensive and provides clear guidance on whether the licensing of a third anesthesia provider will provide greater access to anesthesia care in Virginia.

To this end, we would kindly ask that, in the event a request for a study moves forward, you would consider the following as part of the request:

1. That DHP consider whether an anesthesia provider shortage currently exists in Virginia and if so, whether there are any immediate steps that can be taken (in terms of CRNA or anesthesiologist practice) to mitigate the shortage.

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Tel: (434) 977-3716 Fax: (434) 979-2439
www.vana.org

VANA 1934
Virginia Association of Nurse Anesthetists
CRNA

2. That DHP consider whether the current and future numbers of CRNA and anesthesiologist students and graduates will meet the projected demand for anesthesia care services in the coming years.

3. That DHP include, as part of any licensing feasibility study, an assessment of the anesthesia delivery costs of CRNAs, anesthesiologist and CAAs.

4. That, given the limited number of clinical sites currently available to health care provider students and new graduates, DHP consider the impact a third anesthesia provider may have on site availability and how this will impact the ability of Virginia's CRNA and anesthesiologist students and new graduates to obtain required clinical experience.

5. The impact, if any, a third anesthesia provider may have on current anesthesia jobs in Virginia.

6. The impact, if any, the licensing of a third anesthesia provider will have in terms of access to anesthesia care, particularly in Virginia's rural regions.

7. That the Virginia Board of Nursing, which licenses CRNAs, assist in the study.

We applaud your interest in ensuring Virginia's citizens have access to anesthesia care and we appreciate your consideration of this request.

Sincerely,

Peter

Peter Deforest
President
Virginia Association of Nurse Anesthetists

cc: Dr. David Brown, Director, Department of Health Professions
Jay Douglas, Executive Director, Board of Nursing
Dr. William Harp, Executive Director, Board of Medicine
Michele Satterlund, McGuireWoods Consulting

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COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov
TEL (804) 367-4400
FAX (804) 527-4475

November 29, 2016

The Honorable Stephen D. Newman
P. O. Box 480
Forest, VA 24551

The Honorable Robert L. Orrock, Sr.
P. O. Box 458
Thornburg, Virginia 22565

Dear Senator Newman and Delegate Orrock,

We are in receipt of your letters requesting that the Department of Health Professions undertake a study of the feasibility of licensure for certified anesthesiology assistants (CAAs). As you may know, the Code of Virginia authorizes the Board of Health Professions to conduct such studies in § 54.1-2510:

§ 54.1-2510. Powers and duties of Board of Health Professions.

2. To evaluate all health care professions and occupations in the Commonwealth, including those regulated and those not regulated by other provisions of this title, to consider whether each such profession or occupation should be regulated and the degree of regulation to be imposed. Whenever the Board determines that the public interest requires that a health care profession or occupation which is not regulated by law should be regulated, the Board shall recommend to the General Assembly a regulatory system to establish the appropriate degree of regulation;

To fulfill its statutory duty, the Board has applied seven criteria to any study of the feasibility of regulating a new profession; its criteria are: 1) risk of harm to the consumer, 2) specialized skills and training, 3) autonomous practice, 4) scope of practice, 5) economic impact, 6) alternatives to regulation, and 7) least restrictive regulation. For further explanation and description of the criteria, the Board has published Guidance Document 75-2, which is available on its website at: http://www.dhp.virginia.gov/bhp/bhp_guidelines.htm. The President of the Board of Medicine is also a member of the Board of Health Professions.

The Board will assume responsibility for a feasibility study but will not have the opportunity to adopt a workplan and timeline for its completion until its next scheduled meeting,

which is February 23, 2017. As soon as the Dr. Elizabeth Carter, Executive Director of the Board and her research staff have reviewed the scope of the work, we will share a preliminary schedule for a report of the study results, which will be provided by November 15, 2017. We have also received a copy of a letter sent to you from the Virginia Association of Nurse Anesthetists; it will be provided to the Board along with your letter of request for the study.

We hope that this information is helpful and appreciate the opportunity to respond to your request. Please let us know if there is anything further we can do to assist your office either between or during the upcoming Session of the General Assembly.

Sincerely,

avid E. Brown, D.C.

cc: The Honorable William A. Hazel, M.D.
Elizabeth Carter, Ph.D.

Agenda Item: **Regulatory Actions**

Staff Note: Ms. Yeatts will speak to the Board of Medicine actions underway.

Action: None.

Agenda Item: Regulatory Actions - Chart of Regulatory Actions
As of January 17, 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*
[18 VAC 85 - 20]	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic	CE credit for volunteer practice [Action 4703] Fast-Track - *Register Date: 1/23/17* *Effective: 3/9/17*
[18 VAC 85 - 40]	Regulations Governing the Practice of Respiratory Therapists	CE credit for volunteer practice and academic course [Action 4706] Fast-Track - *Register Date: 1/23/17* *Effective: 3/9/17*
[18 VAC 85 - 50]	Regulations Governing the Practice of Physician Assistants	Elimination of required submission of certain documents [Action 4629] Fast-Track - *DPB Review in progress* [Stage 7797]
[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]
[18 VAC 85 - 80]	Regulations for Licensure of Occupational Therapists	CE credit for volunteer practice [Action 4702] Fast-Track - *Register Date: 1/23/17* *Effective: 3/9/17*
[18 VAC 85 - 101]	Regulations Governing the Licensure of Radiologic Technology	CE credit for volunteer practice [Action 4704] Fast-Track - *Register Date: 1/23/17* *Effective : 3/9/17*
[18 VAC 85 - 101]	Regulations Governing the Licensure of Radiologic Technology	Removal of traineeships [Action 4707] Fast-Track - *Register Date: 1/23/17* *Effective: 3/9/17*
[18 VAC 85 - 140]	Regulations Governing the Practice of Polysomnographic Technologists	CE credit for volunteer practice [Action 4705] Fast-Track - *Register Date: 1/23/17* *Effective: 3/9/17*
[18 VAC 85 - 150]	Regulations Governing the Practice of Behavior Analysis	increase in hours of CE [Action 4331] Final - *Register Date: 2/6/17* *Effective: 3/8/17*
[18 VAC 85 - 170]	Regulations Governing the Practice of Genetic Counselors [under development]	Initial regulations for licensure [Action 4254] Final - *At Secretary's Office*

Agenda Item: **Legislative Report**

Staff Note: Ms. Yeatts will speak to the bills in the 2017 Session of the General Assembly of interest and relevance to the Board of Medicine.

Action: The Board may choose to discuss selected bills and their impact on the mission of the Board.

Board of Medicine
Report of the 2017 General Assembly

House bills that have duplicate Senate bills are not included

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HB 1484 Board of Counseling to amend regulations governing licensure of occupational therapists.

Chief patron: Bell, Richard P.

Summary as introduced:
Board of Counseling to amend regulations governing licensure of occupational therapists to specify Type 1 continuous learning activities. Directs the Board of Counseling to amend regulations governing licensure of occupational therapists to provide that Type 1 continuing learning activities that shall be completed by the practitioner prior to renewal of a license shall consist of an organized program of study, classroom experience, or similar educational experience that is related to a licensee's current or anticipated roles and responsibilities in occupational therapy and approved or provided by one of the following organizations or any of its components: the Virginia Occupational Therapy Association; the American Occupational Therapy Association; the National Board for Certification in Occupational Therapy; a local, state, or federal government agency; a regionally accredited college or university; or a health care organization accredited by a national accrediting organization granted authority by the Centers for Medicare and Medicaid Services to assure compliance with Medicare conditions of participation. Such regulations shall also provide that Type 1 continuing learning activities may also include an American Medical Association Category 1 Continuing Medical Education program.

HB 1610 Drug Control Act; Schedule I.

Chief patron: Garrett

Summary as introduced:

Drug Control Act; Schedule I. Adds certain chemical substances to Schedule I of the Drug Control Act. The Board of Pharmacy has added these substances to Schedule I in an expedited regulatory process. A substance added via this process is removed from the schedule after 18 months unless a general law is enacted adding the substance to the schedule. The bill also removes two substances, benzylfentanyl and thienylfentanyl, from Schedule I. The bill contains technical amendments.

HB 1637 Possession or distribution of marijuana for medical purposes; Crohn's disease.

Chief patron: Davis

Summary as introduced:
Possession or distribution of marijuana for medical purposes; Crohn's disease. Provides an affirmative defense in a prosecution for the possession of marijuana if the marijuana is in the form of cannabidiol oil or THC-A oil possessed pursuant to a valid written certification issued by a practitioner of medicine or osteopathy licensed by the Board of Medicine for purposes of treating Crohn's disease or alleviating such patient's symptoms. The bill provides that a practitioner shall not be prosecuted for distribution of marijuana for the treatment of or for alleviating the symptoms of Crohn's disease.

HB 1661 Administration of medications to treat adrenal crisis.

Chief patron: Greason

Summary as introduced:
Administration of medications to treat adrenal crisis. Provides that a prescriber may authorize an employee of (i) a school board, (ii) a school for students with disabilities, or (iii) an accredited private school who is trained in the administration of injected medications for the treatment of adrenal crisis resulting from a condition causing adrenal insufficiency to administer such medications to a student diagnosed with a condition causing adrenal insufficiency when the student is believed to be experiencing or about to experience an adrenal crisis pursuant to a written order or standing protocol issued within the course of the prescriber's professional practice and with the consent of the student's parents and provides that an employee of a school board, a school for students with disabilities, or an accredited private school who is trained in the administration of injected medications for the treatment of adrenal crisis resulting from a condition causing adrenal insufficiency who administers or assists in the administration of such medications to a student diagnosed with a condition causing adrenal insufficiency when the student is believed to be experiencing or about to experience an adrenal crisis in accordance with the prescriber's instructions shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment.

HB 1750 Dispensing of naloxone; patient-specific order not required.

Chief patron: O'Bannon

Summary as introduced:
Dispensing of naloxone; patient-specific order not required. Provides that a pharmacist may dispense naloxone in the absence of a patient-specific prescription pursuant to a standing order issued by the Commissioner of Health authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

HB 1885 Opioids; limit on amount prescribed.

Chief patron: Hugo

Summary as introduced:
Prescription of opioids; limits. Provides that a prescriber who prescribes a controlled substance containing an opioid to a patient shall not prescribe an amount greater than a seven-day supply unless (i) in the professional medical judgment of the prescriber, more than a seven-day supply of the controlled substance containing an opioid is required to stabilize the patient's acute medical condition, or (ii) the prescription is for the management of pain associated with cancer, use in palliative or hospice care, or management of chronic pain not associated with cancer. The bill also requires a prescriber to obtain information from the Prescription Monitoring Program at the time of initiating a new course of treatment that includes the prescribing of opioids anticipated to last more than seven consecutive days. Currently, a prescriber must request such information when a course of opioid treatment is expected to last more than 14 consecutive days.

HB 1937 Professions and occupations; active supervision of regulatory boards.

Chief patron: Heretick

Summary as introduced:
Professions and occupations; active supervision of regulatory boards. Establishes a statewide policy for the regulation of professions and occupations specifying criteria for government regulation with the objective of increasing opportunities, promoting competition, encouraging innovation, protecting consumers, and complying with applicable federal antitrust laws. In addition, the bill establishes a process for the active supervision of state regulatory boards pursuant to the U.S. Supreme Court decision in North Carolina State Board of Dental Examiners v. Federal Trade Commission, in which the Court held that a state regulatory board that includes active market participants among its board membership must be actively supervised by the state in order for such board and its members to be entitled to immunity for federal antitrust violations. The bill also creates the Division of Supervision of Regulatory Boards in the Office of the Attorney General to be responsible for the active supervision of regulatory boards.

HB 1956 Prescription drug orders; requirements for shipping Schedule VI controlled substances.

Chief patron: Helsel

Summary as introduced:
Delivery of prescription drug orders; shipping Schedule VI controlled substances. Clarifies requirements related to delivery of prescription drug orders, including delivery of such orders by mail, common carrier, or delivery service. Requires the Board of Pharmacy to adopt regulations for the delivery of prescription orders by mail, common carrier, or delivery service.

HB 2042 Suicide prevention; continuing education requirements for providers.

Chief patron: Murphy

Summary as introduced:
Suicide prevention; continuing education requirements for providers. Requires continuing education related to suicide assessment, treatment, and management for all licensed doctors of medicine, osteopathy, and chiropractic medicine; licensed physician assistants; licensed nurse practitioners; licensed occupational therapists; licensed registered nurses; licensed practical nurses; licensed physical therapists and physical therapy assistants; licensed counselors, substance abuse treatment practitioners, and marriage and family therapists; licensed psychologists; and licensed social workers.

HB 2046 Prescription drug orders; information on proper disposal.

Chief patron: Murphy

Summary as introduced:
Prescription drug orders; information on proper disposal. Requires pharmacies to include written instructions for the proper disposal of unused dispensed drugs, including information about prescription drug disposal programs, in every order for opioids or other prescription drugs dispensed to a patient.

HB 2060 Birth control; definition.

Chief patron: Watts

Summary as introduced:
Birth control; definition. Adds a definition of birth control: "Birth control" means contraceptive methods that are approved by the U.S. Food and Drug Administration. Birth control shall not be considered abortion for the purposes of Title 18.2.

HB 2119 Laser hair removal; limits practice.

Chief patron: Keam

Summary as introduced:
Practice of laser hair removal. Limits the practice of laser hair removal to a person licensed to practice medicine or osteopathic medicine or to a properly trained person under the direction and supervision of a licensed doctor of medicine or osteopathic medicine.

HB 2135 Medical marijuana; written certification.

Chief patron: Levine

Summary as introduced:
Medical marijuana; written certification. Allows a person to possess marijuana or tetrahydrocannabinol pursuant to a valid written certification issued by a physician for the treatment of any medical condition and allows a physician or pharmacist to distribute such substances without being subject to prosecution. Under current law, a person has an affirmative defense to prosecution for possession of marijuana if the marijuana is in certain forms and the person has been issued a written certification by a physician that such marijuana is for the purposes of treating or alleviating the person's symptoms of intractable epilepsy. The bill requires that the person issued the written certification register with the Board of Pharmacy which will issue the person an identification card upon registration. The bill also clarifies that the penalties for forging or altering a recommendation for medical marijuana or for making or uttering a false or forged recommendation are the same as the penalties for committing the same acts with regard to prescriptions.

HB 2153 Durable Do Not Resuscitate Orders; reciprocity.

Chief patron: Rasoul

Summary as introduced:
Durable Do Not Resuscitate Orders; reciprocity. Provides that a Durable Do Not Resuscitate order or other order regarding life-sustaining treatment executed in accordance with the laws of another state in which such order was executed shall be deemed to be valid and shall be given full effect in the Commonwealth.

HB 2164 Drugs of concern; drug of concern.

Chief patron: Pillion

Summary as introduced:
Drugs of concern; gabapentin. Adds any material, compound, mixture, or preparation containing any quantity of gabapentin, including any of its salts, to the list of drugs of concern.

SB 841 Marijuana; possession or distribution for medical purposes, affirmative defense for treatment.

Chief patron: Favola

Summary as introduced:
Possession or distribution of marijuana for medical purposes; affirmative defense for treatment of certain conditions. Provides an affirmative defense to prosecution for possession of marijuana if a person has a valid written certification issued by a practitioner for cannabidiol oil or THC-A oil for treatment of, or to alleviate the symptoms of, cancer, human immunodeficiency virus, acquired immune deficiency syndrome, Tourette syndrome, amyotrophic lateral sclerosis, multiple sclerosis, Crohn's disease, or complex regional pain syndrome. Under current law, only the treatment of intractable epilepsy is covered by the affirmative defense.

SB 848 Naloxone; dispensing for use in opioid overdose reversal, etc.

Chief patron: Wexton

Summary as introduced:
Dispensing of naloxone. Allows a person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for use in opioid overdose reversal and who is acting on behalf of an organization that provides substance abuse treatment services to individuals at risk of experiencing opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a controlled substances registration from the Board of Pharmacy pursuant to § 54.1-3423 to dispense naloxone to a person who has completed a training program on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber,(ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, and (iii) without charge or compensation. The bill also provides that a person who dispenses naloxone shall not be liable for civil damages of ordinary negligence for acts or omissions resulting from the rendering of such treatment if he acts in good faith and that a person to whom naloxone has been dispensed pursuant to the provisions of the bill may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

SB 880 Genetic counselors; licensing; grandfather clause.

Chief patron: Howell

Summary as introduced:
Genetic counselors; licensing; grandfather clause. Extends the deadline from July 1, 2016, to December 31, 2017, by which individuals who have at least 20 years of documented work experience practicing genetic counseling and meet other certain requirements may receive a waiver from the Board of Medicine of the requirements of a master's degree and American Board of Genetic Counseling or American Board of Medical Genetics certification for licensure as a genetic counselor.

SB 922 Dept of Professional and Occupational Regulation and Department of Health Professions; licensure.

Chief patron: Petersen

Summary as introduced:
Department of Professional and Occupational Regulation and Department of Health Professions; licensure, certification, registration, and permitting. Provides that certain powers of the Department of Professional and Occupational Regulation, the Department of Health Professions, and health regulatory boards and certain requirements of persons regulated by such entities apply, inclusively, to permits as well as licenses, certifications, and registrations and to holders of permits as well as holders of such licenses, certifications, and registrations.

SB 972 Requests for information by members of the General Assembly; responses not subject to redaction.

Chief patron: DeSteph

Summary as introduced:
Requests for information by members of the General Assembly; responses not subject to redaction. Requires all departments, agencies, and institutions of the Commonwealth and staff and employees thereof to respond to a request for information made by a member of the General Assembly. The bill further provides that notwithstanding the Virginia Freedom of Information Act (§ 2.2-3700 et seq.), a response to a request for information made by a member of the General Assembly shall not be subject to redaction.

SB 981 Charity health care services; liability protection for administrators.

Chief patron: Stanley

Summary as introduced:
Charity health care services; liability protection for administrators. Provides that persons who administer, organize, arrange, or promote the rendering of services to patients of certain clinics shall not be liable for any civil damages for any act or omission resulting from the rendering of such services unless the act or omission was the result of such persons' or the clinic's gross negligence or willful misconduct.

SB 1009 Telemedicine, practice of; prescribing controlled substances.

Chief patron: Dunnavant

Summary as introduced:
Practice of telemedicine; prescribing. Provides that a health care practitioner who performs or has performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment, for the purpose of establishing a bona fide practitioner-patient relationship may prescribe Schedule II through VI controlled substances to the patient, provided that the prescribing of such controlled substance is in compliance with federal requirements for the practice of telemedicine. The bill also authorizes the Board of Pharmacy to register an entity at which a patient is treated by the use of instrumentation and diagnostic equipment for the purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II through VI controlled substances to possess and administer Schedule II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration.

EMERGENCY

SB 1020 Registration of peer recovery specialists and qualified mental health professionals.

Chief patron: Barker

Summary as introduced:
Registration of peer recovery specialists and qualified mental health professionals. Authorizes the registration of peer recovery specialists and qualified mental health professionals by the Board of Counseling. The bill defines "qualified mental health professional" as a person who by education and experience is professionally qualified and registered by the Board of Counseling to provide collaborative mental health services for adults or children. The bill requires that a qualified mental health professional provide such services as an employee or independent contractor of a mental health service provider licensed by the Department of Behavioral Health and Developmental Services. The bill defines "registered peer recovery specialist" as a person who by education and experience is professionally qualified and registered by the Board of Counseling to provide collaborative services to assist individuals in achieving sustained recovery from the effects of addiction or mental illness, or both. The bill requires that a registered peer recovery specialist provide such services as an employee or independent contractor of the Department of Behavioral Health and Developmental Services, a mental health service provider licensed by the Department of Behavioral Health and Developmental Services, a practitioner licensed by or holding a permit issued from the Department of Health Professions, or a facility licensed by the Department of Health. The bill adds qualified mental health professionals and registered peer recovery specialists to the list of mental health providers that are required to take actions to protect third parties under certain circumstances and notify clients of their right to report to the Department of Health Professions any unethical, fraudulent, or unprofessional conduct. The bill directs the Board of Counseling and the Board of Behavioral Health and Developmental Services to promulgate regulations to implement the provisions of the bill within 280 days of its enactment.

SB 1024 Health care practitioners; reporting disabilities of drivers.

Chief patron: Dunnavant

Summary as introduced:
Health care practitioners; reporting disabilities of drivers. Provides that any doctor of medicine, osteopathy, chiropractic, or podiatry, any nurse practitioner, or any physician assistant who reports to the Department of Motor Vehicles the existence, or probable existence, of a mental or physical disability or infirmity of any person licensed to operate a motor vehicle which the reporting individual believes affects such person's ability to operate a motor vehicle safely is not subject to civil liability unless he has acted in bad faith or with malicious intent.

SB 1027 Cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide.

Chief patron: Marsden

Summary as introduced:
Cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide. Authorizes a pharmaceutical processor, after obtaining a permit from the Board of Pharmacy (the Board) and under the supervision of a licensed pharmacist, to manufacture and provide cannabidiol oil and THC-A oil to be used for the treatment of intractable epilepsy. The bill sets limits on the number of permits that the Board may issue and requires that the Board adopt regulations establishing health, safety, and security requirements for permitted processors. The bill provides that only a licensed

practitioner of medicine or osteopathy who is a neurologist or who specializes in the treatment of epilepsy may issue a written certification to a patient for the use of cannabidiol oil or THC-A oil. The bill also requires that a practitioner who issues a written certification for cannabidiol oil or THC-A oil, the patient issued such certification, and, if the patient is a minor or incapacitated, the patient's parent or legal guardian register with the Board. The bill requires further that a pharmaceutical processor shall not provide cannabidiol oil or THC-A oil to a patient or a patient's parent or legal guardian without first verifying that the patient, the patient's parent or legal guardian if the patient is a minor or incapacitated, and the practitioner who issued the written certification have registered with the Board. Finally, the bill provides an affirmative defense for agents and employees of pharmaceutical processors in a prosecution for the manufacture, possession, or distribution of marijuana. This bill contains an emergency clause.

EMERGENCY

SB 1046 Board of Medicine; requirements for licensure.

Chief patron: Stanley

Summary as introduced:
Board of Medicine; requirements for licensure. Removes provisions related to licensure of graduates of an institution not approved by an accrediting agency recognized by the Board of Medicine. Under the bill, only graduates of institutions approved by an accrediting agency recognized by the Board of Medicine are eligible for licensure.

SB 1062 Definition of mental health service provider.

Chief patron: Deeds

Summary as introduced:
Definition of mental health service provider. Adds physician assistant to the list of mental health service providers who have a duty to take precautions to protect third parties from violent behavior or other serious harm.

SB 1178 Buprenorphine without naloxone; prescription limitation.

Chief patron: Chafin

Summary as introduced:
Prescription of buprenorphine without naloxone; limitation. Provides that buprenorphine mono or products containing buprenorphine without naloxone shall be issued only for a patient who is pregnant.

SB 1179 Secretary of Health and Human Resources; workgroup to establish educational guidelines for training.

Chief patron: Chafin

Summary as introduced:
Secretary of Health and Human Resources; workgroup to establish educational guidelines for training health care providers in the safe prescribing and appropriate use of opioids. Requires the Secretary of Health and Human Resources to convene a workgroup that shall include representatives of

the Departments of Behavioral Health and Developmental Services, Health, and Health Professions as well as representatives of the State Council of Higher Education for Virginia and each of the Commonwealth's medical schools, dental schools, schools of optometry, schools of pharmacy, physician assistant education programs, and nursing education programs to develop educational standards and curricula for training health care providers, including physicians, dentists, optometrists, pharmacists, physician assistants, and nurses, in the safe and appropriate use of opioids to treat pain while minimizing the risk of addiction and substance abuse. The workgroup shall report its progress and the outcomes of its activities to the Governor and the General Assembly by December 1, 2017.

SB 1180 Opioids and buprenorphine; Boards of Dentistry and Medicine to adopt regulations for prescribing.

Chief patron: Chafin

Summary as introduced:
Boards of Dentistry and Medicine; regulations for the prescribing of opioids and buprenorphine. Directs the Boards of Dentistry and Medicine to adopt regulations for the prescribing of opioids and products containing buprenorphine. The bill contains an emergency clause.

EMERGENCY

SB 1220 Telemedicine, practice of prescribing controlled substances.

Chief patron: Barker

Summary as introduced:
Practice of telemedicine; prescribing. Provides that a health care practitioner who performs or has performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment, for the purpose of establishing a bona fide practitioner-patient relationship may prescribe Schedule II through VI controlled substances to the patient, provided that the prescribing of such controlled substance is in compliance with federal requirements for the practice of telemedicine. The bill also authorizes the Board of Pharmacy to register an entity at which a patient is treated by the use of instrumentation and diagnostic equipment for the purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II through VI controlled substances to possess and administer Schedule II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration.

EMERGENCY

SB 1230 Opiate prescriptions; electronic prescriptions.

Chief patron: Dunnavant

Summary as introduced:
Opiate prescriptions; electronic prescriptions. Requires a prescription for any controlled substance containing an opiate to be issued as an electronic prescription and prohibits a pharmacist from dispensing a controlled substance that contains an opiate unless the prescription is issued as an electronic prescription, beginning July 1, 2020. The bill defines electronic prescription as a written prescription that is generated on an electronic application in accordance with federal regulations and is transmitted to a

pharmacy as an electronic data file. The bill requires the Secretary of Health and Human Resources to convene a work group to review actions necessary for the implementation of the bill's provisions and report on the work group's progress to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2017 and a final report to such Chairmen by November 1, 2018.

SB 1232 Limits on prescription of controlled substances containing opioids.

Chief patron: Dunnavant

Summary as introduced:
Limits on prescription of controlled substances containing opioids. Prohibits a prescriber providing treatment for a patient in an emergency department of a corporation, facility, or institution licensed, owned, or operated by the Commonwealth to provide health care from prescribing a controlled substance containing an opioid in a quantity greater than a three-day supply, as determined in accordance with the prescriber's directions for use. The bill also prohibits a pharmacist from dispensing a controlled substance containing an opioid pursuant to a prescription issued by a prescriber providing treatment to a patient in the emergency department of a corporation, facility, or institution licensed, owned, or operated by the Commonwealth to provide health care unless the prescription complies with the requirements of the bill. The bill has an expiration date of July 1, 2021.

SB 1298 Possession or distribution of marijuana for medical purposes; affirmative defense for treatment.

Chief patron: Vogel

Summary as introduced:
Possession or distribution of marijuana for medical purposes; affirmative defense for treatment of certain conditions. Provides an affirmative defense to prosecution for possession of marijuana if a person has a valid written certification issued by a practitioner for cannabidiol oil or THC-A oil for treatment of, or to alleviate the symptoms of, cancer, glaucoma, human immunodeficiency virus, acquired immune deficiency syndrome, hepatitis C, amyotrophic lateral sclerosis, Crohn's disease, Alzheimer's disease, nail patella, cachexia or wasting syndrome, multiple sclerosis, or complex regional pain syndrome. Under current law, only the treatment of intractable epilepsy is covered by the affirmative defense.

SB 1321 Ophthalmic prescriptions and eye examinations; definitions, requirements, penalty.

Chief patron: Carrico

Summary as introduced:
Requirements for ophthalmic prescriptions; eye examinations; penalty. Defines "eye examination" and "ophthalmic prescription" and sets out requirements for each. The bill prohibits the dispensing of eyeglasses or contact lenses unless the patient provides a valid ophthalmic prescription and prohibits ophthalmologists and optometrists from requiring patients to purchase ophthalmic goods, pay additional fees, or sign a waiver or release in exchange for a copy of an ophthalmic prescription. The bill provides that a violation of its requirements is a Class 2 misdemeanor.

SB 1327 Licensure of doctors of medical science.

Chief patron: Carrico

Summary as introduced:
Licensure of doctors of medical science. Establishes criteria for license as a doctor of medical science and establishes the Advisory Board on Doctors of Medical Science.

SB 1403 Board of Pharmacy to deschedule or reschedule cannabidiol upon publication of an interim final rule.

Chief patron: Dunnavant

Summary as introduced:
Board of Pharmacy to deschedule or reschedule cannabidiol upon publication of an interim final rule. Directs the Board of Pharmacy to initiate action to deschedule or reschedule cannabidiol or any product containing cannabidiol that has been approved as a prescription medication by the U.S. Food and Drug Administration pursuant to 21 U.S.C. § 360bb and 21 U.S.C. § 355 within 90 days of publication in the Federal Register of an interim final rule.

SB 1452 Possession or distribution of marijuana for medical purposes; affirmative defense for treatment.

Chief patron: Lucas

Summary as introduced:
Possession or distribution of marijuana for medical purposes; affirmative defense for treatment of certain conditions. Provides an affirmative defense to prosecution for possession of marijuana if a person has a valid written certification issued by a practitioner for cannabidiol oil or THC-A oil for treatment of, or to alleviate the symptoms of, cancer. Under current law, only the treatment of intractable epilepsy is covered by the affirmative defense.

17101304D

SENATE BILL NO. 1046

Offered January 11, 2017

Prefiled January 5, 2017

A BILL to amend and reenact § 54.1-2930 of the Code of Virginia and to repeal § 54.1-2935 of the Code of Virginia, relating to Board of Medicine; requirements for licensure.

Patron—Stanley

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2930 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-2930. Requirements for licensure.

The Board may issue a license to practice medicine, osteopathy, chiropractic, and podiatric medicine to any candidate who has submitted satisfactory evidence verified by affidavits that he:

1. Is 18 years of age or more;

2. Is of good moral character;

3. Has successfully completed all or such part as may be prescribed by the Board, of an educational course of study of that branch of the healing arts in which he desires a license to practice, which course of study and the educational institution providing that course of study are acceptable to the Board; and

4. Has completed at least 12 months of satisfactory postgraduate training in one program or institution approved by an accrediting agency recognized by the Board for internships or residency training. At the discretion of the Board, the postgraduate training may be waived if an applicant for licensure in podiatry has been in active practice for four continuous years while serving in the military and is a diplomate of the American Board of Podiatric Surgery. Applicants for licensure in chiropractic need not fulfill this requirement.

In determining whether such course of study and institution are acceptable to it, the Board may consider the reputation of the institution and whether it is approved or accredited by regional or national educational or professional associations, including ~~but not limited to,~~ such organizations as the Accreditation Council for Graduate Medical Education, Liaison Committee on Medical Education, Council on Postgraduate Training of the American Osteopathic Association, Council on Osteopathic College Accreditation, College of Family Physicians of Canada, Committee for the Accreditation of Canadian Medical Schools, Education Commission on Foreign Medical Graduates, Royal College of Physicians and Surgeons of Canada, or their appropriate subsidiary agencies; by any appropriate agency of the United States government; or by any other organization approved by the Board. ~~Supervised clinical training that is received in the United States as part of the curriculum of an international medical school shall be obtained in an approved hospital, institution or school of medicine offering an approved residency program in the specialty area for the relevant clinical training or in a program acceptable to the Board and deemed a substantially equivalent experience. The Board may also consider any other factors that reflect whether that institution and its course of instruction provide training sufficient to prepare practitioners to practice their branch of the healing arts with competency and safety in the Commonwealth.~~

2. That § 54.1-2935 of the Code of Virginia is repealed.

Agenda Item: **Review and Revision of Draft Guidance Document on the Use of Buprenorphine in the Office-Based Treatment of Addiction**

Staff Note: Here you will find a draft guidance document that was put together by a work group of physicians experienced in medication-assisted treatment. This draft was sent to all members of the work group who thought that this version could stand as the group's final product. At the January 6, 2017 meeting of the Regulatory Advisory Panel on opioid regulations, Tom Reach, MD addressed the panel on the concomitant use of buprenorphine and benzodiazepines. Dr. Reach's thoughts are included after the guidance document for consideration of inclusion as guidance rather than regulation. Staff will make a recommendation at the meeting.

Action: Approve the document as written or with revisions for final approval February 16, 2017 by the full Board.

Guidance on Office-Based Treatment of Opioid Use Disorder

Prefacing Comment

The Governor's Task Force on Prescription Drug and Heroin Abuse, formed in September 2014, recommended in late 2015 that the Board of Medicine form a work group to review the literature on buprenorphine and to make recommendations on acceptable practices for the Board's consideration of promulgating regulations. The Board assembled its Work Group on Buprenorphine in early 2016. The effort brought together physicians of various specialties that were experienced in the treatent of opioid use disorder with buprenorphine as well as representatives from state governmental agencies and insurance companies. At its first meeting on May 13, 2016, the Work Group chose to use the Federation of State Medical Boards "Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office" (2013) as its starting point. With the permission of the Federation, the Model Policy has been edited and revised by the Work Group as its representation of acceptable practices for the physicians, physician assistants, nurse practitioners, and citizens of the Commonwealth. All references in the FSMB document remain included at the end.

Work Group Members

David Buchsbaum, MD
Martin Buxton, MD
Lawrence Conell, MD
Margaret Gregorczyk, MD
Caroline Juran, RPh
Matthew Keats, MD
Robert Lowe, MD
Mary McMasters, MD
Mark Mattingly, MD
Renee Miskimmin, MD
Katherine Neuhausen, MD
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Kellie Randall
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Mark Stevens, MD
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With assistance from Hughes Melton, MD and Art Van Zee, MD

Introduction

The profile of opioid addiction in the United States is changing, in that nonmedical use of prescription opioids has become a problem as significant as the use of heroin. Recent data indicate that approximately 1.6 million persons in the U.S. misused or were addicted to prescription opioids in 2010 [1], while 323,000 persons misused or were addicted to heroin [2]. Despite the dimensions of the problem, nearly 80% of opioid-addicted persons do not receive treatment for their addiction because of limited treatment capacity, financial obstacles, social stigma, and other barriers to care [3].

To address this need, researchers, federal health agencies, and pharmaceutical manufacturers have focused on developing medications that can be used to treat opioid addiction in medical office settings, rather than being limited to use only in specialized Opioid Treatment Programs (OTPs) [4]. As a result of those efforts, two major products are now available for use in office settings: buprenorphine (alone and in combination with naloxone) and naltrexone (in an oral formulation and an extended-release injectable formulation). These medications have been shown to be effective when used in office-based settings in conjunction with behavioral health services, and it is the Board's desire to increase access to medication-

assisted treatment (MAT) for patients with addiction in office-based settings as well as other qualified practice settings.

Regardless of setting, the primary goals of addiction treatment are to cease opioid misuse and abuse and to improve the patient's overall health and social functioning, and to help the patient avoid some of the more serious consequences of opioid use disorder. Treatment can also help patients see their problems from a different perspective, improve self-reliance, and empower them to make positive changes in their lives [8].

Buprenorphine: Buprenorphine is a partial opioid agonist that was approved by the FDA to treat opioid addiction in 2002. It is available in multiple formulations, both as a mono-product of buprenorphine and combined with naloxone. The addition of naloxone to buprenorphine does not reduce the efficacy of the medication when it is taken sublingually, yet it appears to serve as a deterrent to injection misuse [9]. For this reason, the buprenorphine/naloxone combination is the preferred formulation for nearly all patients, with the possible exception of pregnant women, for whom current guidelines recommend use of the mono-product [10]. Physicians should use their clinical judgement to determine if there is a compelling medical reason to use mono-products for non-pregnant patients. Exceptions should be rare, bearing in mind that the presenting history may be inaccurate. Whenever the mono-product is used, extra attention should be given to the risks of misuse and diversion.

Multiple studies have shown that, administered sublingually and at therapeutic doses in appropriately selected patients, buprenorphine is safe and effective [11-15]. The blockade of the opioid receptor imposed by buprenorphine limits the effect of subsequently administered opioid agonists or antagonists, reducing the risk of opioid overdose. The "ceiling effect" appears to confer a higher safety profile and generally milder withdrawal symptoms (compared to full agonists) when the drug is tapered after prolonged administration [16-17].

Nevertheless, overdoses and deaths due to buprenorphine can occur and have been reported [18]. Most overdoses, especially fatal ones, involve concurrent use of other CNS depressants, such as benzodiazepines, other opioids, or alcohol [19-22]. Buprenorphine also poses a significant risk to non-tolerant individuals, especially children [23].

Relatively few serious adverse events have been associated with buprenorphine. Where such events have been reported, most have involved abuse of the drug by injection, rather than sublingual administration in a clinical setting [24-28]. A national evaluation of pharmacotherapies for opioid addiction in Australia involving more than 1,200 patients found no significant difference in rates of serious adverse events between methadone, LAAM, and buprenorphine, or between different doses of buprenorphine [29].

Although early reports based on animal studies suggested that buprenorphine would have a low potential for misuse to achieve euphoria, researchers have documented a measurable level of misuse and diversion of buprenorphine [30-31]. Varying levels of misuse and diversion were predicted by early investigators [32] because buprenorphine is prescribed to high-risk individuals who are addicted to opioids. Subsequent research confirms that misuse and diversion have been reported worldwide wherever buprenorphine has been used for the treatment of addiction [33-36].

Role of Federal Legislation: The use of buprenorphine for the treatment of opioid addiction is governed by the federal Drug Addiction Treatment Act of 2000, commonly referred to as "DATA 2000" (Public Law 106-310, Title XXXV, Sections 3501 and 3502). This legislation is of particular interest to state medical boards because, for the first time in almost a century, it allows physicians to treat opioid addiction with FDA-approved controlled drugs in office-based settings. Specifically,

DATA 2000 allows physicians to use buprenorphine and other controlled substances in CSA Schedules III, IV, and V, which have been approved by the FDA for the treatment of opioid dependence, to treat patients in office-based settings, provided certain conditions are met.

DATA 2000 thus has enlarged treatment capacity by lifting the requirement that patients who need opioid agonist treatment can receive such treatment only in specially licensed opioid treatment programs (OTPs), often referred to as "methadone clinics."

Implementation of DATA 2000 required changes in the oversight systems within the Department of Health and Human Services (HHS) and the Drug Enforcement Administration (DEA). The Secretary of HHS delegated authority in this area to the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration (SAMHSA).

Role of State Medical Boards: The use of opioid agonist medications to treat opioid-addicted patients in the offices of individual physicians significantly increases the role of state medical boards in overseeing such treatment. For this reason, the Federation of State Medical Boards entered into an agreement with SAMHSA to develop model guidelines for use by state medical boards in regulating office-based treatment of addiction. This resulted in the Model Policy adopted by the Federation in 2002 [37].

The Model Policy presented here reflects the large body of research and experience accrued in the decade since buprenorphine was approved in 2002 for the treatment of opioid addiction. The Model Policy is designed to encourage state medical boards to adopt consistent standards, to promote the public health by making appropriate treatment available to opioid-addicted patients, and to educate the regulatory and physician communities about the potential of new treatment modalities for opioid addiction.

The Federation acknowledges with gratitude the efforts of the state Board members and directors who worked to update the Model Policy, as well as the contributions of the independent experts and medical organizations that advised the drafting committee and reviewed its work. The Federation also thanks SAMHSA for its support of this important project.

Section I: Preamble

The Virginia Board of Medicine is obligated under the laws of the Commonwealth of Virginia to protect health and safety of the public through regulation of healthcare professionals. The Board recognizes that enforcing the principles of sound medical practice will ensure that the people of Virginia have access to appropriate, safe and effective medical care, including the treatment of addiction. The application of up-to-date knowledge and evidence-based treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from addiction. Accordingly, the Board acknowledges the body of evidence for the effectiveness of buprenorphine in the office-based treatment of opioid addiction [38], when such treatment is delivered in accordance with current standards of care and the requirements of the Drug Addiction and Treatment Act of 2000 (DATA 2000).

Federal Requirements to Prescribe Buprenorphine for Addiction: Physicians who wish to treat opioid addiction with buprenorphine in their medical offices must demonstrate that they have met the requirements of the DATA 2000 legislation and obtained a waiver from SAMHSA.[i] To qualify for such a waiver, physicians must hold a current controlled substance registration with the Drug Enforcement Administration and a current license in the state in which they practice. They also must meet one or more of the following qualifications [39]:

- Subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties
- Subspecialty board certification in addiction medicine from the American Osteopathic Association
- Addiction certification from the American Board of Addiction Medicine
- Completion of not less than eight hours of training related to the treatment and management of opioid addiction provided by the American Academy of Addiction Psychiatry, the American Society of Addiction Medicine, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or other approved organizations
- Participation as an investigator in one or more clinical trials leading to the approval of an opioid drug in Schedule III, IV, or V or a combination of such drugs for treatment of opioid-addicted patients

To obtain a waiver, a physician must notify SAMHSA in writing of his/her intent to prescribe an approved opioid medication to treat addiction, certifying the physician's qualifications and listing his/her DEA registration number. SAMHSA will then notify DEA whether a waiver has been granted. If SAMHSA grants a waiver, DEA will issue an identification number no later than 45 days after receipt of the physician's written notification. If SAMHSA does not act on the physician's request for a waiver within the 45-day period, DEA will automatically assign the physician an identification number. This process is explained, and can be accessed at the following website: http://buprenorphine.samhsa.gov/howto.html.

If a physician wishes to prescribe or dispense an appropriately available and approved opioid medication for maintenance treatment or detoxification on an emergency basis before the 45-day waiting period has elapsed, the physician must notify SAMHSA and the DEA of his/her intent to provide such emergency treatment.

In addition to a waiver, a physician who wishes to prescribe buprenorphine or another approved opioid for the treatment of addiction in the office setting must have a valid DEA registration number and a DEA identification number that specifically authorizes him or her to engage in office-based opioid treatment.

Prescription Requirements: Prescriptions for buprenorphine and buprenorphine/naloxone must include full identifying information for the patient, including his/her name and address, the drug name, strength, dosage form, quantity, and directions for use. Prescriptions for buprenorphine and/or buprenorphine/naloxone must be dated as of, and signed on, the day they are issued. (21)

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[i] The "waiver" allows an exception to the Harrison Narcotics Act of 1914, which made it illegal for a physician to prescribe an opioid to any patient with opioid addiction for the purpose of managing that addiction or acute withdrawal. Prior to DATA 2000, the only exception to the Harrison Act was federal legislation that allowed the establishment of methadone maintenance treatment (MMT) clinics, now referred to as Opioid Treatment Programs (OTPs). That exception only allowed the use of methadone to treat addiction or withdrawal within specially licensed and regulated facilities, but not in office-based medical practices (CFR 1306.05[a]). Both the physician's regular DEA registration number and the physician's DATA 2000 identification number (which begins with the prefix X) must be included on the prescription (21 CFR 1301.28 [d][3]). [39]

For detailed guidance, physicians are referred to the Buprenorphine Clinical Practice Guidelines published by CSAT/SAMHSA, which can be accessed at http://www.samhsa.gov/centers/ csat/opat.html.

State Medical Board Requirements: The Virginia Board of Medicine will determine the appropriateness of a particular physician's prescribing practices on the basis of that physician's overall treatment of patients and the available documentation of treatment plans and outcomes. The goal is to provide appropriate treatment of the patient's opioid addiction, either directly or through referral, while adequately addressing other aspects of the patient's functioning, including co-occurring medical and psychiatric conditions and pressing psychosocial issues.

Section II: Guidelines

Multiple studies have shown that opioid addiction treatment with buprenorphine can be successfully integrated into office practice by physicians who are not addiction specialists. In such studies, patient outcomes are comparable to or better than outcomes of patients treated in specialized clinics [40-48]. However, as in the treatment of any medical disorder, physicians who choose to offer addiction treatment need to understand the nature of the underlying disorder, the specific actions of each of the available medications, as well as any associated contraindications or cautions, and the importance of careful patient selection and monitoring [40].

The Board has adopted the following guidelines for the treatment of opioid addiction in office-based settings. The guidelines are not a complete compendium on best practices in qualified office practice settings, but rather a communication to prescribers regarding what the Board considers to be acceptable professional practice.

Physician Qualifications: The diagnosis and medical management of the disease of addiction, including opioid addiction, should be based on current knowledge and research and should encompass the use of both pharmacologic and nonpharmacologic treatment modalities. Thus, before beginning to treat patients for opioid addiction, the physician should become knowledgeable about opioid addiction and its treatment, including the use of approved pharmacologic therapies and evidence-based nonpharmacologic therapies [49-50].

As described in the Preamble, physicians who wish to prescribe or dispense buprenorphine for the treatment of opioid addiction must meet the requirements of DATA 2000 [51], which are that the physician must be licensed in the state, have a valid DEA controlled substances registration and identification number, comply with federal and state regulations applicable to controlled substances, and hold a current waiver [39].

In addition to these requirements, regulations limit the number of patients that a physician is permitted to treat at any one time to 30 in the first year after obtaining a waiver, then 100 for a year or more, and then to 275 patients thereafter. The physician who wishes to treat more than 30 patients after the first year must file an application with the DEA to extend his/her waivered capacity to do so [39,51]. Likewise, a physician who has treated 100 patients for at least one year must apply to treat up to 275 patients per year. To do so, a physician must have additional credentialing or practice in a qualified practice setting. Details can be found at http://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/understanding-patient-limit275.pdf

DATA 2000 also requires that a physician who wishes to treat opioid addiction with buprenorphine in the office setting must demonstrate a capacity to offer, or refer patients for, appropriate counseling and other ancillary services, and to recognize when those services are needed [51].

Physicians have not been permitted to delegate the prescribing of buprenorphine to non-physicians. However, with the passage of the Comprehensive Addiction and Recovery Act in July 2016, physician assistants and nurse practitioners will be able to prescribe buprenorphine for opioid use disorder.

Physician assistants and nurse practitioners must take 24 hours of training on the topics of opioid maintenance and detoxification, clinical use of all FDA-approved drugs for medication-assisted treatment, patient assessment, treatment planning, psychosocial services, staff roles and diversion control. They will be able to apply in early 2017 to treat 30 patients.

Physicians should review and comply with the DEA regulations (Title 21 US Code of Controlled Substances Act 1301.28 and 21 USC 823 9GO(2)(G) [51]. Review of the resources available on the DEA's website (at www.deadiversion.usdoj.gov) , the Virginia Drug Control Act, Board of Pharmacy and Board of Medicine regulations and guidance documents governing the issuance of prescriptions for controlled substances is strongly recommended.

Patient Assessment: The following is not meant to be an all-inclusive list but suggestive of what needs to be in the assessment. For more details, refer to the American Society of Addiction Medicine National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Abuse.

The objectives of the patient assessment are to determine a given patient's eligibility for treatment, to provide the basis for a treatment plan, and to establish a baseline measure for use in evaluating a patient's response to treatment. Accordingly, the assessment should be designed to achieve the following [49,53]:

- Establish the diagnosis of opioid addiction, including the duration, pattern and severity of opioid misuse; the patient's level of tolerance; results of previous attempts to discontinue opioid use disorder; past experience with agonist therapies; the nature and severity of previous episodes of withdrawal; and the time of last opioid use and current withdrawal status
- Document the patient's use of other substances, including alcohol and other drugs of abuse, date of last use, route of administration, injection history, intranasal use, presence of track marks, and history of seizures
- Identify comorbid medical and psychiatric conditions and disorders and to determine how, when and where they will be addressed
- Screen for communicable diseases and address them as needed
- Evaluate the patient's level of physical, psychological and social functioning or impairment
- Assess the patient's access to social supports, family, friends, employment, housing, finances and legal problems
- Determine the patient's readiness to participate in treatment

Assessment usually begins at the time of the patient's first office visit and continues throughout treatment. Consensus opinion is that an initial patient assessment should include the following:

- Medical and psychiatric history
- Substance abuse history
- Evaluation of family and psychosocial supports
- Appropriate examination in accordance with state and federal law, COV §54.1-3303, focused on evaluating neurocognitive function, identifying sequelae of opioid addiction, and looking for evidence of severe hepatic dysfunction [10,53]
- Urine drug screen or other toxicologic screen should be included in the initial evaluation to confirm recent opioid use disorder and to screen for unreported use of other drugs
- Access the patient's prescription drug use history through the Virginia Prescription Monitoring Program, both to confirm compliance in taking prescribed medications and to detect any unreported use of other prescription medications

The drug screen should include all opioids commonly prescribed and/or misused in the local community, as well as illicit drugs that are available locally [54]. It also is advisable to strongly suggest a pregnancy test for all women of childbearing age and HIV, Hepatitis B and C, and tuberculosis testing for all patients.

Information from family members and significant others can provide useful additional perspectives on the patient's status, as can contact with or records from clinicians who have treated the patient in the past [46].

Treatment Planning: There is an emerging consensus among addiction experts that treatment medications such as buprenorphine should be considered as an option for every opioid-addicted patient [38]. However, the failure to offer medication-assisted treatment does not in itself constitute substandard care. No single treatment is appropriate for all persons at all times. Therefore, an individualized treatment plan is critical to the patient's ultimate success in returning to productive functioning [5,54].

The treating physician should balance the risks and benefits of medication-assisted treatment in general, and treatment with buprenorphine in particular, against the risks associated with no treatment or treatment without medication [4,55]. Psychosocial and other nonpharmacologic interventions often are useful components of treatment [48,50,55]. Such interventions typically work best in conjunction with medication-assisted therapies. In fact, there is some evidence that the combination of pharmacologic and non-pharmacologic interventions may be more effective than either approach used alone [56]. As noted earlier, the ability to offer patients psychosocial supports, either on-site or through referral, is a requirement of the DATA 2000 legislation. Given that the evidence for the combination of buprenorphine products and psychosocial supports results in better outcomes for patients, this combined treatment approach is considered best practice unless there are specific reasons not to use it. In cases where combined treatment is not appropriate for a particular patient other options may include:

- Simple detoxification under limited circumstances and no other treatment
- Detoxification followed by antagonist therapy
- Counseling and/or peer support without medication-assisted therapy
- Referral to short- or long-term residential treatment
- Referral to an OTP for methadone maintenance

Patients may be suitable candidates for treatment with buprenorphine even if past treatment episodes were not successful [50].

If a decision is made to offer the patient treatment with buprenorphine, the risks associated with possible misuse and diversion are such that the combination buprenorphine/naloxone product is preferable for most patients [38,40,43]. Since the mono-product does have higher diversion and abuse potential, it should be rarely used, excepting pregnancy and breastfeeding, and the reasons for choosing the mono-product should be well-documented in the medical record.

Educating the Patient: Every patient to whom buprenorphine is prescribed should be cautioned to follow the directions exactly, particularly during the induction stage. Critical points of education are when to begin dosing, the frequency of subsequent doses, and the importance of avoiding the use of any other illicit or prescription opioid. Concurrent use of non-opioid sedating medications or over-the-counter products should also be discussed. Patients should be advised to avoid the use of alcohol [7].

Patients should be cautioned about potential sedation or impairment of psychomotor function during the titration phase of induction with buprenorphine [57].

Finally, because opioids can contribute to fatal overdoses in individuals who have lost their tolerance to opioids or in those who are opioid-naïve, including children or other family members, proper and secure storage of the medication must be discussed. Particularly where there are young people in the patient's home, the subject of safe storage and use should be revisited periodically throughout the course of treatment, with the discussions documented in the patient record [57]. Prescribers should consider providing a naloxone prescription for emergency overdose situations.

Informed Consent: Although agonist medications such as buprenorphine are clearly effective for the treatment of opioid dependence, they do entail substitute physical dependence on the prescribed medication to replace the prior physical dependence on the misused opioid [46]. This issue should be thoroughly discussed with the patient in terms of potential risks and benefits as part of the informed consent process. Patients and family members often are ambivalent about agonist treatment for this reason, and their concerns may influence subsequent treatment choices. Possible topics of discussion include the difference between addiction and physical dependence, including an explanation of why agonist therapy is not simply "switching one addiction for another", the likelihood of relapse with and without medication-assisted treatment, the projected duration of treatment, the potential for successfully tapering from agonist therapy at some point in the future, and the role and importance of adjunctive therapies such as counseling and peer support. Other topics important to discuss might be the greatly reduced risk of overdose and death with buprenorphine as compared to illicit opioids, and that patients are more likely to be able to achieve their highest level of functioning with buprenorphine than with street drugs, which nearly always cause continued decline in functioning including incarceration, job loss, inability to parent children, etc. With the patient's consent, this conversation could include family members, significant other(s), or a guardian [7].

A written *informed consent* document, discussed with and signed by the patient, can be helpful in reinforcing this information and establishing a set of "ground rules." The practitioner should document the informed consent in the patient's medical record [58].

Treatment Agreement: The terms of *treatment agreements* vary widely, but typical provisions include an acknowledgement of the potential benefits and risks of therapy and the goals of treatment; identification of one provider and one pharmacy from whom the patient will obtain prescriptions; authorization to communicate with all providers of care (and sometimes significant others) to consult the Virginia Prescription Monitoring Program; other treatments or consultations in which the patient is expected to participate, including recovery activities; avoidance of illicit substances; permission for drug screens of blood, urine, saliva or hair/nails; pill counts as appropriate; mechanisms for prescription renewals, including exclusion of early renewals; expected interval between office visits; and specification of the conditions under which therapy will be continued or discontinued [59].

The agreement also should include a statement instructing the patient to stop taking all other opioid medications. Such a statement reinforces the need to adhere to a single treatment regimen. Inclusion in the agreement of a pharmacy address and telephone number reinforces to the patient the importance of using one pharmacy to fill prescriptions, with recognition that there may be exceptions to this for certain patients.

Finally, the treatment agreement should set forth the objectives that will be used to evaluate treatment success, such as freedom from intoxication, improved physical and psychosocial function, and adherence to the treatment regimen [59].

Copies of the treatment agreement and informed consent should be provided to the patient and all other care providers, and filed in the patient's medical record. The agreement should be reviewed regularly and revised as needed [58].

Induction, Stabilization, and Follow-up: The goal of induction and stabilization is to find the lowest dose of buprenorphine at which the patient discontinues the use of illicit opioids without experiencing withdrawal symptoms, significant side effects, or uncontrollable cravings for the drug of abuse [60].

In general, patients should not concurrently take buprenorphine products with benzodiazepines, sedative hyponotics, carisoprodol, or other opioids including tramadol due to the higher risk for fatal overdose. Stimulants are a separate area of concern given the theoretical risk of continuing to stimulate the dopamine reward pathways, theoretically increasing the risk of relapse. However, there may be patients in whom it is judged that the potential benefits of treating severe ADHD may outweigh the risks, in part via improved function and decreased impulsivity. There is data that untreated ADHD predisposes to substance use disorders and cautious treatment with careful monitoring may support substance use treatment and abstinence from other drugs of abuse. Clinical judgment and careful documentation are required in such cases, rather than hard and fast rules.

Practitioners should remain aware that it is now Virginia law that if he/she anticipates giving more than 14 days of an opioid, there must be a check of the Virginia Prescription Monitoring Program when initiating treatment.

The initial induction process requires a higher degree of attention and monitoring than the later maintenance phase [59]. Patients need to be seen more frequently during the induction or early treatment, typically 1-3 times per week. Particular attention should be given to the timing of the initial doses so as to minimize untoward outcomes. Withdrawal symptoms can occur if either too much or too little buprenorphine is administered. Spontaneous withdrawal can occur if too little buprenorphine is given. Precipitated withdrawal can occur if buprenorphine is administered while the opioid receptors are substantially occupied by an opioid agonist. Overmedication should be avoided by starting the patient on lower doses, such as 4 mg per day.

The stabilization phase is focused on finding the right dose for an individual patient. A patient is stabilized when the dose allows him/her to conduct activities of daily living and to be aware of his/her surroundings without intoxication and without suffering withdrawal or significant drug craving [61-62]. Although there is no precise way to determine in advance what the optimal dose for a particular patient will be [63], most patients will stabilize on 8 to 12 mg of buprenorphine per day. Rarely, some patients may need doses up to 24 mg per day [64].

Buprenorphine blood concentrations stabilize after approximately seven days of consistent dosing [17]. If withdrawal symptoms subsequently emerge during any 24-hour dosing interval, the dose may be too low. The patient should be assessed for other factors that can cause cravings and withdrawal prior to increasing the dose of buprenorphine. Medical factors that may cause a patient's dose requirements to change include, but are not limited to, starting, stopping, or changing the dose of other prescription medications; onset and progression of pregnancy; onset of menopause; progression of liver disease; and significant increase or decrease in weight [61].

Dose adjustments generally should be made in increments of 2 mg/day. Because buprenorphine has a long plasma half-life and an even longer duration of action at the mu opioid receptor, five to seven days should be allowed between dose adjustments [53].

Patient adherence to medication regimens and session appointments is associated with better treatment outcomes. Regular monitoring can help patients plan for possible obstacles and teach them ways to handle any problems that occur [65]. Regular assessment of the patient's level of engagement in treatment and the strength of the therapeutic alliance allows for modification of the treatment plan and level of care in response to the patient's progress or lack thereof [56].

Early in treatment, medications should be prescribed and follow-up visits scheduled commensurate with the patient's demonstrated stability. Until patients have shown the ability to be compliant with the treatment plan and responsible with their medication supplies, and have discontinued high-risk behaviors and associated diversion risks, they should be seen more frequently and given medication only needed until the next visit.

Clinicians should take steps to reduce the chances of buprenorphine diversion. Recommended strategies include using the lowest effective dose, frequent office visits, urine drug testing, including testing for buprenorphine and its metabolites, recall visits for medication dose counts, and checking the Virginia Prescription Monitoring Program.

As patients demonstrate stability and the risks decline, they can be seen less often, but at least monthly. Larger amounts of medication may be prescribed to last from visit to visit, but not to increase the dose [46,59].

It is strongly recommended that prescribers ensure that they are capable of providing psychosocial services, either in their own practice or through referrals to reputable behavioral health practitioners in the community. It is the prescriber's responsibility to ensure the patient receives psychosocial treatment. Failure of the patient to keep their psychosocial appointments should be considered non-compliance with the treatment plan.

Patient monitoring during follow-up visits should address the following points [46,54,59,66]:

- Whether the patient continues to use alcohol or illicit drugs, or to engage in non-medical use of prescription drugs
- The degree of compliance with the treatment regimen, including the use of prescribed medications as directed
- Changes, positive or negative, in social functioning and relationships
- Avoidance of high-risk individuals, situations, and diversion risks
- Review of whether and to what degree the patient is involved in counseling and other psychosocial therapies, as well as in self-help activities through participation in mutual support meetings of groups such as Narcotics Anonymous
- The presence or absence of medication side effects
- The presence or absence of medical sequelae of substance use and its remission
- Periodic urine drug screens, a minimum of four per year and more frequently based on clinical need
- Regular checks of the Prescription Monitoring Program, typically once a month and in accordance with the treatment plan

Individuals engaged in medication-assisted treatment often demonstrate dramatic improvement in addiction-related behaviors and psychosocial functioning. Such positive changes should be acknowledged and reinforced by the prescribing physician whenever possible. Reducing the frequency of monitoring visits, with their associated costs, and increasing the patient's responsibility for medications are examples of how positive, responsible behaviors can be reinforced [46,67].

Adjusting the Treatment Plan: Outcomes typically are positive for patients who remain in medication-assisted treatment such as with buprenorphine [46,68]. However, some patients struggle to discontinue their misuse of opioids or other drugs, are inconsistent in their compliance with treatment agreements, or succeed in achieving some therapeutic goals while not doing well with others [69].

Behaviors that are not consistent with the treatment agreement should be taken seriously and used as an opportunity to further assess the patient and adapt the treatment plan as needed. In some cases, where the patient's behavior raises concerns about safety or diversion of controlled medications, there may be a need to refer the patient for treatment in a more structured environment, such as an OTP, intensive outpatient program or residential treatment. [69]. With the exception of diversion, behavior that violates the treatment agreement or a relapse to nonmedical drug use may not automatically constitute grounds for termination of treatment. Rather, they should be taken as a signal to reassess the patient's status, to implement changes in the treatment plan as by intensifying the treatment structure or intensity of services, and to document such changes in the patient's medical record [46].

Whenever the best clinical course is not clear, consultation with another practitioner may be helpful. The results of the consultation should be discussed with the patient and any written consultation reports added to the patient's record [59].

Patients with more serious or persistent problems may benefit from referral to a specialist for additional evaluation and treatment. For example, the treatment of addiction in a patient with a comorbid psychiatric disorder may be best managed through consultation with or referral to a specialist in psychiatry or addiction psychiatry [10]. In other instances, aberrant or dysfunctional behaviors may indicate the need for more vigorous engagement in peer support, counseling or psychotherapies, or possibly referral to a more structured treatment setting [56].

Preventing and Managing Relapse: Relapse should always be ruled out as a reason for loss of stability [56]. Relapse to drug use has been described as "an unfolding process in which the resumption of substance abuse is the last event in a long series of maladaptive responses to internal or external stressors or stimuli" [70]. It rarely is caused by any single factor; rather, it is a dynamic process in which the patient's readiness to change interacts with other external and internal factors [59, 71]. Patients in relapse vary in the quantity and frequency of their substance use, as well as the accompanying medical and psychosocial sequelae.

Clinical strategies to prevent and address relapse generally encompass the following steps [10,61,71]:

- Identify environmental cues and stressors that act as relapse triggers
- Help patients develop skills to cope with or manage negative emotional states
- Help the patient work toward a more balanced lifestyle
- Understand and manage craving
- Identify and interrupt lapses and relapses. Patients should have an emergency plan to address a lapse so that a full-blown relapse can be avoided. If relapse does occur, be prepared to intervene
- Develop a recovery support system. Families are more likely to provide such support if they are engaged in the treatment process and have an opportunity to ask questions, share their concerns and experiences, and learn practical coping strategies and behaviors to avoid
- Consult with psychiatry in the circumstance of multiple relapses

It should be noted that lack of adherence to pharmacologic regimens occurs in a substantial portion of patients being treated for addiction, with some studies reporting that a majority of patients fail to follow

the treatment plan at some point in their care. Retention in treatment also is a problem [72]. This is no different from the challenges encountered in managing any chronic disease, such as diabetes, hypertension, epilepsy, and other potentially life-threatening disorders [46], and is not an indication to terminate treatment.

Patients who continue to misuse opioids after sufficient exposure to buprenorphine and psychosocial services or who experience continued symptoms of withdrawal or craving at 16 mg of buprenorphine should be considered for therapy with methadone [5,7,52,73].

Duration of Treatment: Available evidence does not support routinely discontinuing medication-assisted treatment once it has been initiated and the patient has stabilized. However, this possibility frequently is raised by patients or family members. When it is, the physician and patient should carefully weigh the potential benefits and risks of continuing medication-assisted treatment and determine whether buprenorphine therapy can be safely discontinued [74].

Studies indicate that opioid-dependent patients are at high risk for relapse when medication-assisted therapy is discontinued, even after long periods of stable maintenance [7,74]. Research also shows that longer duration of treatment is associated with better treatment outcomes. Such long-term treatment, which is common to many medical conditions, should not be seen as treatment failure, but rather as a cost-effective way of prolonging life and improving the quality of life by supporting the natural and long-term process of change and recovery. Therefore, the decision to discontinue treatment should be made only after serious consideration of the potential consequences [3,7-8].

As with any other disease, the continuation of medication-assisted treatment should be linked directly to the patient's response, for example, his/her attainment of treatment goals. Relapse risk is highest in the first 6 to 12 months after initiating abstinence, and the risk gradually diminishes over a period of years. Therefore, it is reasonable to continue treatment for at least a year if the patient responds well, [3,7,10]. However, some patients may require longer treatment with buprenorphine products.

If buprenorphine is discontinued, the patient should be tapered off the medication through use of a safely structured regimen, and followed closely [46]. It may be necessary to reinstate pharmacotherapy with buprenorphine or a different medication or other treatment services if relapse appears imminent or actually occurs [59]. Such relapse poses a significant risk of overdose, which should be carefully explained to the patient [74]. Patients also should be assured that relapse need not occur for them to be reinstated to medication-assisted therapy [46].

Medical Records: Accurate and up-to-date medical records protect both the physician and the patient. In the event of a legal challenge, detailed medical records that document what was done and why are essential elements of the practitioner's defense [75-76].

A written informed consent and a treatment agreement articulating measurable treatment goals are key documents. The treatment agreement should be updated as new information becomes available. Both the informed consent and treatment agreement should be carefully explained to the patient and signed by both the patient, guardian if applicable, and the treating physician [76]. The document should reflect that the patient may be required to participate in observed urine drug screens, call backs for medication counts, and checks of the Prescription Monitoring Program. The medical record should clearly reflect the decision-making process that resulted in any given treatment regimen.

The patient's chart should contain a summary of the information needed to understand the treatment plan, even without a thorough knowledge of the patient. This includes some demographic data, the names of other practitioners caring for the patient, all diagnoses, therapies employed, and a list of all medications

prescribed. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed [10,76].

Other documents that should be part of the medical record, where available, include [10,74,76]:

- Diagnostic assessments, including the patient history, physical examination, and any laboratory tests ordered, with their results
- Actual copies of, or references to, medical records of past hospitalizations or treatments by other providers
- The treatment plan, treatment agreement, and informed consent
- Authorization for release of information to other treatment providers
- Documentation of discussions with and consultation reports from other health care providers
- Medications prescribed and the patient's response to them, including any adverse events

The medical record must also include all prescription orders, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record [75].

Monitoring visits should be carefully documented in the medical record, along with any subsequent changes to the treatment plan [illegible]. The patient's record should also contain documentation of steps taken to prevent the diversion of treatment medications, including any communications with other treating physicians and use of the Prescription Monitoring Program to verify that all prescribed medicines have been obtained and that no other prescriptions for controlled drugs have been dispensed without the physician's knowledge [77-78].

Records, including drug logs if buprenorphine is dispensed in the office, should be up-to-date and maintained in an accessible manner, readily available for review [75]. Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records can protect the physician as well as the patient [10,74,76].

Physicians who treat patients for addiction must observe the special confidentiality requirements of federal law 42 CFR, Part 2, which addresses the confidentiality of patients being treated for alcohol or drug addiction. 42 CFR Part 2 prohibits release of records, redisclosure of other information without the patient's consent or a valid court order, or in cases of a *bona fide* medical emergency, or in the course of mandatory reporting of child abuse [7].

Section III: Special Populations

The Work Group members with expertise in treating certain groups of patients were asked to provide guidance for their colleagues engaged in buprenorphine treatment of substance use disorders. Names of the members follow the sections.

Treatment of Pregnant Women with Buprenorphine

- Opioid use disorder among pregnant women is increasingly common, and the cost to society, especially in terms of treating premature babies and/or those with neonatal abstinence syndrome, is staggering.

- As with all patients with opioid use disorder, pregnant women achieve abstinence from illicit opioid and other drug use roughly ten times more often with medication-assisted treatment than with abstinence-based treatment.

- Treatment of pregnant women with opioid use disorder with buprenorphine reduces risk of prematurity and greatly reduces the incidence of neonatal abstinence syndrome.

- Therefore, all pregnant women that present already addicted to opioids should be encouraged to accept medication-assisted treatment.

- Methadone is still acceptable, but buprenorphine is preferable for most women not already on methadone. There is less overdose risk with buprenorphine, and fetal outcomes are better.

- Buprenorphine mono-product is still the recommended form of buprenorphine for pregnant and breastfeeding women, but growing evidence suggests that use of the buprenorphine-naloxone combination is equivalent in efficacy and safety, and may be more appropriate for some patients, especially those at high risk for IV misuse of the buprenorphine mono-product.

- Pregnant women should be counseled to take buprenorphine only as prescribed, and reasonable steps should be taken to discourage diversion and misuse of buprenorphine. Such steps might include increased frequency of visits, examination for evidence of nasal and IV use, and periodic random call-backs for drug screens and pill counts.

- In addition to seeing pregnant women on buprenorphine more frequently, the physician should give special attention to ensuring psychosocial supports to help improve compliance with treatment. This may include seeing the substance abuse counselor and/or recovery coach more frequently, supportive counseling with the physician, and/or group therapy and peer support groups.

- Most pregnant women will not require more than 16mg of buprenorphine daily, and many can be managed with 8mg or less.

- Acute opioid withdrawal causes fetal distress and can cause fetal demise, and needs to be avoided throughout treatment. Despite this, a pregnant woman unconscious from a presumed opioid overdose should still be administered naloxone in the field to avoid maternal death.

- Pregnant women should not be prescribed a benzodiazepine in addition to buprenorphine unless there are compelling medical indications which should be well-documented in the medical record.

- After delivery, additional buprenorphine should be given by the patient's usual buprenorphine prescriber for post-delivery pain instead of short-acting opioids, which will not be very effective due to the buprenorphine blockade of the mu receptors in the brain. For most vaginal deliveries, an extra 2mg of buprenorphine every 4 hours prn pain

for 2 or 3 days is efficacious. After a Cesarean section, an extra 4mg every 4 hours prn for 2-3 days, then an extra 2mg every 4 hours prn for 2-3 days, usually works well. Communication with the obstetrician about this approach is critical to avoid relapse after delivery with the commonly prescribed short-acting opioids.

- Breastfeeding may help reduce the incidence and severity of neonatal abstinence syndrome, and is encouraged in HIV-negative women, provided they are able to remain abstinent from the use of alcohol, benzodiazepines, or other sedating substances.

- Co-sleeping of mother and infant is discouraged due to increased risk of inadvertent infant asphyxiation if the mother becomes sedated from the use of alcohol, benzodiazepines, or other sedating substances.

- There should not be arbitrary time limits on buprenorphine treatment, especially for pregnant women.

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Neonatal Abstinence Syndrome

Neonatal abstinence syndrome (NAS) occurs when a developing fetus is exposed to opiates in utero from a mother who is taking opioid pain relievers, illicit opiates including heroin, or participating in medication-assisted treatment. When born, the infant may exhibit a constellation of symptoms due to physical withdrawal from the opiates and may require pharmacologic management with opiates, morphine or methadone, in addition to non-pharmacologic measures to reduce the severity of the withdrawal.

Over the past decade, the opioid epidemic has worsened across the United States and the effects on the exposed infants were not well understood. The incidence of NAS has increased dramatically over the past decade, from 3.4 infants/1000 deliveries in 2009[1] to 5.8 infants/1000 deliveries in 2012.[2] There are definite regional differences in NAS, with the South Central census division (TN, AL, MS, KY) with rates of 15-20/1000 and New England having rates of 10-15/1000.[2] Current rates of NAS in Virginia are estimated at 6/1000, very close to the national average, but there are concerns that the overall rate may be higher due to under-reporting. National cost estimates for the initial hospitalization of these infants is approximately $93,000 per infant, with an annual total expenditure of greater than $55 million for infants born in Virginia hospitals.

Over the past few years, there has been increased interest in improving the care of infants and families affected by NAS. There have been a few regional neonatal collaboratives[3,4,5] that have worked on

improving the care of infants and families affected by NAS. Desired outcomes include decreased length of stay, decreased number of days of pharmacological treatment and improved breastfeeding rates of NAS infants. These collaboratives introduced many potentially-better practices (PBP's) that have helped shape the development of policies and protocols to standardize the care of these infants.

There have been a few studies evaluating the use of buprenorphine for medication-assisted treatment and its effects on NAS. The MOTHER study which randomized pregnant women to either methadone or buprenorphine treatment for medication-assisted treatment demonstrated a significant reduction in both length of stay and duration of pharmacologic therapy in the buprenorphine group when compared to the methadone group for NAS infants.[7] Additional recent studies have found similar results with a lower length of stay, decreased need for pharmacologic therapy for exposed infants, and lower total morphine exposure for the treated infants.[8,9]

In summary, neonatal abstinence syndrome affects the most vulnerable patients of the Commonwealth of Virginia and its incidence continues to increase each year due to the national opioid epidemic which has touched more and more families in our state. Medication-assisted treatment is the mainstay for all patients with opioid substance disorders especially pregnant women due to the effects of opioids on the fetus. While methadone may be appropriate for pregnant mothers in certain situations, treatment with buprenorphine is also an accepted therapy which may lessen the effects of NAS on exposed infants. Continued support of these infants and their families with publically available services such as WIC, Early Intervention and developmental follow-up can only help to improve the care of infants and families affected by opiates and NAS.

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Adolescents

The use of buprenorphine for the treatment of opioid addiction in adolescents has not been systematically studied. It is known, however, that patients younger than 18 years of age, with relatively short addiction histories, are at particularly high risk for serious complications of addiction, e.g., overdose deaths, suicide, HIV, other infectious diseases. Many experts in the field of opioid addiction treatment believe

that buprenorphine should be the treatment of choice for adolescent patients with short addiction histories. Additionally, buprenorphine may be an appropriate treatment option for adolescent patients who have histories of opioid abuse and addiction and multiple relapses, but who are not currently dependent on opioids. Buprenorphine may be preferred to methadone for the treatment of opioid addiction in adolescents because of the relative ease of withdrawal from buprenorphine treatment.

Because adolescents often present with short histories of drug use, detoxification with buprenorphine followed by drug-free or naltrexone treatment, should be attempted before proceeding to opioid maintenance. Naltrexone may be a valuable therapeutic adjunct after detoxification. Naltrexone has no abuse potential and may help to prevent relapse by blocking the effects of opioids if the patient relapses to opioid use. Naltrexone has been a valuable therapeutic adjunct in some opioid-abusing populations, particularly youth and other opioid users early in the course of addiction. Naltrexone is most likely to be effective for patients with strong support systems that include one or more individuals willing to observe, supervise, or administer the naltrexone on a daily basis. In those adolescent patients in whom detoxification is followed by relapse, buprenorphine maintenance may then be the appropriate alternative. The treatment of patients younger than 18 years of age can be complicated due to psychosocial considerations, the involvement of family members, and Virginia law concerning consent and reporting requirements for minors (TIP 40)

In Virginia, a minor shall be deemed an adult for the purposes of giving consent to medical or health services needed in the case of outpatient care, treatment or rehabilitation for substance abuse as defined in Section 37.2-100. Adolescent patients however should be 16 or older. Buprenorphine is not currently recommended for use in those less than 16 years of age (FDA 2010).

Mark Stevens, MD

Patients with Pain (adapted from TIP 40)

- Patients who need treatment for pain but not for addiction should be treated within the context of their regular medical or surgical setting. They should not be transferred to an opioid maintenance treatment program simply because they are being prescribed an opioid and have become physically dependent on it in the course of their medical treatment.

- It can be difficult to distinguish between the legitimate desire to use opioids for pain relief and the desire to procure them for purposes of diversion or obtaining a high. It is important to remember that the subjective goal of pain relief should be accompanied by objective improvements in functioning. Even patients at the end of a terminal illness will demonstrate improved functioning if their pain is controlled, for example: reviewing their lives, making out a will, conferring with spiritual advisors, "getting their house in order."

- Functional objectives should be keyed to developmental tasks keeping in mind that the achievement of developmental tasks in ALL phases of life is paramount to the happiness and fulfillment of human beings. Adequate pain relief for a 12-month old child should result in his/her learning to walk and beginning to put words together. Adequate pain relief for a young adult should result in forward motion towards independence and would include obtaining employment and forming adult relationships. For most adults, returning to gainful employment is a developmentally appropriate functional goal.

- Functional objectives can be identified, quantified and independently verified if possible. An example of this would be attendance in physical therapy with verification of good effort by the

physical therapist. Even retired individuals can establish measureable goals such as spending more time with grandchildren or actively pursuing hobbies. Family members can be helpful in verifying the achievement of functional goals.

- Failure to achieve functional goals should raise questions about the original diagnoses and the plan of care. Not all pain responds to opioids. Also, the risks of opioids can outweigh their benefits, especially in patients with the disease of addiction.

- In addition to poor functioning, the more obvious signs of harm due to prescribed opioids can not be ignored: overdoses, concomitant use of illicit substances, and diversion. If it becomes evident that the negative effects of opioids outweigh the positives, the opioids should be discontinued. Prescribers should be familiar with how to safely discontinue any medication they prescribe.

Mary McMasters, MD

Patients with Medical Comorbidities

(Adapted from TIP 40 and the Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction http://www.ncbi.nlm.nih.gov/books/NBK64237/)

Patients addicted to opioids who present for treatment often have other comorbid medical problems. These conditions are often a consequence of high-risk behaviors, including injection drug use by intravenous, intramuscular, or subcutaneous routes, mucosal exposure from snorting, or of the direct toxic effects of the active and inert ingredients in illicit drugs. The prevalence of infectious diseases, e.g. HIV/AIDS, hepatitis B and C, tuberculosis, skin and soft tissue infections, syphilis and other sexually transmitted diseases [STDs], is increased in these patients, which should have screening tests. Other comorbid conditions, e.g. seizure disorders, valvular heart disease secondary to talc granulomatosis, lymphedema, pseudo aneurysms of the neck and groin secondary to thrombophlebitis, and renal insufficiency secondary to heroin-associated nephropathy, also are seen in the population and may require special attention. Patients with a history of endocarditis need antibiotic prophylaxis before certain dental procedures. Patients with a history of hepatitis C may require hepatitis A and B vaccinations and may be intolerant of potentially hepatotoxic medications. There have been some reports of elevated liver function tests in patients treated with buprenorphine who also have a history of hepatitis; it is suggested that liver function tests be monitored in these patients on a regular basis during buprenorphine treatment. A detailed discussion of medical comorbidities in addiction is beyond the scope of this chapter and is reviewed extensively in THE ASAM PRINCIPLES OF ADDICTION MEDICINE, 5th edition, Ries, Fiellin, Miller, Saitz, 2014 Wolters-DKluwer.

Treatment of opioid addiction in patients with comorbid medical conditions is likely to result in better outcomes for the comorbid conditions than would be achieved in the absence of treatment of the substance use disorder. However, it is important to remember that treatments of comorbid medical disorders may have important drug interactions with buprenorphine due to shared pharmacokinetic properties. Buprenorphine is metabolized by the hepatic cytochrome P450 3A4 enzyme system and will likely interact with other medications metabolized ty the same system. For example, certain antiretrovirals may occupy the cytochrome P450 3A4 system and thus inhibit the metabolism of buprenorphine. Other drugs that induce the cytochrome P450 3A4 system, e.g. certain antituberculosis, anticonvulsant, and antiretroviral medications, may decrease serum concentrations of buprenorphine, resulting in opioid withdrawal or decreased effectiveness.

Detection of comorbid medical conditions most often occurs during a thorough physical exam with particular attention paid to signs and symptoms common to patients with active addiction.

Laboratory evaluation of patients who are addicted to opioids can also detect comorbid medical conditions. However, obtaining laboratory tests should not delay the appropriate treatment of active addiction, particularly addiction to opioids, due to the high risk of overdose and death in this population.

In summary, it is important to screen for and manage common comorbid medical conditions in patients being treated with buprenorphine for opioid addiction and to anticipate known and potential drug interactions.

Mary McMasters, MD

Geriatrics (from SAMHSA TIP 40)

"Literature on the use of buprenorphine in geriatric patients is extremely limited. Due to potential differences in rates of metabolism and absorption compared to younger individuals, care should be exercised in the use of buprenorphine in geriatric patients. Particular care should be exercised during buprenorphine induction both because of differences in body composition and because of the possibility of medication interactions. "

Kenneth Walker, MD

Patients with Significant Psychiatric Comorbidity (adapted from SAMHSA TIP 40)

The association of psychopathology and opioid addiction is well established. The rate of psychiatric diagnosis in individuals seeking treatment at methadone clinics is approximately 39 percent. Although the etiological significance of psychiatric disorders in the genesis of opioid addiction is not established, it is known that treatment for both conditions is necessary for substance abuse treatment to be effective. Therefore, the presence and severity of comorbid psychiatric conditions must be assessed in patients who are opioid-addicted before, or while, initiating buprenorphine treatment, and a determination must be made whether referral to specialized behavioral health services is indicated. Untreated or inadequately treated psychiatric disorders can interfere with the effective treatment of addiction.

Primary psychiatric disorders may improve but do not dissipate with abstinence or maintenance therapies, and these disorders may require additional treatment. The most commonly encountered psychiatric disorders in opioid-addicted patients are other substance use disorders, depressive disorders, bipolar spectrum disorders, posttraumatic stress disorder, substance-induced psychiatric disorders, and antisocial and borderline personality disorders.

The presence of a psychiatric disorder should not exclude a patient from buprenorphine treatment. However, if there is suicidal or homicidal ideation, symptoms of acute psychosis, or other acute or chronic issues that may render a patient unstable, referral for specialized assessment and treatment is indicated prior to embarking upon buprenorphine treatment.

William L. Harp, MD

Patients Recently Discharged from Controlled Environments (adapted from SAMHSA TIP 40)

Considered here are individuals that have been incarcerated in prison and involuntarily detoxified from opioids, patients discharged from extended hospital or rehab center stays, patients returning from extended overseas travel to countries without access to opioids, and other situations that caused an

involuntary break in the use and addiction to opioids. Assessment of invididuals with these circumstances is to determine if they will resume their addiction if not treated with buprenorphine.

The following factors should be part of the assessment: length of incarceration, post-release addiction patterns and cycles, addiction treatment history, self-help involvement, reported triggers of illegal drug use and addiction upon release, comorbid psychiatric issues, and the patient's level of commitment to treatment and the likelihood of self-control.

Psychosocial issues that should be assessed are the number and length of incarcerations, types of crimes committed, gang affiliations, type and length of parole or probation, the patient's collateral contacts and reporting requirements, prior and current opioid abuse problems in the family, recent familiar or marital relationships, whether permission from the criminal justice system is required for treatment with buprenorphine, and the plan for a stable lifestyle.

The decision to treat will be based upon the patient's medical history, subjective report, the risk of diversion and overdose, the ability of the physician and treatment to have an impact, cost and other considerations.

Section IV: Definitions

Accurate use of terminology is essential to understanding office-based treatment of opioid addiction [70]. However, terminology in this area is changing. For many years, the most commonly used terms have been "drug abuse" and "drug dependence," with the latter indicating a severe condition considered synonymous with the term "addiction" (the chronic brain disease). The terms "abuse" and "dependence," in use since the third edition of the *Diagnostic and Statistical Manual of Mental Disorders* [79] has been replaced in the fifth edition [80] by the term "substance use disorder." Other new terms include "opioid use disorder" for the activity of using opioids benignly or pathologically, and "opioid use disorder" for the disease associated with compulsive, out-of-control use of opioids.

For the purposes of this Model Policy, the following terms are defined as shown.

Abuse: The definition of "abuse" varies widely, depending on the context in which it is used and who is supplying the definition. The Code of Virginia defines "substance abuse" as the use of drugs or alcohol that results in dependence, danger to self or others, mental, emotional or physical impairment that causes dysfunctional behavior. The *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, of the American Psychiatric Association defines "substance use disorders" as "a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems."

Addiction: Addiction is widely defined as a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm [56]. (As discussed below, physical dependence and tolerance are normal physiological consequences of extended opioid therapy and are not the same as addiction.)

A recent definition of addiction, adopted by the American Society of Addiction Medicine in 2011, reads as follows: "Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain,

impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death" [82].

Controlled Substance: In Virginia, the definition of a "controlled substance" means a drug, substance or immediate precursor in Schedules I through VI.

The federal definition of a "controlled substance" is a drug that is subject to special requirements under the federal Controlled Substances Act [75], which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs [83]. Civil and criminal sanctions for serious violations of the statute are part of the government's drug control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA.

The CSA [75], confers responsibility for scheduling controlled substances on the FDA and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither has primacy over the other, but that both are necessary to ensure the public welfare. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

Most opioids are classified as Schedule II or III drugs under the CSA, indicating that they have a high potential for abuse and a currently accepted medical use in treatment in the U.S., and that abuse of the drug may lead to psychological or physical dependence [75]. (Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled substances have some potential for abuse.)

Dependence: Physical dependence is a state of biologic adaptation that is evidenced by a class-specific withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist [76]. It is important to distinguish addiction from the type of physical dependence that can and does occur within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the *International Classification of Mental and Behavioural Disorders, 10th Edition* (*ICD-10*) of the World Health Organization (WHO) [84] and the *Diagnostic and Statistical Manual (DSM)* of the American Psychiatric Association [80,81]. In the DSM-IV-TR, a diagnosis of "substance dependence" meant addiction. In the upcoming DSM V, the term *dependence* is reestablished in its original meaning of physiological dependence; when symptoms are sufficient to meet criteria for substance misuse or addiction, the term "substance use disorder" is used, accompanied by severity ratings [80].

It may be important to clarify this distinction during the informed consent process, so that the patient understands that physical dependence and tolerance are likely to occur if opioids are taken regularly for a period of time, but the risk of addiction is relatively low unless the patient has additional risk factors. According to the World Health Organization, "The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid" [8].

Detoxification: Detoxification (also termed "medically supervised withdrawal") refers to a gradual reduction, or tapering, of a medication dose over time, under the supervision of a physician, to achieve the elimination of tolerance and physical dependence [85].

"Detoxification" is a legal and regulatory term that has fallen into disfavor with some in the medical community; indeed, some experts view "detoxification" as a misnomer because many abusable drugs are not toxic when administered in proper doses in a medical environment [86].

Diversion: The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA [75].

Pharmaceuticals that make their way outside this closed system are said to have been "diverted" from the system, and the individuals responsible for the diversion (including patients) are in violation of the law. The degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system [30,87].

Maintenance Treatment: Maintenance treatment involves the dispensing or administration of an opioid medication (such as methadone or buprenorphine) at a stable dose and over a period of 21 days or more, for the treatment of opioid addiction. When maintenance treatment involves the use of methadone, such treatment must be delivered in an Opioid Treatment Program (OTP). However, maintenance treatment with buprenorphine may be delivered in either an OTP or a medical office by a properly credentialed physician [7].

Medication-Assisted Treatment (MAT): MAT is any treatment for opioid addiction that includes a medication (such as methadone, buprenorphine, or naltrexone) that is approved by the FDA for opioid detoxification or maintenance treatment. MAT may be provided in a specialized OTP or, for buprenorphine or naltrexone, in a physician's office or other health care setting [7,55].

Misuse: The term *misuse* (also termed *non-medical use*) incorporates all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice [56].

Opioid: An opioid is any compound that binds to an opioid receptor. The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides [7,51,83]. Most physicians use the terms "opiate" and "opioid" interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. "Opioid" is the broader, more appropriate term because it includes the entire class of agents that act at opioid receptors in the nervous system, whereas "opiates" refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are "positive for opiates" have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM); drug tests that are "negative for opiates" have found no detectable levels of opiates in the sample, even though other opioids that were not tested for, including the most common currently used and misused prescription opioids, may well be present in the sample that was analyzed.

Opioid agonists are compounds that bind to the mu opioid receptors in the brain, producing a response that is similar in effect to the natural ligand that would activate it. With full mu opioid agonists, increasing the dose produces a more intense opioid effect. Most opioids that are misused, such as morphine and heroin, are full mu opioid agonists, as is methadone.

Opioid partial agonists occupy and activate the opioid receptors, but the activation they produce reaches a plateau, beyond which additional opioid doses do not produce a greater effect. It should be noted that the plateau (or "ceiling effect") may limit a partial agonist's therapeutic activity as well as its toxicity. Buprenorphine is a partial mu opioid agonist.

Opioid antagonists bind to and block the opioid receptors and prevent them from being activated by an opioid agonist or partial agonist. Naltrexone and naloxone both are opioid antagonists, and both can block the effect of opioid drugs.

Opioid Treatment Program *(OTP)* (sometimes referred to as a "methadone clinic" or "narcotic treatment program"): An OTP is any treatment program certified by SAMHSA in conformance with 42 Code of Federal Regulations (CFR), Part 8, to provide supervised assessment and medication-assisted treatment of patients who are addicted to opioids. An OTP can exist in a number of settings, including intensive outpatient, residential, and hospital facilities. Treatments offered by OTPs include medication-assisted therapy with methadone, buprenorphine or naltrexone, as well as medically supervised withdrawal or detoxification, accompanied by varying levels of medical and psychosocial services and other types of care. Some OTPs also can provide treatment for co-occurring mental disorders [58].

Recovery: A process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential [88]. As used in the ASAM *Patient Placement Criteria*, "recovery" refers to the overall goal of helping a patient achieve overall health and well-being [56]. SAMHSA's 10 guiding principles recognize that recovery [89]:

- Emerges from hope;
- Is person-driven;
- Occurs via many pathways;
- Is holistic;
- Is supported by peers and allies;
- Is supported through relationship and social networks;
- Is culturally-based and influenced;
- Is supported by addressing trauma;
- Involves individual, family and community strengths and responsibility;
- Is based on respect.

Relapse: Relapse has been variously defined as "a breakdown or setback in a person's attempt to change or modify any target behavior" and as "an unfolding process in which the resumption of substance misuse is the last event in a long series of maladaptive responses to internal or external stressors or stimuli" [70]. Relapse rarely is caused by any single factor and often is the result of an interaction of physiologic and environmental factors [59].

The term *lapse* (sometimes referred to as a *slip*) refers to a brief episode of drug use after a period of abstinence. A lapse usually is unexpected, of short duration, with relatively minor consequences, and marked by the patient's desire to return to abstinence. However, a lapse also can progress to a full-blown relapse, marked by sustained loss of control [56].

Tolerance: Tolerance is a state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug's effects over time [76]. Tolerance may occur both to an opioid's analgesic effects and to its unwanted side effects, such as respiratory depression, sedation, or nausea. Most investigators agree that absolute tolerance to the analgesic effects of opioids does not occur.

In general, tolerance to the side effects of opioids develops more rapidly than does tolerance to the drug's analgesic effects.

Tolerance may or may not be evident during treatment with opioids and is not the same as addiction [70].

Trial Period: A period of time, which can last weeks or even months, during which the efficacy of a medication or other therapy for the treatment of addiction is tested to determine whether the treatment goals can be met. If the goals are not met, the trial should be discontinued and an alternative approach (i.e., a different medication or non-pharmacologic therapy) adopted [76].

Waiver: A documented authorization from the Secretary of Health and Human Services, issued by SAMHSA under the DATA 2000 regulations, that exempts a qualified physician from the rules applied to OTPs and allows him or her to use buprenorphine for the treatment of addiction in office-based practice [51].

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Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

Participation by federal agency representatives and third parties was in an advisory capacity only and does not imply endorsement of any draft or final version of the policy

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Rulemaking for Benzodiazepines

Rule: Benzodiazepines should only be prescribed to a patient after careful evaluation while utilizing caution and good judgement. Benzodiazepines may be prescribed to a patient on buprenorphine or buprenorphine/naloxone combination with the following restrictions:

1. Benzodiazepines may not be initiated on a patient with opiate use disorder or the disease of addiction who has never been prescribed or misused/abused these products, except in extreme circumstances for severe anxiety or panic disorder, and only after evaluation by a Board Certified Psychiatrist.
2. Patients who present with a longstanding prescription for benzodiazepines for a legitimate medical condition from another prescriber may be prescribed buprenorphine products by a DATA 2000 waived physician. Contact should be initiated with that physician to coordinate care and clear documentation should be recorded in the patient's chart.
3. A DATA 2000 waivered physician may assume management of a patient's benzodiazepine prescribing from another physician if the patient is willing to initiate a program of tapering.
4. If a patient presents with the dual diagnosis of opiate use disorder and a clear history of benzodiazepine use disorder, the duration and extent of the abuse should be clearly documented in the medical record. A DATA 2000 waivered physician may prescribe a long acting benzodiazepine such as clonazepam or its equivalent under the following conditions:
    a. A defined plan for tapering the benzodiazepine should be initiated and clearly documented in the patient record.
    b. The patient should be prescribed the lowest effective dose to prevent benzodiazepine withdrawal syndrome.
    c. The maximum allowed dose of clonazepam or its equivalent is 2mg twice daily.
    d. Prescribing more than 2mg of clonazepam or its equivalent daily is considered "high-dose therapy".

e. Patients receiving high dose therapy should have justification for the dosing clearly documented in the medical record.
f. Patients receiving high dose therapy should be tapered as rapidly as possible to 2 mg clonazepam or its equivalent or less, and if the taper is unsuccessful, the reasons shall be clearly documented in the medical record.
g. A patient receiving high dose therapy for a period longer than 6 (six) weeks must be managed by a physician who is Board Certified in Addiction Medicine or who is Fellowship Trained in Addiction Psychiatry, or by a DATA 2000 waived physician who has obtained a formal consult from a physician who is Board Certified in Addiction Medicine or who is Fellowship trained in Addiction Psychiatry. The formal consult shall be clearly documented in the medical record.
h. A patient may continue on benzodiazepine therapy as medically indicated as long as there is an ongoing effort to taper to the lowest effective dose and clear documentation of this effort.

Agenda Item: **Review and Revision of Draft Regulations on Pain Management and the Use of Buprenorphine in the Office-Based Treatment of Addiction**

Staff Note: Here you will find the minutes from the January 6, 2017 Regulatory Advisory Panel that developed two sets of regulations--pain management and the use of buprenorphine. The minutes are followed by the draft regulations as "Regulations Governing Prescribing for Pain and Prescribing of Buprenorphine." Staff may have recommendations for section 18VAC85-21-90.

Action: Review, discuss, revise as indicated to create a draft to be forwarded to the full Board on February 16, 2017.

DRAFT UNAPPROVED

VIRGINIA BOARD OF MEDICINE
Regulatory Advisory Panel on Opioid Regulations
Minutes

Friday, January 6, 2017 | Department of Health Professions | Henrico, VA

CALL TO ORDER: The meeting convened at 9:11 a.m.

MEMBERS PRESENT:
Barbara Allison-Bryan, MD, Chair
Stephen Long, MD
Hughes Melton, MD
Katherine Neuhausen, MD
Paul Spector, DO

MEMBERS ABSENT: None

STAFF PRESENT:
William L. Harp, MD, Executive Director
Jennifer Deschenes, JD, Deputy Executive Director, Discipline
David Brown, DO, DHP Director
Elaine Yeats, DHP Senior Policy Analyst
Colanthia Morton Oliver, Operations Manager
Sherry Gibson, Administrative Assistant

OTHERS PRESENT:
W. Scott Johnson, [illegible], Medical Society of VA
Thomas Reach, MD, Watauga Recovery Center
Tyler Cox, Medical Society of VA
Julie Galloway, Medical Society of VA
Lauren Bates-Rowe, Medical Society of VA
Mark Hickman, CSG
Donna Proffitt, DMAS

Dr. Allison-Bryan invited all panel members to introduce themselves.

She then stated that the goal for the day was to produce draft regulations for buprenorphine and other opioids that were clear and would provide greater protection for the public.

ADOPTION OF AGENDA

Dr. Allison-Bryan asked for a motion to adopt the agenda. The motion was seconded and carried unanimously.

DRAFT UNAPPROVED

VIRGINIA BOARD OF MEDICINE
Regulatory Advisory Panel on Opioid Regulations
Minutes

Friday, January 6, 2017 Department of Health Professions Henrico, VA

PUBLIC COMMENT

W. Scott Johnson, JD provided feedback on the Draft Regulations for Pain Management and the Draft Regulations for the Use of Buprenorphine in Office-Based Treatment of Opioid Addiction.

Thomas Reach, MD of Watauga Recovery Center addressed concerns on the prescribing of benzodiazepines and emphasized that caution and good judgement should be utilized.

NEW BUSINESS

Dr. Allison-Bryan led the panel through a thorough discussion of the proposed Draft Regulations for the Use of Buprenorphine in Office-Based Treatment of Opioid Addiction included in the packet. There were a number of revisions and edits made to reflect the expertise of the panel members. Consensus on a set of regulations to send forward to the Legislative Committee on January 27, 2017 was attained.

Dr. Allison-Bryan called a break at 10:40 a.m.

The panel reconvened at 10:51 a.m.

Dr. Allison-Bryan then led the panel through a thorough discussion of the proposed Draft Regulations for Pain Management included in the packet. The 2012 framework of the draft regulations was updated with revisions, deletions and additions. The panel added essential elements from the Centers for Disease Control Guideline for Prescribing Opioids for Pain Management released in 2016. It also streamlined the language to achieve more clarity and remove redundancy. Again, consensus was gained on a work product that could go forward to the Legislative Committee.

Dr. Brown expressed his thanks to the panel for its commitment to this effort and acknowledged Dr. Harp's contribution.

VIRGINIA BOARD OF MEDICINE
Regulatory Advisory Panel on Opioid Regulations
Minutes

Friday, January 6, 2017 Department of Health Professions Henrico, VA

ADJOURNMENT

With no further business to conduct, the meeting adjourned at 12:29 p.m.

Barbara Allison-Bryan, MD
Chairperson

William L. Harp, MD
Executive Director

Sherry Gibson
Recording Secretary

Commonwealth of Virginia

REGULATIONS

GOVERNING PRESCRIBING FOR PAIN AND PRESCRIBING OF 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:

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TABLE OF CONTENTS

Part I. General Provisions.

18VAC85-21-10. Applicability.

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

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.

Part II. Management of Acute Pain.

18VAC85-21-30. Evaluation of the 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 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 the Code of Virginia and conduct an assessment of the patient's history and risk of substance abuse as a part of the initial evaluation.

18VAC85-21-40. Treatment with opioids.

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

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

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

2. Prior to exceeding 120 MME/day, the practitioner shall refer or consult with a pain management specialist.

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

C. Due to a higher rise of fatal overdose when buprenorphine is 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 a tapering plan if these medications are used.

18VAC85-21-50. Medical records.

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 (including date, type, dosage and quantity prescribed).

Part II. Management of Chronic Pain.

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

A. Prior to initiating management of chronic pain with a controlled substance, a medical history and physical examination to include a mental status examination and 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 his family;

6. A urine drug screen;

7. A query the Prescription Monitoring Program as set forth in 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 analgesia 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. 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 with opioids.

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

B. Initiation of opioid treatment for opioid naïve patients shall be with short-acting opioids.

C. In initiating opioid treatment for all patients, the practitioner shall:

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

2. Prior to exceeding 120 MME/day, refer or consult with a pain management specialist;

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

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

D. Due to a higher rise of fatal overdose when buprenorphine is 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 a tapering plan if these medications are used.

E. The practitioner shall regularly screen for opioid use disorder and shall initiate or refer the patient for evaluation for treatment if indicated.

18VAC85-21-80. Treatment plan.

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 record in the patient records the presence or absence of any indicators for medication misuse, abuse or diversion and take appropriate action.

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

A. The prescriber 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 in the medical record that addresses the parameters of treatment, including those behaviors which will result in a cessation of treatment or dismissal from care.

C. The treatment agreement shall include, but not be limited to permission for the practitioner to:

1. Obtain urine/serum medication levels, when requested;

2. Query and receive reports from the Prescription Monitoring Program; and

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

D. Established expected outcome and improvement in both pain relief and function or just pain relief as well as limitations

(This paragraph needs to be worked in detail incorporating modern treatment plans)

18VAC85-21-100. Periodic review.

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

B. Continuation of treatment with controlled substances shall be supported by documentation of continued benefit from the prescribing. If the patient's progress is unsatisfactory, the prescriber 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 the initiation of treatment with opioids that will extend beyond 14 days, and a least every three months thereafter.

D. Practitioner shall order and review a urine drug screen at the initiation of chronic pain management at least every three months in the first year, and at least annually thereafter.

E. The practitioner shall regularly screen for opioid use disorder and shall initiate or refer the patient for evaluation for treatment if indicated.

18VAC85-21-110. Consultation.

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

B. When a practitioner makes the diagnosis of opioid disorder, he shall initiate or refer the patient for evaluation and treatment.

18VAC85-21-120. Medical records.

A. The prescriber shall keep current, accurate and complete records in an accessible manner and 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 dates, doses and quantity prescribed and refills).

11. Patient instructions; and

12. Periodic reviews.

Part IV. Prescribing of Buprenorphine.

18VAC85-21-120. General provisions.

A. Prescribers engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a waiver from the Substance Abuse Mental Health Services Administration and the appropriate Drug Enforcement Administration registration.

B. Prescribers shall abide by all federal and state laws and regulations governing the prescribing of buprenorphine for the treatment of opioid addiction.

C. Physician assistants and nurse practitioners shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a waivered physician.

D. Practitioners engaged in medication-assisted treatment shall refer the patient to a licensed mental health professional for counseling or provide counseling in their practice and document such in the medical record.

18VAC85-21-130. Patient assessment and treatment planning.

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, infectious disease testing for HIV, Hepatitis B, Hepatitis C and TB, and a check of the Prescription Monitoring Program.

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.

18VAC85-21-140. Treatment with buprenorphine.

A. Buprenorphine mono-product shall only be prescribed to pregnant women, to individuals with demonstrated intolerance to naloxone, or to aid individuals compliant with medication-assisted treatment who are in financial hardship. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

B. Due to a higher rise of fatal overdose when buprenorphine is 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 a tapering plan if these medications are used.

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

D. During the induction phase, except for medically indicated circumstances patients shall be started on 8 mg. of buprenorphine. The patient shall be seen at least once a week.

E. 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.

F. Practitioners shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, urine drug screens, pill counts and checks of the Prescription Monitoring Program.

G. Documentation of the rationale for doses exceeding 16 mg. of buprenorphine per day shall be placed in the patient record. Dosages exceeding 24 mg. of buprenorphine per day are not FDA approved.

H. Behaviors that are inconsistent with the treatment agreement shall be discussed and resolved with the patient and documented in the medical record. Appropriate steps to address these behaviors shall also be documented.

I. The practitioner shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a licensed mental health professional.

18VAC85-21-140. Special populations.

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 is not stable. The patient should be referred for psychiatric evaluation and treatment prior to initiating medication-assisted treatment.

18VAC85-21-160. Medical records.

A. Records shall be timely, accurate, legible and complete.

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

C. Confidentiality requirements of 42 CFR, Part 2 which prohibits release of records, re-disclosure or other information without the patient's consent or a court order, or in cases of a bona fide medical emergency, or in the mandatory reporting of child abuse, 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.

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

February 27, 2017