Executive Committee Meeting

Virginia Board of Medicine
December 2, 2022
8:30 a.m.

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 3

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.

Executive Committee

Friday, December 2, 2022 @ 8:30 a.m.
Perimeter Center
9960 Mayland Drive, Suite 201, Board Room 3
Henrico, VA 23233

====No motion needed to adjourn if all business has been conducted====

VIRGINIA BOARD OF MEDICINE
EXECUTIVE COMMITTEE MINUTES

Friday, August 5, 2022 Department of Health Professions Henrico, VA

CALL TO ORDER: Mr. Marchese called the meeting of the Executive Committee to order at 8:30 a.m.

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

MEMBERS PRESENT:
Blanton Marchese – President, Chair
David Archer, MD
Alvin Edwards, MDiv, PhD
Jane Hickey, JD
Joel Silverman, MD

MEMBERS ABSENT: Karen Ransone, MD

STAFF PRESENT:
William L. Harp, MD - Executive Director
Jennifer Deschenes, JD - Deputy Exec. Director for Discipline
Colanthia Morton Opher - Deputy Exec. Director for Administration
Michael Sobowale, LLM - Deputy Exec. Director for Licensure
David E. Brown, DC – DHP Director
Barbara Matusiak, MD - Medical Review Coordinator
Deirdre C. Brown - Executive Assistant
Erin Barrett, JD – DHP Senior Policy Analyst

OTHERS PRESENT:
Jennie Wood – Discipline Staff
W. Scott Johnson, JD - Hancock Daniel & Johnson, PC
Ben Traynham, JD - Hancock Daniel & Johnson, PC
Fran Bradford, JD - McGuireWoods

EMERGENCY EGRESS INSTRUCTIONS

Dr. Archer provided the emergency egress instructions for Board Room 4.

APPROVAL OF MINUTES OF APRIL 8, 2022

Dr. Edwards moved to approve the minutes from April 8, 2022 as presented. The motion was seconded by Ms. Hickey and carried unanimously.

ADOPTION OF AGENDA

Dr. Edwards moved to adopt the agenda as presented. The motion was seconded by Dr. Archer and carried unanimously.

PUBLIC COMMENT

Mr. Marchese opened the floor for public comment; there was none.

DHP DIRECTOR'S REPORT

Dr. Brown reported that Governor Youngkin is interested in decreasing regulation. He stated that this gives DHP an opportunity to look at and simplify what we do. Governor Youngkin has established the Office of Regulatory Management, which will be meeting in October. Erin Barrett, DHP Senior Policy Analyst, will be attending the meeting. Also, Dr. Brown shared that the agency has seen a lot of changes, including bringing Human Resources back in-house and hiring a new Director for the Healthcare Workforce Data Center and a new Director for the Prescription Monitoring Program.

PRESIDENT'S REPORT

Mr. Marchese had no report.

EXECUTIVE DIRECTOR'S REPORT

Dr. Harp shared with the Board that Michael Sobowale, Deputy for Licensure, is recruiting for a licensing supervisor with interviews to occur later this month.

The biennial budget for FY23-24 has been submitted and includes the request for a full-time licensing specialist to work the front end of the application process. Also, in the spring of each year, the Board begins to receive applications from students graduating medical school and others who need Internship/Residency/Fellowship training licenses. This year, the Board received 1,200 applications for training licenses. As usual, other licensing staff had to pitch in to help. To remedy this situation, getting a temporary employee each March for 4 months would be a big help. This position has been included in the budget.

Dr. Harp announced that there will be a Statewide Pharmacy Protocols Work Group meeting on Monday, August 8, 2022. The Board of Pharmacy was in charge of this effort for the last 2 years and produced 7 protocols. The legislation from the 2022 Session requires another 3 protocols to be developed. In the meeting there will be three Board of Medicine members, three Board of Pharmacy members, and one pharmacist and one physician from VDH.

Dr. Harp updated the Committee on the changes in Board membership. The Board bid farewell to Jim Arnold, DPM, Amanda Barner, MD, Milly Rambhia, MD, Brenda Stokes, MD and Khalique Zahir, MD as they were not reappointed for second terms. The newly appointed members are Peter Apel, MD, Randy Clements, DPM, Hazem Elariny, MD, Bill Hutchens, MD, and Krishna Madiraju, MD.

Dr. Harp stated that the OCME quarterly report on opioid overdose deaths indicates that in the last 15 years, deaths from prescribed opioids have been flat. Currently, fentanyl is responsible for 76% of the fatal opioid overdoses.

NEW BUSINESS

1. Exempt Action Based on HB145 (Physician Assistant Practice) – Erin Barrett

Exempt changes to regulations governing physician assistants based on changes from 2022 legislation (HB145)

MOTION: Dr. Edwards moved to adopt the exempt regulatory changes as presented. The motion was properly seconded by Ms. Hickey and carried unanimously**.**

2. Exempt Action Based on HB598 (Surgical Technologists) – Erin Barrett

Exempt changes to regulations governing surgical technologist certification based on changes from 2022 legislation (HB598)

MOTION: Dr. Edwards moved to adopt the exempt regulatory changes as presented. The motion was properly seconded by Dr. Archer and carried unanimously**.**

3. Approval of Bylaws for All Advisory Boards – Erin Barrett

Draft Guidance Document 85-3

MOTION: Dr. Edwards moved to adopt the newly derived Guidance Document 85-3. The motion was properly seconded by Ms. Hickey and carried unanimously.

4. Consideration of Response to Petition for Rulemaking – Erin Barrett

Ms. Barrett reviewed the petition for rulemaking from Michael Moates, public comment that was received by the Board, and public comment posted on Town Hall in response to the petition. Ms. Barrett shared with the Board that Virginia Code 54.1-2409.5 already prohibits conversion therapy and that the use of the graduated electronic decelerator would be dealt with as a standard of care issue in the disciplinary process.

MOTION: Dr. Edwards moved to take no action on the petition. The motion was properly seconded by Dr. Archer and carried unanimously**.**

5. Adoption of Fast-Track Action Regarding Clinical Nurse Specialists – Erin Barrett

Exempt changes to 18VAC90-30-125 regarding practice agreements for clinical nurse specialists.

Chapter 197 of the 2022 Acts of Assembly.

MOTION: Ms. Hickey moved to adopt the fast-track regulatory change to the requirement for practice agreements by clinical nurse specialists as presented. The motion was properly seconded by Dr. Edwards and carried unanimously**.**

6. Vacant Offices on the Board – Dr. Harp

The Board voted in a new slate of officers at the Full Board meeting held on June 16, 2022. However, the first terms of the individuals elected to the offices of Vice-President and Secretary-Treasurer expired June 30, 2022; they were not reappointed. The Board of Medicine Bylaws, Guidance Document 85-1, make provisions for filling the offices of those that were not reappointed. But the Bylaws are not completely clear on the best way to proceed at this juncture. The options appear to be as follows:

1. The President appoints a Secretary-Treasurer, but not a Vice-President.
2. The newly appointed Secretary-Treasurer fills the Vice-President position, and the President then appoints a second individual for Secretary-Treasurer.
3. Appoint a Nominating Committee to develop a slate for the vacant offices for discussion/approval at the October Full Board meeting.

Mr. Marchese then opened the floor for discussion. Dr. Brown commented that the Committee may wish to wait until the October Full Board meeting to fill the positions. Mr. Marchese expressed concern for leadership of the Legislative Committee in September. The Committee members agreed that the best option would be to make the decision today.

MOTION: Dr. Edwards moved to allow the President to appoint a Secretary-Treasurer, who would then fill the Vice-President position. Then the President would appoint a second individual for Secretary-Treasurer. The motion was properly seconded by Dr. Silverman and carried unanimously**.**

Dr. Harp then stated that since the work of the Nominating Committee, the prepared slate, and the vote were all public, Mr. Marchese may wish to make the appointments in the meeting. Mr. Marchese then called for anyone interested in the Secretary-Treasurer seat. Dr. Archer acknowledged his interest. Hearing no others, Mr. Marchese appointed Dr. Archer as the Secretary-Treasurer. Dr. Archer immediately moved to the Vice-President position. Then Mr. Marchese appointed Dr. Edwards as the Secretary-Treasurer of the Board.

7. Update on Reciprocity – Dr. Harp

Dr. Harp briefly reviewed the meeting that occurred June 3, 2022 and provided an update from the July 22, 2022 meeting.

At the July meeting, a draft Memorandum of Agreement (MOA) prepared by the DC Board Counsel was reviewed; all jurisdictions provided suggestions that will be incorporated. Board Counsels and the boards for all 3 jurisdictions will need to approve the MOA. Applications will be individualized for each jurisdiction and will be kept as brief as possible. The group agreed upon an optimistic start date of January 1, 2023 for the reciprocal licensing pathway.

Ms. Barrett noted that regulations were not required since the Board has already been given authority for reciprocal licensing in statute.

ACTION: For informational purposes only.

ANNOUNCEMENTS

All were reminded to submit their Travel Expense Reimbursement Vouchers within 30 days after completion of their trip (CAPP Topic 20335, State Travel Regulations, p. 7).

The next meeting of the Executive Committee will be December 2, 2022 @ 8:30 a.m.

ADJOURNMENT

With no additional business, the meeting adjourned at 9:27 a.m.

_____
William L. Harp, MD
Executive Director

Agenda Item: **Report of Officers**

Staff Note:
- President
- Executive Director

Action: Informational presentation. No action required.

From: Lisa A. Robin (FSMB) <LRobin@fsmb.org>
Sent: Friday, November 18, 2022 3:48 PM
To: Lisa A. Robin (FSMB) <LRobin@fsmb.org>
Subject: PA Compact

Dear Executive Directors,

Since 2019, the Federation of State Medical Boards, the American Academy of PAs, The Council of State Governments' National Center for Interstate Compacts, and the National Commission on Certification of Physician Assistants have collaborated on a project to develop a licensure compact for PAs. The project is supported by a grant under the U.S. Health and Human Services, Health Resources and Services Administration, License Portability Grant Program.

The model PA compact legislation, once adopted by the requisite number of states, would authorize a PA to practice in a remote state based on a full and unrestricted license in a participating state. In order to qualify, the PA would be required to meet certain criteria, including, but not limited to, graduation from an accredited PA program, current NCCPA certification, no felony or misdemeanor convictions or controlled substance restrictions.

Additional important features of the PA Compact include:

- Compact Privilege Model – a compact privilege is the authorization granted by a remote state to allow a PA from another participating state to practice. A compact privilege must be obtained from each remote state the PA wishes to practice in.

- Practitioner Identification – PAs utilizing the compact will be required to have a unique identifier, as determined by the Compact Commission once it is operational.

- Preservation of State Laws and Regulations - a PA providing medical services and other licensed activity under a compact privilege must abide by the laws and regulations of the state in which the services occur. Participating states may require the PA to pass a jurisprudence exam. For each remote state in which a PA seeks authority to prescribe controlled substances, the PA must satisfy all related requirements imposed by the remote state.

- Funding for States and the Compact Commission - The Commission may impose compact privilege fees on licensees of participating states to whom a compact privilege is granted. States participating in the compact may also charge a fee to the PA for granting a compact privilege.

This work was initiated in November 2019 with a meeting in Washington, DC, bringing together representatives from state medical, osteopathic and PA boards and other stakeholders to identify the elements of a potential compact to facilitate PA license portability. The COVID-19 pandemic

forced the cancellation of a planned in-person stakeholder meeting in Spring 2020, but an additional meeting was successfully held in November 2021.

A drafting committee, with legal and technical expertise provided by CSG, met several times to develop legislative language over the project period. A draft of proposed model legislation was distributed to state boards in April 2021. The model was later discussed at the PA Forum held during the 2022 FSMB Annual Meeting. The model language has been revised multiple times to accommodate concerns and to address questions raised. The "privilege to practice" model remains the consensus of the PA community because it provides a pragmatic middle ground between the expense of expedited licensure and the borderless practice implications of a "driver's license" compact model.
Changes made to the compact based on the feedback received include:

- In addition to PA and public members, commission delegates may include physician members of PA Boards.
- Amended reporting requirements for investigations to include only significant information. See definition and related requirements for significant investigative information in the model compact for further information.
- Amended compact language to protect a participating state's ability to utilize alternative programs.

The PA licensure compact model legislation may be accessed at www.pacompact.org in addition to a fact sheet and other resources.

Thank you,
Lisa

Lisa Robin
Chief Advocacy Officer

Federation of State Medical Boards
1775 Eye Street NW | Suite 410 | Washington, DC 20006
202-463-4006 direct | lrobin@fsmb.org

FEDERATION OF STATE MEDICAL BOARDS

Agenda Item: Board of Medicine Current Regulatory Actions

Staff Note: Erin Barrett will cover the Board's current regulatory activity which you will find in the following pages.

Action: None anticipated. Questions and discussion per Committee members.

Board of Medicine
Current Regulatory Actions
As of October 5, 2022

In the Governor's Office

None.

In the Secretary's Office

VAC	Stage	Subject Matter	Date submitted*	Time in office**	Notes
18VAC85-150	NOIRA	Conforming licensure requirements to Code	7/1/2022	138 days	Amendment to 18VAC85-150-60, which sets out requirements for licensure as a behavior analyst or assistant behavior analyst, to conform to Virginia Code § 54.1-2957.16(B)(1).
18VAC85-160	Final	Changes consistent with a licensed profession	7/5/2022	134 days	Proposed regulations consistent with surgical assistants changing from certification to licensure
18VAC85-160	Fast-track	Reinstatement as a surgical technologist	8/30/2022	78 days	Action to allow certified surgical technologists to voluntarily request inactive status, and for surgical technologists to reinstate certification from inactive status or from suspension or revocation following disciplinary action.
18VAC85-80	Proposed	Implementation of OT Compact	9/2/2022	75 days	Adoption of regulations to replace emergency regulations

* Date submitted to current location
** As of November 16, 2022

At DPB or OAG

VAC	Stage	Subject Matter	Date submitted*	Time in office**	Notes
18VAC85-15	Fast-track	Implementation of changes following 2022 periodic review of Chapter	10/6/2022	41 days	Periodic review changes voted on at October Board meeting
18VAC85-20	Fast-track	Implementation of changes following 2022 periodic review of Chapter	10/6/2022	41 days	Periodic review changes voted on at October Board meeting
18VAC85-40	Fast-track	Implementation of changes following 2022 periodic review of Chapter	10/6/2022	41 days	Periodic review changes voted on at October Board meeting
18VAC85-50	Fast-track	Implementation of changes following 2022 periodic review of Chapter	10/6/2022	41 days	Periodic review changes voted on at October Board meeting
18VAC85-80	Fast-track	Implementation of changes following 2022 periodic review of Chapter	10/6/2022	41 days	Periodic review changes voted on at October Board meeting
18VAC85-101	Fast-track	Implementation of changes following 2022 periodic review of Chapter	10/6/2022	41 days	Periodic review changes voted on at October Board meeting
18VAC85-110	Fast-track	Implementation of changes following 2022 periodic review of Chapter	10/6/2022	41 days	Periodic review changes voted on at October Board meeting
18VAC85-120	Fast-track	Implementation of changes following 2022 periodic review of Chapter	10/6/2022	41 days	Periodic review changes voted on at October Board meeting

18VAC85-130	Fast-track	Implementation of changes following 2022 periodic review of Chapter	10/6/2022	41 days	Periodic review changes voted on at October Board meeting
18VAC85-140	Fast-track	Implementation of changes following 2022 periodic review of Chapter	10/6/2022	41 days	Periodic review changes voted on at October Board meeting
18VAC85-150	Fast-track	Implementation of changes following 2022 periodic review of Chapter	10/6/2022	41 days	Periodic review changes voted on at October Board meeting
18VAC85-170	Fast-track	Implementation of changes following 2022 periodic review of Chapter	10/6/2022	41 days	Periodic review changes voted on at October Board meeting

Recently effective/awaiting publication

None

Agenda Items: Adopt revisions to Guidance Document 90-56

Included in your agenda package are:

- Proposed revisions to Guidance Document 90-56 related to practice agreements for nurse practitioners in both marked up and clean version

Staff Note: This guidance document pertains to licensees jointly regulated by the Boards of Nursing and Medicine. The Board of Nursing has already approved this document. Any changes will need to be returned to the Board of Nursing for review.

Action needed:

- Motion to revise Guidance Document 90-56 as presented.

Practice Agreement Requirements for Licensed Nurse Practitioners (Advanced Practice Registered Nurses)

~~**Revised by the Board of Nursing – July 20, 2021**~~
~~**Adopted by the Board of Medicine –**~~

KEY POINTS:

- Certified Registered Nurse Anesthetist ("CRNA") – A practice agreement is *not* required for nurse practitioners licensed in the category of CRNA. The CRNA practices under the supervision of a licensed doctor of medicine, osteopathy, podiatry, or dentistry.
- Certified Nurse Midwife ("CNM") – **Prior to completion of 1,000 practice hours, a nurse practitioner licensed in the category of CNM must enter into a** practice agreement ~~is required~~ with either a CNM who has practiced for at least two years or a licensed physician ~~for nurse practitioners licensed in the category of CNM prior to completion of 1,000 practice hours~~.
- Clinical Nurse Specialist ("CNS") – A **nurse practitioner licensed in the category of CNS and who prescribes controlled substances must enter into a** practice agreement with a licensed physician. ~~is required for nurse practitioners licensed in the category of CNS~~
- Nurse Practitioner ("NP") – A **nurse practitioner with less than 5 years of clinical experience must enter into** a practice agreement with a patient care team physician ~~is required for nurse practitioners with less than 2 years of clinical experience~~; **this requirement** does not apply to NPs in the categories of CNM, CRNA, or CNS.
- Nurse practitioners who are required to have a practice agreement are responsible for maintaining the practice agreement and making it available for review by the Board of Nursing upon request.
- Practice agreements do *not* need to be submitted to the Board of Nursing to obtain or renew the professional license.

~~**FURTHER STATUTORY DETAILS:**~~ **Applicable statutes by category:**

CNM ~~– §§54.1-2957(H) and 54.1-2957.01(G)~~

~~A CNM who has practiced fewer than 1,000 hours shall practice in consultation through a practice agreement with a CNM who has practiced for at least two years prior to entering into the practice agreement or a licensed physician.~~

- ~~The~~ **A practice agreement entered into between a CNM and a CNM with more than 2 years of experience or a licensed physician must** ~~practice agreement shall~~ address the availability of the consulting CNM or the licensed physician for routine and urgent consultation on patient care. **(Va. Code § 54.1-2957(H).)**
- If the CNM will prescribe, the practice agreement ~~shall~~ **must** include the parameters of such prescribing of Schedules II through VI controlled substances. **(Va. Code § 54.1-2957.01(G).)**
- **Virginia Code § 54.1-2957(H) describes the requirements for CNMs to practice without a practice agreement.**

~~Requirements for CNM autonomous practice can be found in **§ 54.1-2957(H)**~~

CNS ~~– §§ 54.1-2957(J) and 54.1-2957.01(G~~B~~)~~

A CNS who **prescribes controlled substances** shall practice in consultation with a licensed physician in accordance with a practice agreement

- **A practice agreement entered into between a CNS and a licensed physician must** ~~The practice agreement shall~~ address the availability of the physician for routine and urgent consultation on patient care. **(Va. Code §§ 54.1-2957(J).)**
- If the CNS will prescribe, the practice agreement ~~shall~~ **must** include the parameters of such prescribing of Schedules II through V controlled substances. **(Va. Code § 54.1-2957.01(B).)**
- ~~Inclusion of the prescribing of Schedule VI controlled substances is not required in the practice agreement.~~

~~NOTE: There are no conditions in Virginia Code under which a CNS may practice without a practice agreement~~

NP ~~– §§ 54.1-2957(C) & (D) and 54.1-2957.01(B)~~

~~An NP not qualified for autonomous practice shall maintain appropriate collaboration and consultation with at least one patient care team physician, as evidenced in a written or electronic practice agreement which is periodically reviewed and revised. The practice agreement shall~~
A nurse practitioner with less than 5 years of clinical experience must enter into a practice agreement with a patient care team physician as defined in Va. Code § 54.1-2900. Pursuant to Virginia Code §§ 54.1-2957(C), (D) and 54.1-2957.01(B), when a practice agreement is required for NP practice, it must include:

- Provisions for the periodic review of health records by the patient care team physician and may include provisions for visits to the site where health care is delivered in the manner and at the frequency determined by the patient care team;
- Provisions for appropriate input from health care providers in complex clinical cases and patient emergencies and for referrals;
- Categories of drugs and devices that may be prescribed;
- Guidelines for availability and ongoing communications that provide for and define consultation among the collaborating parties and the patient;
- Provisions for periodic joint evaluation of services provided;
- Provisions for periodic review and revision of the practice agreement; and
- The signature of the patient care team physician or the name of the patient care team physician clearly stated.

Virginia Code § 54.1-2957(I) describes the requirements for NP autonomous practice.
~~Requirements for NP autonomous practice can be found in **§ 54.1-2957(I)**~~

Practice Agreement Requirements for Licensed Nurse Practitioners (Advanced Practice Registered Nurses)

KEY POINTS:

- Certified Registered Nurse Anesthetist ("CRNA") – A practice agreement is *not* required for nurse practitioners licensed in the category of CRNA. The CRNA practices under the supervision of a licensed doctor of medicine, osteopathy, podiatry, or dentistry.
- Certified Nurse Midwife ("CNM") – Prior to completion of 1,000 practice hours, a nurse practitioner licensed in the category of CNM must enter into a practice agreement with either a CNM who has practiced for at least two years or a licensed physician.
- Clinical Nurse Specialist ("CNS") – A nurse practitioner licensed in the category of CNS and who prescribes controlled substances must enter into a practice agreement with a licensed physician.
- Nurse Practitioner ("NP") – A nurse practitioner with less than 5 years of clinical experience must enter into a practice agreement with a patient care team physician; this requirement does not apply for NPs in the categories of CNM, CRNA, or CNS.
- Nurse practitioners who are required to have a practice agreement are responsible for maintaining the practice agreement and making it available for review by the Board of Nursing upon request.
- Practice agreements do *not* need to be submitted to the Board of Nursing to obtain or renew the professional license.

Applicable statutes by category:

CNM

- A practice agreement entered into between a CNM and a CNM with more than 2 years of experience or a licensed physician must address the availability of the consulting CNM or the licensed physician for routine and urgent consultation on patient care. (Va. Code § 54.1-2957(H).)
- If the CNM will prescribe, the practice agreement must include the parameters of such prescribing of Schedules II through VI controlled substances. (Va. Code § 54.1-2957.01(G).)
- Virginia Code § 54.1-2957(H) describes the requirements for CNMs to practice without a practice agreement.

CNS

A CNS who prescribes controlled substances must practice in consultation with a licensed physician in accordance with a practice agreement.

- A practice agreement entered into between a CNS and a licensed physician must address the availability of the physician for routine and urgent consultation on patient care. (Va. Code § 54.1-2957(J).)
- If the CNS will prescribe, the practice agreement must include the parameters of such prescribing of Schedules II through V controlled substances. (Va. Code § 54.1-2957.01(B).)

NP

A nurse practitioner with less than 5 years of clinical experience must enter into a practice agreement with a patient care team physician as defined in Virginia Code § 54.1-2900. Pursuant to Virginia Code §§ 54.1-2957(C), (D), and 54.1-2957.01(B), when a practice agreement is required for NP practice, it must include:

- Provisions for the periodic review of health records by the patient care team physician and may include provisions for visits to the site where health care is delivered in the manner and at the frequency determined by the patient care team;
- Provisions for appropriate input from health care providers in complex clinical cases and patient emergencies and for referrals;
- Categories of drugs and devices that may be prescribed;
- Guidelines for availability and ongoing communications that provide for and define consultation among the collaborating parties and the patient;
- Provisions for periodic joint evaluation of services provided;
- Provisions for periodic review and revision of the practice agreement; and
- The signature of the patient care team physician or the name of the patient care team physician clearly stated.

Virginia Code § 54.1-2957(I) describes the requirements for NP autonomous practice.

Agenda Item: Reciprocal Licensing Process and Application

Staff Note: Over the last 18 months, the Virginia Board of Medicine has been discussing the possibilities and benefits of reciprocal licensing to the public and physicians with the DC Board of Medicine and the Maryland Board of Physicians. The three boards are closing in on a Memorandum of Agreement to facilitate expedited licensure for physicians licensed in the 3 jurisdictions. Each board will have to develop their own process and application that will smoothly work with the other jurisdictions. Board staff will outline the process for the Committee. Also there is a draft application for review and approval.

Action: To discuss the process generally and in detail if necessary, and to review and revise the draft application as appropriate for approval.

Virginia Department of Health Professions

Board of Medicine
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463
Phone: (804) 367-4600
Fax: (804) 527-4426
Email: medbd@dhp.virginia.gov

Application for a RECIPROCITY license between Virginia, District of Columbia, and Maryland

To Practice Medicine and Surgery OR Osteopathy and Surgery

To the Board of Medicine of Virginia: I hereby make application for a license to practice as an (please circle one) MD or a DO in the Commonwealth of Virginia and submit the following statements:

1. Name in Full (Please Print or Type)

Last	First	Middle
Date of Birth _____ _____ _____ MO DAY YEAR	Social Security No. or VA Control No.*	Maiden Name if applicable
Public Address: This address will be public information:	House No. Street or PO Box	City State and Zip
Board Address: This address will be used for Board Correspondence and may be the same or different from the public address.	House No. Street or PO Box	City State and Zip
Work Phone Number	Home/Cell Phone Number	Email Address
		Professional School Degree

Please submit address changes in writing immediately to medbd@dhp.virginia.gov

Please attach check or money order payable to the Treasurer of Virginia for $302.00. Applications will not be processed without the fee. Do not submit fee without an application. **IT WILL BE RETURNED.**

APPLICANTS DO NOT USE SPACES BELOW THIS LINE – FOR OFFICE USE ONLY

APPROVED BY: _____
Date

LICENSE NUMBER	PROCESSING NUMBER	FEE
MD- 0101-		**$302.00**
DO – 0102-		**$302.00**

*In accordance with §54.1-116 Code of Virginia, you are required to submit your Social Security Number or your control number** issued by the *Virginia* Department of Motor Vehicles. If you fail to do so, the processing of your application will be suspended and fees will not be refunded. This number will be used by the Department of Health Professions for identification and will not be disclosed for other purposes except as provided by law. Federal and state law requires that this number be shared with other state agencies for child support enforcement activities. NO LICENSE WILL BE ISSUED TO ANY INDIVIDUAL WHO HAS FAILED TO DISCLOSE ONE OF THESE NUMBERS.

**In order to obtain a Virginia driver's license control number, it is necessary to appear in person at an office of the Department of Motor Vehicles in Virginia. A fee and disclosure to DMV of your Social Security Number will be required to obtain this number.

CURRENT PRACTICE ADDRESS

Street
Street 2
City, State, Zip
Contract Number:

PROJECTED PRACTICE ADDRESS IN VIRGINIA

Street
Street 2
City, State, Zip
Contract Number:

	ALL QUESTIONS MUST BE ANSWERED. If any of the following questions is answered Yes, you are ineligible for reciprocal licensure.	**YES**	**NO**
1.	Do you have any restrictions on your license in any state?		
2.	Do you have pending disciplinary matters or are you under investigation by any medical board at this time?		
3.	Do you currently have any physical condition or impairment that affects or limits your ability to perform any of the Obligations and responsibilities of professional practice in a safe and competent manner? "Currently" means recently enough so that the condition could reasonably have an impact on your ability to function as a practicing physician.		
4.	Do you currently have any mental health condition or impairment that affects or limits your ability to perform any of the obligations and responsibilities of professional practice in a safe and competent manner? "Currently" means recently enough so that the condition could reasonably have an impact on your ability to function as a practicing physician.		
5.	Do you currently have any condition or impairment related to alcohol or other substance use that affects or limits your ability to perform any of the obligations and responsibilities of professional practice in a safe and competent manner? "Currently" means recently enough so that the condition could reasonably have an impact on your ability to function as a practicing physician.		
6.	Are you being monitored in a physicians' health program?		
7.	Have you had 3 malpractice paid claims of $75,000 or more within the most recent 10-year period?		

AFFIDAVIT OF APPLICANT

I, , am the person referred to m the foregoing application and supporting documents.

I hereby authorize all hospitals, institutions, or organizations, my references, personal physicians, employers (past and present), business and professional associates (past and present), and all governmental agencies and instrumentalities (local, state, federal, or foreign) to release to the Virginia Board of Medicine any information, files or records requested by the Board in connection with the processing of individuals and groups listed above, any information which is material to me and my application.

I have carefully read the questions in the foregoing application and have answered them completely, without reservations of any kind, and I declare under penalty of perjury that my answers and all statements made by me herein are true and correct. Should I furnish any false information in this application, I hereby agree that such act shall constitute cause for the denial, suspension, or revocation of my license to practice medicine and surgery or osteopathic surgery in the Commonwealth of Virginia.

I have carefully read the laws and regulations related to the practice of my profession which are available at www.dhp.virginia.gov and I understand that fees submitted as part of the application process shall not be refunded.

_____ _____

Signature of Applicant Date

Agenda Item: Greater Delegation to Staff for Review of Non-Routine Applications

Staff Note: Licensing specialists are authorized to sign and issue a license for an application that is pristine, e.g., has no non-routine information. If potential non-routine information exists, the application is forwarded to the Deputy for Licensure. If the Deputy analyzes the information to be routine, he may approve the application. However, if the information is determined to be non-routine, it is forwarded to a Board member for review.

Some non-routine information is not seen to be predictive that the applicant would be a risk to the public. Information that is non-routine, but not predictive of risk to the public, could perhaps be reviewed by staff, saving Board member time. The Chair of the Credentials Committee and the President of the Board have provided their thoughts on this matter. In the following pages, you will find a copy of the traditional pathway license application and a consensus approach suggested for the review of non-routine information.

Action: Discuss the suggested approach and vote to approve or amend as appropriate.

INSTRUCTIONS FOR COMPLETING AN APPLICATION TO PRACTICE MEDICINE IN VIRGINIA FOR GRADUATES OF ALLOPATHIC MEDICAL SCHOOLS AND OSTEOPATHIC MEDICAL SCHOOLS

APPLICATION FEES ARE NONREFUNDABLE

BEFORE YOU PROCEED, READ THE FOLLOWING POINTS CAREFULLY!

NOTE

AN APPLICATION THAT IS NOT COMPLETE EXPIRES ONE YEAR AFTER IT IS SUBMITTED TO THE BOARD. IT IS THE RESPONSIBILITY OF THE APPLICANT TO ENSURE THAT ALL NECESSARY SUPPORTING DOCUMENTS ARRIVE AT THE BOARD PRIOR TO THE EXPIRATION DATE. IF THE ORIGINAL APPLICATION EXPIRES, THE APPLICANT MUST SUBMIT ANOTHER APPLICATION, PAY THE APPLICATION FEE AGAIN AND ENSURE THAT NEW SUPPORTING DOCUMENTS ALSO GET TO THE BOARD.

This is not the application for a training license to practice as a resident or fellow. This application is for a full and unrestricted MD or DO license to practice medicine in Virginia.

This is the application for a full and unrestricted license to practice as an MD or DO in Virginia.

You should familiarize yourself with the qualifications required for a full license by reviewing the laws and regulations governing the practice of allopathic medicine and osteopathic medicine in Virginia. They can be found at: https://www.dhp.virginia.gov/medicine/medicine_laws_regs.htm.

The Board works as efficiently as possible to process applications. The time from filing an application with the Board until the issuance of a license is dependent upon entities over which the Board has no control. It is the applicant's responsibility to ensure that outside entities send the necessary documentation to the Board. You should not expect the process to take less than 2-3 months, so plan accordingly if you are pursuing a practice position in Virginia.

A completed application must be returned to this office along with the fee of $302.00. Applications and fees must be received together. Only checks or money orders are accepted. Please make your payment instrument payable to the "Treasurer of Virginia."

The phone number to the Virginia Board of Medicine is 804-367-4600. The Board's email address for MD license applicants is med-medbd@dhp.virginia.gov . The Board's email address for DO license applicants is do-medbd@dhp.virginia.gov

Mailing Address
Virginia Board of Medicine
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

The Board of Medicine discourages the use of the United States Postal Service to send documents. The Board is unable to trace documents not delivered by courier/overnight mail. If you wish to send your documents by overnight mail, please use FED EX or UPS. If requested in the instructions below, you may have your documents sent by electronic mail pdf attachment to med-medbd@dhp.virginia.gov or facsimile to (804) 527-4426. The Board's email address for DO license applicants is do-medbd@dhp.virginia.gov

NB: Virginia law considers material misrepresentation of fact in an application for licensure to be a Class 1 misdemeanor. Misrepresentation may be by commission or omission. Be sure of your facts and provide full responses to the Board's questions.

PROCEEDING TO THE APPLICATION SIGNIFIES THAT YOU HAVE READ AND ACCEPT THE FOREGOING PRINCIPLES REGARDING THE BOARD'S PROCESSES.

☐1. **Application and Fee** – The completed four (4) page application should be returned with the required fee of $302.00. Applications submitted without the application fee will be returned. Checks should be made payable to the "Treasurer of Virginia." This document **should not** be faxed.

☐2. **Examination Scores – If you took all three steps of the USMLE examination or the FLEX examination,** contact the Federation of State Medical Boards (FSMB) at (817) 868-4000 or www.fsmb.org to have your scores submitted to the Board. Scores MAY NOT be faxed and MUST come directly from the FSMB. **If using the FCVS credentialing service, scores will be included.**

If you took the National Board of Osteopathic Medical Examinations or the COMLEX you may request copies of your transcripts at http://www.nbome.org/transcript-request.asp or by calling (866) 479-6828. Scores MAY NOT be faxed and MUST come directly from the National Board. **If using the FCVS credentialing service, scores will be included.**

If you took the National Board of Medical Examiners or a combination of the USMLE examination, contact the National Board of Medical Examiners at (215) 590-9500 or www.nbme.org to have your scores submitted to the Board. Scores MAY NOT be faxed and MUST come directly from the National Board. **If using the FCVS credentialing service, scores will be included.**

If you took the LMCC examination, contact the Medical Council of Canada (MCC) at (613) 521-6012. Scores MAY NOT be faxed and MUST come directly from the MCC. **If using the FCVS credentialing service, scores will be included.**

If you took a state examination, contact the state agency or licensure board to have your scores submitted to the Board. Scores MAY NOT be faxed and MUST come directly from the agency maintaining your score. **If using the FCVS credentialing service, scores will be included.**

☐3. **Transcripts – Official medical school transcripts must be received by the Virginia Board of Medicine.** Medical school transcripts must be official and bear the school seal. Transcripts will only be accepted if they come directly from the medical school to the Board or if sent to the Board by the applicant in the same unopened envelope in which they were received. **If using the FCVS credentialing service, transcripts will be included. Official school transcript can be emailed directly from the school to med-medbd@dhp.virginia.gov . For Osteopathic physician school transcript, this document can be emailed to do-medbd@dhp.virginia.gov**

☐4. **Postgraduate Training -** A completion certificate or program director's letter of completion must be received directly from the postgraduate training institution for the internships, residencies, and fellowships completed within the past 5 years. If your postgraduate training occurred more than 5 years ago, you may fulfill this requirement by sending a copy of your letter or certificate of completion. A PDF attachment of the letter of completion or copy of certificate may be emailed to med-medbd@dhp.virginia.gov , faxed to (804) 527-4426, or mailed to the Board. DO postgraduate training verification can be emailed to do-medbd@dhp.virginia.gov .

☐5. **Employment Activity –** List all activities from the date of graduation from your professional school including but not limited to internships, employment, affiliations, periods of non-activity or unemployment, observerships, and volunteer service in the "Employment Activity" section of the application beginning with your first activity following professional school graduation. If you are employed by a group practice or locum tenens/traveler company, please list all locations where you have provided service or held privileges. If more space is needed to record your activities, follow this link to obtain and submit a supplemental form with your application:
Supplemental Form: https://www.dhp.virginia.gov/media/dhpweb/docs/med/forms/SupplementalForm.pdf

☐6. **Verification of professional licenses** from a jurisdiction within the United States, its territories and possessions or Canada in which you have been issued a full license must be received by the Board. **Please contact the jurisdiction where you have been issued a license to practice medicine to inquire about having official license verification forwarded to the Virginia Board of Medicine.** Verification must come from the jurisdiction and maybe sent by email to med-medbd@dhp.virginia.gov, faxed to (804) 527-4426, or mailed. DO license verification can be emailed to do-medbd@dhp.virginia.gov

☐7. **NPDB Self Query – Complete the online Place a Self-Query Order form at https://www.npdb.hrsa.gov/**. Be ready to provide:

- o Identifying information such as name, date of birth, Social Security number
- o State health care license information (if you are licensed)
- o Credit or debit card information for the $4.00 fee (charged for each copy you request)

Verify your identity. This can be done electronically as part of your order or by completing a paper form and having it notarized. You will receive full instructions as you complete your order.

Wait for your response. Once your identity is verified, the NPDB will process your order. A paper copy of your response will be sent the next business day by regular U.S. mail.

Please note that the Board will accept a digitally-certified electronic copy of the NPDB report that is emailed to the Board, in lieu of a mailed report.

Should you choose to mail your report, when you receive your report in the mail from NPDB, **DO NOT OPEN IT. Place your unopened NPDB report in an oversized envelope and forward it to the Virginia Board of Medicine. The Board recommends using Fed EX or UPS for tracking purposes.**

The Board of Medicine is unable to track any mail or other package that is sent via the United States Postal Service. Any NPDB report received for an application not completed within 6 months of receipt of the NPDB report will have to be resubmitted.

☐ 8. **For graduates of medical schools outside of the U.S. and Canada. - ECFMG Certification:** To request your ECFMG certification Status Report follow this link https://cvsonline2.ecfmg.org/ . ECFMG will deliver your requested report to the Board.

☐9. Copies of documentation supporting any name change.

☐10. If you answer "yes" to any question in #6-18, provide documentation to the Board in addition to providing a narrative explaining your answer. Please provide court documentation for any convictions.

Please note:

*Please be aware that consistent with Virginia law and the mission of the Department of Health Professions, public addresses on file with the Board of Medicine are made available to the public. The Board address noted on your application may be different from the public address and is not released to the public. This notice is to reiterate that the Board of Medicine will allow the Board address of record to be a Post Office Box or practice location.

*Applications will be acknowledged after receipt if items are missing.

*Applications not completed within 12 months will expire and may be purged without notice from the board.

*Additional information may be requested after review by Board representatives.

*Application fees are non-refundable.

* Do not begin practice until you have been notified of approval. Submission of an application does not guarantee a license. A review of your application could result in the finding that you may not be eligible pursuant to Virginia laws and regulations.

*Certain forms may be faxed to 804-527-4426.

Virginia Department of Health Professions

Board of Medicine
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463
Phone: (804) 367-4600
Fax: (804) 527-4426
Email: medbd@dhp.virginia.gov

Application for a license **To Practice Medicine and Surgery OR Osteopathy and Surgery**

To the Board of Medicine of Virginia: I hereby make application for a license to practice as an (please circle one) MD or a DO in the Commonwealth of Virginia and submit the following statements:

1. Name in Full (Please Print or Type)

Last	First	Middle
Date of Birth _____ _____ _____ MO DAY YEAR	Social Security No. or VA Control No.*	Maiden Name if applicable
Public Address: This address will be public information:	House No. Street or PO Box	City State and Zip
Board Address: This address will be used for Board Correspondence and may be the same or different from the public address.	House No. Street or PO Box	City State and Zip
Work Phone Number	Home/Cell Phone Number	Email Address
Professional School Name and Location	Professional School Graduation Date	Professional School Degree

Please submit address changes in writing immediately to medbd@dhp.virginia.gov

Please attach check or money order payable to the Treasurer of Virginia for $302.00. Applications will not be processed without the fee. Do not submit fee without an application. **IT WILL BE RETURNED.**

APPLICANTS DO NOT USE SPACES BELOW THIS LINE – FOR OFFICE USE ONLY

APPROVED BY: _____
Date

LICENSE NUMBER	PROCESSING NUMBER	FEE
MD- 0101-		**$302.00**
DO – 0102-		**$302.00**

*In accordance with §54.1-116 Code of Virginia, you are required to submit your Social Security Number or your control number** issued by the *Virginia* Department of Motor Vehicles. If you fail to do so, the processing of your application will be suspended and fees will not be refunded. This number will be used by the Department of Health Professions for identification and will not be disclosed for other purposes except as provided by law. Federal and state law requires that this number be shared with other state agencies for child support enforcement activities. NO LICENSE WILL BE ISSUED TO ANY INDIVIDUAL WHO HAS FAILED TO DISCLOSE ONE OF THESE NUMBERS.

**In order to obtain a Virginia driver's license control number, it is necessary to appear in person at an office of the Department of Motor Vehicles in Virginia. A fee and disclosure to DMV of your Social Security Number will be required to obtain this number.

2. List in chronological order all professional practices including each location of service since graduation, including internships, residencies, hospital affiliations and absences from work. Also list all periods of non-professional activity or employment. **PLEASE ACCOUNT FOR ALL TIME**. If engaged in private practice, list all clinical affiliations.

From	To	Name and Address of Location Where Service was Provided	Position Held
________	________	____	____________________
________	________	____	____________________
________	________	____	____________________
________	________	____	____________________
________	________	____	____________________
________	________	____	____________________
________	________	____	____________________
________	________	____	____________________

3. Do you intend to engage in the active practice of medicine in the Commonwealth of Virginia? ☐ Yes ☐ No

   If Yes, give location _____

4. List all jurisdictions in which you have been issued a license to practice medicine: include all active, inactive, expired, suspended or revoked licenses. Indicate number and date issued.

Jurisdiction	Number Issued	Active/Inactive/Expired

5. Which of the following have you taken: ☐National Board Examination ☐USMLE 1 ☐USMLE 2 ☐USMLE 3 ☐FLEX ☐LMCC ☐ State Equivalency ☐ COMLEX

QUESTIONS MUST BE ANSWERED. If any of the following questions (6-18) is answered **Yes**, explain and Substantiate with documentation.

		Yes	No
6.	Have you ever been denied a license or the privilege of taking a licensure/competency examination by any testing entity or licensing authority?	☐	☐
7.	Have you ever been convicted of a violation of/or pled Nolo Contendere to any federal, state, or local statute, or regulation or ordinance, or entered into an plea bargaining relating to a felony or misdemeanor? (Excluding traffic violations, except convictions for driving under the influence.) **Additionally, any information concerning an arrest, charge, or conviction that has been sealed, including arrests, charges, or convictions for possession of marijuana, does not have to be disclosed.**	☐	☐
8.	Have you ever been denied privileges or voluntarily surrendered your clinical privileges for any reason?	☐	☐
9.	Have you ever been placed on a corrective action plan, placed on probation or been dismissed or suspended or requested to withdraw from any professional school, training program, hospital, etc?	☐	☐
10.	Have you ever been terminated from employment or resigned in lieu of termination from any training program, hospital, healthcare facility, healthcare provider, provider network or malpractice insurance carrier?	☐	☐
11.	Do you have any pending disciplinary actions against your professional license/certification/permit/registration related to your practice of medicine?	☐	☐
12.	Have you voluntarily withdrawn from any professional society while under investigation?	☐	☐
13.	Within the past five years, have you exhibited any conduct or behavior that could call into question your ability to practice in a competent and professional manner?	☐	☐
14.	Within the past five years, have you been disciplined by any entity?	☐	☐
15.	Do you currently have any physical condition or impairment that affects or limits your ability to perform any of the Obligations and responsibilities of professional practice in a safe and competent manner? "Currently" means recently enough so that the condition could reasonably have an impact on your ability to function as a practicing physician.	☐	☐
16.	Do you currently have any mental health condition or impairment that affects or limits your ability to perform any of the obligations and responsibilities of professional practice in a safe and competent manner? "Currently" means recently enough so that the condition could reasonably have an impact on your ability to function as a practicing physician.	☐	☐
17.	Do you currently have any condition or impairment related to alcohol or other substance use that affects or limits your ability to perform any of the obligations and responsibilities of professional practice in a safe and competent manner? "Currently" means recently enough so that the condition could reasonably have an impact on your ability to function as a practicing physician.	☐	☐

		Yes	No
18.	Within the past five years, have you any condition or restrictions been imposed upon you or your practice to avoid disciplinary action by any entity?	☐	☐
19.	Have you requested a certification report from ECFMG?	☐	☐
20.	Have you requested a current report (Self Query) from NPDB?	☐	☐

Malpractice Information

21.	Have you had any malpractice paid claims in the past ten (10) years, or do you have any pending malpractice suits? If so, please provide a narrative for each paid claim or pending case during this time period.	☐	☐

Military Service:

22.	Are you a spouse of someone who is on a federal active duty orders pursuant to Title 10 of the U.S. Code or of a veteran who has left active-duty service within one year of submission of this application and who is accompanying your spouse to Virginia or an adjoining state of the District of Columbia?	☐	☐
23.	Are you active duty military?	☐	☐

24. AFFIDAVIT OF APPLICANT

I, _____, am the person referred to in the foregoing application and supporting documents.

I hereby authorize all hospitals, institutions, or organizations, my references, personal physicians, employers (past and present), business and professional associates (past and present), and all governmental agencies and instrumentalities (local, state, federal, or foreign) to release to the Virginia Board of Medicine any information, files or records requested by the Board in connection with the processing of individuals and groups listed above, any information which is material to me and my application.

I have carefully read the questions in the foregoing application and have answered them completely, without reservations of any kind, and I declare under penalty of perjury that my answers and all statements made by me herein are true and correct. Should I furnish any false information in this application, I hereby agree that such act shall constitute cause for the denial, suspension, or revocation of my license to practice medicine and surgery or osteopathic surgery in the Commonwealth of Virginia.

I have carefully read the laws and regulations related to the practice of my profession which are available at www.dhp.virginia.gov and **I understand that fees submitted as part of the application process shall not be refunded.**

_____ _____

Signature of Applicant Date

Effective:

Greater Delegation to Licensing Staff for Non-Routine Applications

1. **Denial of a license by another state** - review by Board member
2. **Denial to sit for an examination** - review by Board member
3. **Misdemeanor convictions** – review by staff for convictions prior to professional school
4. **Felony convictions** – review by Board member
5. **Convictions of Moral Turpitude** – review by staff for convictions prior to professional school
6. **Denial of privileges** – review by staff if > 5 years prior to application
7. **Voluntarily surrendered privileges** – review by staff if > 5 years prior to application
8. **Placed on a corrective action plan** – review by staff if > 5 years prior to application
9. **Placed on probation** - review by staff > 5 years prior to application
10. **Dismissed, suspended or requested to withdraw from school, training program, hospital, etc.** - review by staff if > 5 years of active practice prior to application
11. **Been terminated from employment or resigned in lieu of termination from a training program, hospital, healthcare facility, healthcare provider, provider network or malpractice carrier** - review by staff if > 5 years prior to application
12. **Any pending disciplinary actions on any license to practice** – review by Board member

13. **Withdrawn from a professional society while under investigation** – review by staff with discretion
14. **In the past 5 years**: - All 3 for review by Board member
    -Conduct or behavior that may have impacted your ability to safely practice
    -Disciplined by any entity
    -Conditions or restrictions on your practice in lieu of disciplinary action
15. **Current physical impairment** – review by Board member
16. **Current mental health impairment** – review by Board member
17. **Current substance abuse impairment** – review by Board member
18. **Malpractice** – review by staff with discretion

Agenda Item: Regulatory Advisory Panel for Updating the Board of Medicine Regulations Governing Prescribing of Opioids and Buprenorphine

Staff Note: The Board's regulations became effective in March 2017. The regulations were derived from several sources, including the 2016 Guideline from the CDC. Just a month ago, the CDC published its 2022 Clinical Practice Guideline for Prescribing Opioids for Pain. Given that the revised guideline is now available, it should be reviewed for new principles that need to be incorporated into the Board's current regulations. The optimal way to approach this is to establish a Regulatory Advisory Panel. The panel should have Board of Medicine members, content experts and a range of stakeholders. In the following pages, you will find the summary of the 2022 guideline and the current Virginia Board of Medicine regulations.

Action: Discuss the composition of the Regulatory Advisory Panel to be formed in 2023.

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 71 / No. 3
November 4, 2022

CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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CONTENTS (Continued)

The *MMWR* series of publications is published by the Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

Suggested citation: [Author names; first three, then et al., if more than six.] [Title]. MMWR Recomm Rep 2022;71(No. RR-#):[inclusive page numbers].

CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022

Deborah Dowell, MD[1]; Kathleen R. Ragan, MSPH[1]; Christopher M. Jones, PharmD, DrPH[2]; Grant T. Baldwin, PhD[1]; Roger Chou, MD[3]

[1]*Division of Overdose Prevention, National Center for Injury Prevention and Control, CDC;*
[2]*Office of the Director, National Center for Injury Prevention and Control, CDC;*
[3]*Pacific Northwest Evidence-based Practice Center and Oregon Health & Science University, Portland, Oregon*

Summary

This guideline provides recommendations for clinicians providing pain care, including those prescribing opioids, for outpatients aged ≥18 years. It updates the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 (MMWR Recomm Rep 2016;65[No. RR-1]:1–49) *and includes recommendations for managing acute (duration of <1 month), subacute (duration of 1–3 months), and chronic (duration of >3 months) pain. The recommendations do not apply to pain related to sickle cell disease or cancer or to patients receiving palliative or end-of-life care. The guideline addresses the following four areas: 1) determining whether or not to initiate opioids for pain, 2) selecting opioids and determining opioid dosages, 3) deciding duration of initial opioid prescription and conducting follow-up, and 4) assessing risk and addressing potential harms of opioid use. CDC developed the guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework. Recommendations are based on systematic reviews of the scientific evidence and reflect considerations of benefits and harms, patient and clinician values and preferences, and resource allocation. CDC obtained input from the Board of Scientific Counselors of the National Center for Injury Prevention and Control (a federally chartered advisory committee), the public, and peer reviewers. CDC recommends that persons with pain receive appropriate pain treatment, with careful consideration of the benefits and risks of all treatment options in the context of the patient's circumstances. Recommendations should not be applied as inflexible standards of care across patient populations. This clinical practice guideline is intended to improve communication between clinicians and patients about the benefits and risks of pain treatments, including opioid therapy; improve the effectiveness and safety of pain treatment; mitigate pain; improve function and quality of life for patients with pain; and reduce risks associated with opioid pain therapy, including opioid use disorder, overdose, and death.*

Introduction

Background

Pain is one of the most common reasons adults seek medical care in the United States (*1*). Acute pain, a nearly universal experience, is a physiologic response to noxious stimuli that can become pathologic. Acute pain is usually sudden in onset and time limited (defined in this clinical practice guideline as having a duration of <1 month) and often is caused by injury, trauma, or medical treatments such as surgery (*2*,*3*). Unresolved acute pain or subacute pain (defined in this clinical practice guideline as pain that has been present for 1–3 months) can evolve into chronic pain (*4*). Chronic pain typically lasts >3 months (*4*) and can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or unknown cause (*2*). Approximately one in five U.S. adults had chronic pain in 2019 and approximately one in 14 adults experienced "high-impact" chronic pain, defined as having pain on most days or every day during the past 3 months that limited life or work activities (*5*). Pain, especially chronic pain, can affect almost every aspect of a person's life, leading to impaired physical functioning, poor mental health, and reduced quality of life, and contributes to substantial morbidity each year (*6*). In 2011, the economic costs of chronic pain were estimated to range from $560 to $635 billion in annual direct medical costs, lost productivity, and disability (*2*).

Pain is a complex phenomenon influenced by multiple factors, including biologic, psychological, and social factors (*7*). This complexity means substantial heterogeneity exists in the effectiveness of various pain treatments, depending on the type of underlying pain or condition being treated (*7*–*11*). Patients might experience persistent pain that is not well controlled (*6*). Chronic pain often co-occurs with behavioral health conditions, including mental and substance use disorders (*12*,*13*). Patients with chronic pain also are at increased risk for suicidal ideation and behaviors (*14*,*15*). Data from death investigations in 18 states during 2003–2014 indicate that approximately 9% of suicide decedents had

Corresponding author: Division of Overdose Prevention, National Center for Injury Prevention and Control, CDC. Email: cdcinfo@cdc.gov.

evidence of having chronic pain at the time of death; however, this is likely an underestimate because of the limitations of the underlying data sources used in the study (*16*). These factors and potentially harmful outcomes associated with chronic pain for some persons add to the clinical complexity and underscore the importance of adequately treating and providing care to persons with pain. Thus, prevention, assessment, and treatment of pain is a persistent challenge for clinicians. Pain might go unrecognized, and some persons (e.g., members of marginalized racial and ethnic groups; women; older persons; persons with cognitive impairment; persons with mental and substance use disorders, sickle cell disease, or cancer-related pain; and persons at the end of life) can be at risk for inadequate pain treatment (*2*,*6*,*17*–*23*).

Although substantial opportunity exists for improved pain management broadly across the United States, data underscore opportunities for addressing specific, long-standing health disparities (*24*–*26*) in the treatment of pain. For example, patients who identify as Black or African American (Black), Hispanic or Latino (Hispanic), and Asian receive fewer postpartum pain assessments relative to White patients (*27*). Black (*28*,*29*) and Hispanic (*29*) patients are less likely than White patients to receive analgesia for acute pain. Among Black and White patients receiving opioids for pain, Black patients are less likely to be referred to a pain specialist, and Black patients receive prescription opioids at lower dosages than White patients (*24*,*30*). Racial and ethnic differences remain even after adjusting for access-related factors, the needs and preferences of patients, and the appropriateness of the intervention (*25*). These disparities appear to be further magnified for Black and Hispanic patients who live in socioeconomically disadvantaged neighborhoods (*26*). Women might be at higher risk for inadequate pain management (*31*), although they have higher opioid prescription fill rates (*32*) than men at a population level. Geographic disparities contribute to increased use of opioids for conditions for which nonopioid treatment options might be preferred but are less available. For example, adults living in rural areas are more likely to be prescribed opioids for chronic nonmalignant pain than adults living in nonrural areas (*33*). Although not Hispanic or Latino (non-Hispanic) American Indian or Alaska Native and non-Hispanic White populations have experienced much higher rates of prescription opioid–related overdose deaths than non-Hispanic Black, Hispanic, or non-Hispanic Asian or Pacific Islander populations (*34*), application of safeguards in opioid prescribing are disproportionately applied to Black patients. In one study, Black patients were more likely than White patients to receive regular office visits and have restricted early refills (*35*). In another study, clinicians were substantially more likely to discontinue opioids if there was evidence of misuse for Black patients compared with White patients (*36*). Differentially untreated or undertreated pain as a result of clinician biases persists and demands immediate and sustained attention and action (*37*–*40*).

Because of the clinical, psychological, and social consequences associated with pain, including limitations in activities, lost work productivity, reduced quality of life, and pervasive stigma, it is essential that clinicians have the training, education, guidance, and resources to provide appropriate, holistic, and compassionate care for patients with pain (*2*,*6*). An important aim of pain management is the provision of person-centered care built on trust between patients and clinicians. Such care includes appropriate evaluation to identify potentially reversible causes of pain and establish a diagnosis and measurable treatment outcomes that focus on optimizing function and quality of life (*6*). To achieve this aim, it is important that clinicians consider the full range of pharmacologic and nonpharmacologic treatments for pain care, and that health systems, payers, and governmental programs and entities make the full spectrum of evidence-based treatments accessible to patients with pain and their treating clinicians.

The range of therapeutic options has historically been inaccessible to many patients because of factors such as inadequate clinician education, training, and guidance; unconscious bias; a shortage of pain management specialists; insufficient access to treatment modalities such as behavioral therapy; siloed health systems; insurance coverage and reimbursement policies; and lack of clarity about the evidence supporting different pain treatments (*6*,*17*,*41*–*46*). Partly because of these factors affecting access to a wide range of treatment modalities, for many years medications such as prescription opioids have been the mainstay to treat pain, despite very limited evidence to support their long-term (>1 year) benefits; most placebo-controlled trials have been <6 weeks in duration (*2*,*6*,*47*,*48*).

Opioids can be essential medications for the management of pain; however, they carry considerable potential risk. A systematic review published in 2014 by the Agency for Healthcare Research and Quality (AHRQ) found insufficient evidence to demonstrate long-term benefits of prescription opioid treatment for chronic pain, and long-term prescription opioid use was found to be associated with increased risk for overdose and opioid misuse, among other risks (*47*). Some risks, such as overdose, were dose dependent (*47*). In 2014, on the basis of accumulating evidence of potential risks to patients, the Food and Drug Administration (FDA) required new safety labeling changes for extended-release and long-acting opioids. Changes included a boxed warning on the "risks of addiction, abuse, and misuse, which can lead to overdose and death" and, for patients receiving opioids during pregnancy, the risk

for neonatal abstinence syndrome (a group of conditions that can occur when newborns withdraw from certain substances including opioids; withdrawal caused by in utero exposure to opioids also is called neonatal opioid withdrawal syndrome) (*49*). In 2016, these warnings were added to the labels for immediate-release opioids (*50*).

In addition to the potential risks to patients, prescribed opioids have the potential for diversion and nonmedical use among persons to whom they were not prescribed (*51*). In the United States, opioid prescribing increased fourfold during 1999–2010; this increase was paralleled by an approximately fourfold increase in overdose deaths involving prescription opioids during the same period (*52*) and increases in prescription opioid use disorder (*53*). In addition to the increased overall volume of opioid prescriptions during this period, how opioids were prescribed also changed; opioids increasingly were prescribed at higher dosages and for longer durations, prescribing behaviors associated with opioid use disorder and overdose (*54*,*55*). The limited evidence of long-term effectiveness of opioids for chronic pain, coupled with risks to patients and to persons using prescription opioids that were not prescribed to them, underscored the importance of reducing inappropriate opioid prescribing while advancing evidence-based pain care to improve the lives of persons living with pain.

CDC recognized the need for a national guideline on pain management that could improve appropriate opioid prescribing while minimizing opioid-related risks and released the *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016* (referred to as the 2016 CDC Opioid Prescribing Guideline hereafter). The 2016 CDC Opioid Prescribing Guideline included 12 recommendations for the prescribing of opioids for chronic pain by primary care clinicians in outpatient settings, excluding active cancer treatment, palliative care, and end-of-life care (*56*). The recommendations in the 2016 CDC Opioid Prescribing Guideline were based on a systematic review of the best-available evidence at the time, along with input from experts and the public and review and deliberation by the Board of Scientific Counselors (BSC) of the National Center for Injury Prevention and Control (NCIPC) (a federally chartered advisory committee). The goals of the guideline were to 1) ensure that clinicians and patients considered safer and more effective pain treatment; 2) improve patient outcomes, such as reduced pain and improved function; and 3) reduce the number of persons who developed opioid use disorder, experienced overdose, or experienced other prescription opioid–related adverse events (*56*). To facilitate uptake and implementation of the 2016 CDC Opioid Prescribing Guideline in clinical practice, CDC used a broad-reaching strategy that included clinician education and training, partnerships with health systems and payers, and multiple clinical tools and fact sheets (*57*).

The number of overall opioid prescriptions in the United States declined after 2012, and further declines have been observed after the release of the 2016 CDC Opioid Prescribing Guideline (*58*). The timing of this release was associated with accelerated decreases in overall opioid prescribing and declines in potentially high-risk prescribing (e.g., high-dosage opioid prescribing and concurrent prescribing of opioid pain medication and benzodiazepines) (*58*,*59*). The release of the 2016 CDC Opioid Prescribing Guideline also was temporally associated with modest increases in the prescribing of nonopioid pain medication (*60*). Although not the intent of the 2016 CDC Opioid Prescribing Guideline, design and implementation of new laws, regulations, and policies also appeared to reflect its recommendations. For example, since 2016, consistent with SUPPORT Act requirements (*61*), some state Medicaid programs have used the guideline and other resources to promote nonopioid options for chronic pain management (*62*). Approximately half of all states have passed legislation limiting initial opioid prescriptions for acute pain to a ≤7-day supply (*63*), and many insurers, pharmacy benefit managers, and pharmacies have enacted similar policies (*64*). At least 17 states have passed laws requiring or recommending the coprescription of naloxone in the presence of overdose risk factors, such as high dosages of opioids or concomitant opioid pain medications and benzodiazepines (*65*).

Although some laws, regulations, and policies that appear to support recommendations in the 2016 CDC Opioid Prescribing Guideline might have had positive results for some patients, they are inconsistent with a central tenet of the guideline: that the recommendations are voluntary and intended to be flexible to support, not supplant, individualized, patient-centered care. Of particular concern, some policies purportedly drawn from the 2016 CDC Opioid Prescribing Guideline have been notably inconsistent with it and have gone well beyond its clinical recommendations (*6*,*66*,*67*). Such misapplication includes extension to patient populations not covered in the 2016 CDC Opioid Prescribing Guideline (e.g., cancer and palliative care patients), rapid opioid tapers and abrupt discontinuation without collaboration with patients, rigid application of opioid dosage thresholds, application of the guideline's recommendations for opioid use for pain to medications for opioid use disorder treatment (previously referred to as medication assisted treatment), duration limits by insurers and pharmacies, and patient dismissal and abandonment (*66*–*68*). These actions are not consistent with the 2016 CDC Opioid Prescribing Guideline and have contributed to patient harm, including untreated and undertreated pain, serious withdrawal symptoms, worsening

pain outcomes, psychological distress, overdose, and suicidal ideation and behavior (*66*–*71*).

Rationale

Since release of the 2016 CDC Opioid Prescribing Guideline, new evidence has emerged on the benefits and risks of prescription opioids for both acute and chronic pain, comparisons with nonopioid pain treatments, dosing strategies, opioid dose-dependent effects, risk mitigation strategies, and opioid tapering and discontinuation (*7*–*11*). This evidence includes studies on misapplication of the 2016 CDC Opioid Prescribing Guideline (*66*), benefits and risks of different tapering strategies and rapid tapering associated with patient harm (*68*,*71*–*73*), challenges in patient access to opioids (*6*), patient abandonment and abrupt discontinuation of opioids (*71*), a seminal randomized clinical trial comparing prescription opioids to nonopioid medications on long-term pain outcomes (*74*), the association of characteristics of initial opioid prescriptions with subsequent likelihood for long-term opioid use (*75*,*76*), and the small proportion of opioids used by patients compared with the amount prescribed to them for postoperative pain (*77*–*79*).

Opioid medications remain a common treatment for pain despite declines in the number of opioid prescriptions after 2012 (*58*). During 2015–2018, approximately 6% of U.S. adults reported use of one or more prescription opioids during the past 30 days (*80*), and in 2020, approximately 143 million opioid prescriptions were dispensed from pharmacies in the United States (*81*). Rates of opioid prescribing continue to vary across states, medical specialties, patient demographics, and pain conditions in ways that cannot be explained by the underlying health status of the population, and often are discordant with the 2016 CDC Opioid Prescribing Guideline recommendations (*25*,*77*,*82*–*84*). The prevalence of prescription opioid misuse and prescription opioid use disorder also has declined in recent years. In 2019, among persons aged ≥12 years in the United States, 9.7 million reported misuse of prescription opioids during the past year (a decrease from 12.5 million in 2015), and 1.4 million met criteria for a past-year prescription opioid use disorder (a decrease from 2.0 million in 2015) (*85*). However, in 2020, prescription opioids remained the most commonly misused prescription drug in the United States (*51*). Also in 2020, among those reporting misuse during the past year, 64.6% reported the main reason for their most recent misuse was to "relieve physical pain" compared with 11.3% to "feel good or get high" and 2.3% "because I am hooked or have to have it" (*51*). Taken together, these factors underscore the need for an updated clinical practice guideline on appropriate opioid prescribing for pain and pain management.

This clinical practice guideline expands and updates the 2016 CDC Opioid Prescribing Guideline to provide evidence-based recommendations for prescribing opioid pain medication for acute, subacute, and chronic pain for outpatients aged ≥18 years, excluding pain management related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care (Boxes 1 and 2). Lessons learned from the development of the 2016 CDC Opioid Prescribing Guideline informed the process used to generate this update. This update leverages new data to expand content on prescription opioids for acute and subacute pain throughout the recommendations. Importantly, the update also aims to clearly delineate recommendations that apply to patients who are being considered for initial treatment with prescription opioids and patients who have been receiving opioids as part of their ongoing pain management.

CDC developed a draft clinical practice guideline on the basis of five systematic reviews of the best-available evidence on the benefits and risks of prescription opioids, nonopioid pharmacologic treatments, and nonpharmacologic treatments. The draft clinical practice guideline was reviewed by an independent federal advisory committee (the Board of Scientific Counselors of the National Center for Injury Prevention and Control), peer reviewers, and the public and was revised after feedback from these reviews. Additional insights from patients, caregivers, and clinicians shared during virtual conversations held in 2020 were incorporated in the update. Importantly, to discourage the misapplication of opioid pain medication dosage thresholds as inflexible standards, revised recommendation statement language emphasizes principles such as avoiding increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients. More-specific considerations related to dosage have been moved to implementation considerations that follow each recommendation statement, where more nuance is offered to inform clinical decision-making and individualized patient care.

This clinical practice guideline provides recommendations but does not replace clinical judgment and individualized, patient-centered decision-making. The recommendations are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations; thus, they should be considered in the context of the clinician-patient relationship built on shared understanding and a whole-person approach that considers such factors as the patient's physical and psychological functioning, support needs, expected health outcomes and well-being, home environment, and home and work responsibilities. Flexibility for clinicians and patients is paramount when making patient-centered clinical treatment decisions. The recommendations aim to improve

BOX 1. Executive summary of the CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022

This clinical practice guideline updates and expands the *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016* (MMWR Recomm Rep 2016;65[No. RR-1]:1–49]) and provides evidence-based recommendations for primary care and other clinicians (including physicians, nurse practitioners and other advanced practice registered nurses, physician assistants, and oral health practitioners) providing pain care, including those prescribing opioids, for outpatients aged ≥18 years with acute (duration of <1 month) pain, subacute (duration of 1–3 months) pain, or chronic (duration of >3 months) pain. Recommendations on use of opioids for acute pain and on tapering opioids for patients already receiving opioid therapy have been substantially expanded in this update. These recommendations do not apply to patients experiencing pain associated with the following conditions or settings: pain management related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care. Applicable outpatient settings include clinician offices, clinics, and urgent care centers. The recommendations do not apply to providing care to patients who are hospitalized or in an emergency department or other observational setting from which they might be admitted to inpatient care. These recommendations do apply to prescribing for pain management when patients are discharged from hospitals, emergency departments, or other facilities.

This clinical practice guideline addresses the following areas:

1. Determining whether or not to initiate opioids for pain
2. Selecting opioids and determining opioid dosages
3. Deciding duration of initial opioid prescription and conducting follow-up
4. Assessing risk and addressing potential harms of opioid use

CDC developed this clinical practice guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, and recommendations are made based on a systematic review of the available scientific evidence while considering benefits and harms; values and preferences of patients, caregivers, and clinicians; and resource allocation (e.g., costs to patients or health systems, including clinician time). CDC obtained input on this clinical practice guideline through individual conversations with patients, caregivers, and clinicians and public comment opportunities available via *Federal Register* notices. CDC also sought input from the Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC) (a federally chartered advisory committee), federal partners, and peer reviewers with scientific and clinical expertise.

The clinical evidence reviews found that a number of nonpharmacologic treatments and a number of nonopioid medications are associated with improvements in pain, function, or both, that appear comparable to improvements associated with opioid use. Multiple noninvasive nonpharmacologic interventions (e.g., exercise and psychological therapies) are associated with improvements in pain, function, or both, that are sustained after treatment and are not associated with serious harms. Nonopioid drugs, including serotonin and norepinephrine reuptake inhibitor (SNRI) antidepressants, pregabalin and gabapentin, and nonsteroidal anti-inflammatory drugs (NSAIDs), are associated with small to moderate improvements in chronic pain and function for certain chronic pain conditions. Nonopioid drug class–specific adverse events include serious cardiovascular, gastrointestinal, or renal effects with NSAIDs and sedation with anticonvulsants. Opioid therapy is associated with similar or decreased effectiveness for pain and function versus NSAIDs across several acute pain conditions and with small improvements in short-term (1 to <6 months) pain and function compared with placebo; evidence was found of attenuated pain reduction over time with opioids (between 3 and 6 months versus between 1 and 3 months). Opioid therapy is associated with increased risk for serious harms (including opioid use disorder and overdose) that appears to increase with increase in opioid dosage, without a clear threshold below which there is no risk. No validated, reliable way exists to predict which patients will suffer serious harm from opioid therapy. Evidence was sparse for long-term improvement of pain or function for any treatment for chronic pain. Some evidence indicated that beneficial effects of some nonpharmacologic therapies persist for up to 12 months after the end of a course of a treatment. Among 154 trials of nonopioid medications rated as good or fair quality, eight were long term (≥1 year). A single trial evaluated outcomes at 1 year for opioid medications (compared with nonopioid medications).

Continued on the next page.

BOX 1. (*Continued*) Executive summary of the CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022

CDC invited input on the draft clinical practice guideline and received approximately 5,500 public comments. Many of these comments were related to experiences with pain or with the aftermath of a family member's, friend's, or significant person's overdose; barriers to and access to pain care and evidence-based treatment; concerns about the level of specificity of recommendations; and overall communication and implementation of the clinical practice guideline. Some respondents expressed concerns that insufficient specificity of recommendations might leave clinicians without sufficient practical advice or context, whereas others were concerned that inclusion of more-specific recommendations or information in the guideline could facilitate misapplication through adaption of the clinical practice guideline or components of the guideline into rigid policies and laws. CDC incorporated insights from public comments into the clinical practice guideline, including special considerations for each recommendation. To help prevent misapplication of recommendations as inflexible rules and enable clinicians to account for individualized, person-centered clinical considerations, specific prescription dosages and durations are generally not included in the summary recommendation statements, which highlight general principles. Greater specificity is provided in implementation considerations and supporting rationales, which can offer more flexibility to help clinicians weigh benefits and risks of different therapeutic courses for specific patients.

Recommendation statements emphasize that opioids should be used only when benefits for pain and function are expected to outweigh risks. Before initiating opioid therapy for patients with pain, clinicians should discuss with patients the realistic benefits and known risks of opioid therapy. Before starting ongoing opioid therapy for patients with subacute or chronic pain, clinicians should work with patients to establish treatment goals for pain and function and consider how opioid therapy will be discontinued if benefits do not outweigh risks. When opioids are initiated, clinicians should prescribe the lowest effective dosage of immediate-release opioids for no longer than needed for the expected duration of pain severe enough to require opioids. During ongoing opioid therapy, clinicians should collaborate with patients to evaluate and carefully weigh benefits and risks of continuing opioid therapy and exercise care when increasing, continuing, or reducing opioid dosage. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk for opioid-related harms and should work with patients to incorporate relevant strategies to mitigate risk, including offering naloxone and reviewing potential interactions with any other prescribed medications or substances used. Clinicians should offer or arrange treatment with evidence-based medications to treat patients with opioid use disorder.

CDC recommends that persons with pain receive appropriate pain treatment with careful consideration of the benefits and risks of all treatment options in the context of the patient's circumstances. Clinicians should collaborate with patients when making treatment decisions and designing a treatment plan, including when initiating or changing pain management strategies and particularly when considering initiating, increasing, tapering, or discontinuing opioids. Clinicians should avoid abrupt discontinuation of opioids, especially for patients receiving high dosages of opioids, should avoid dismissing patients from care, and should ensure (provide or arrange) appropriate care for patients with pain and patients with complications from opioid use (e.g., opioid use disorder). Quality and equitable care across sociodemographic groups requires attention to mitigation of potential barriers to care, such as through linguistically tailored care and cost-assistance programs to ensure access to appropriate pharmacotherapy, psychological support, and physical therapy as needed.

This voluntary clinical practice guideline provides recommendations only and is intended to support, not supplant, clinical judgment and individualized, person-centered decision-making. This clinical practice guideline should not be applied as inflexible standards of care across patient populations by health care professionals; health systems; pharmacies; third-party payers; or state, local, or federal organizations or entities. This clinical practice guideline is intended to improve communication between clinicians and patients about the benefits and risks of pain treatment, including opioid therapy for pain; improve the safety and effectiveness of pain treatment; mitigate pain; improve function and quality of life for patients with pain; and reduce risks associated with opioid pain therapy, including opioid use disorder, overdose, and death.

BOX 2. Intended use of CDC's Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022

This clinical practice guideline is

- a clinical tool to improve communication between clinicians and patients and empower them to make informed, person-centered decisions related to pain care together;
- intended for primary care clinicians and other clinicians providing pain care for outpatients aged ≥18 years with
  - acute pain (duration of <1 month),
  - subacute pain (duration of 1–3 months), or
  - chronic pain (duration of >3 months); and
- intended to be flexible to enable person-centered decision-making, taking into account a patient's expected health outcomes and well-being.

This clinical practice guideline is not

- a replacement for clinical judgment or individualized, person-centered care;
- intended to be applied as inflexible standards of care across patients or patient populations by health care professionals, health systems, pharmacies, third-party payers, or governmental jurisdictions or to lead to the rapid tapering or abrupt discontinuation of opioids for patients;
- a law, regulation, or policy that dictates clinical practice or as a substitute for Food and Drug Administration–approved labeling;
- applicable to
  - management of pain related to sickle cell disease,
  - management of cancer-related pain, or
  - palliative care or end-of-life care; or
- focused on opioids prescribed for opioid use disorder.

communication between clinicians and patients about the benefits and risks of prescription opioids and other pain treatment strategies; improve the safety and effectiveness of pain treatment; improve pain, function, and quality of life for persons with pain; and reduce the risks associated with opioid pain treatment (including opioid use disorder, overdose, and death) and with other pain treatment.

This clinical practice guideline provides voluntary clinical practice recommendations for clinicians that should not be used as inflexible standards of care. The recommendations are not intended to be implemented as absolute limits for policy or practice across populations by organizations, health care systems, or government entities.

Scope and Audience

This clinical practice guideline is intended for clinicians who are treating outpatients aged ≥18 years with acute (duration of <1 month), subacute (duration of 1–3 months), or chronic (duration of >3 months) pain, and excludes pain management related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care. The recommendations are most relevant to clinicians whose scope of practice includes prescribing opioids (e.g., physicians, nurse practitioners and other advanced-practice registered nurses, physician assistants, and oral health practitioners). Because clinicians might work within team-based care, this clinical practice guideline also refers to and promotes integrated pain management and collaborative working relationships among clinicians (e.g., behavioral health specialists such as social workers or psychologists, pharmacists, and registered nurses). This guideline update includes recommendations for primary care clinicians (e.g., internists and family physicians) and other clinicians managing pain in outpatient settings (e.g., surgeons, emergency medicine clinicians, occupational medicine clinicians, physical medicine and rehabilitation clinicians, and neurologists). Applicable settings include clinician offices, clinics, and urgent care centers. The recommendations do not apply to care provided to patients who are hospitalized or in an emergency department or other observational setting from which they might be admitted to inpatient care. These recommendations do apply to prescribing for pain management for patients when they are discharged from hospitals, emergency departments, or other facilities.

In addition to updating recommendations on the basis of new evidence regarding management of chronic pain, this clinical practice guideline is intended to assist clinicians in weighing benefits and risks of prescribing opioid pain medication for painful acute conditions (e.g., low back pain, neck pain, other musculoskeletal pain, neuropathic pain, dental pain, kidney stone pain, and acute episodic migraine) and pain related to procedures (e.g., postoperative pain and pain from oral surgery). In 2020, several of these indications were prioritized by an ad hoc committee of the National Academies of Sciences, Engineering, and Medicine (*86*) as those for which evidence-based clinical practice guidelines would help inform prescribing practices, with the greatest potential effect on public health. This update includes content on management of subacute painful conditions, when duration falls between that typically considered acute (defined as lasting <1 month) and chronic (defined as lasting >3 months). The durations used to define acute, subacute, and chronic pain might imply more specificity than is found in real-life patient experience, when pain often gradually transitions from acute to chronic. These time-bound definitions are not meant to be

absolute but rather to be approximate guides to facilitate the consideration and practical use of the recommendations by clinicians and patients.

The 2016 CDC Opioid Prescribing Guideline focused on recommendations for primary care physicians. This clinical practice guideline expands the scope to additional clinicians. Although primary care physicians prescribe approximately 37% of all opioid prescriptions, other clinicians, including pain medicine clinicians (8.9%) and dentists (8.6%), account for considerable proportions of prescriptions. Pain medicine and physical medicine and rehabilitation clinicians prescribe opioids at the highest rates, followed by orthopedic and family medicine clinicians (*83*). Thus, expanding the scope to outpatient opioid prescribing can provide evidence-based advice for many additional clinicians, including dentists and other oral health providers, clinicians managing postoperative pain in outpatients, and clinicians providing pain management for patients being discharged from emergency departments.

Many principles of pain management are similar whether or not the treating clinician is a pain management specialist, and many of the recommendations might be relevant for pain management specialists. Many pain management specialists already follow principles outlined in this clinical practice guideline; however, use by pain management specialists is not the focus of this clinical practice guideline. Pain management specialists often have extensive training and expertise in pain management modalities that other clinicians do not, and they might treat patients with clinical situations that are more complex, less prevalent, and not well addressed by the available evidence; therefore, the balance of benefits and risks to patients might differ when the treating clinician is a pain management specialist.

The recommendations address the use of opioid pain medication in certain special populations (e.g., older adults and pregnant persons) and in populations with conditions posing special risks (e.g., a history of a substance use disorder). The recommendations do not address the use of opioid pain medication in children or adolescents aged <18 years. The available evidence concerning the benefits and risks of long-term opioid therapy in children and adolescents remains limited, and few opioid medications provide information in their labeling regarding safety and effectiveness in pediatric patients. Guidelines and recommendations are available for pain management in children with sickle cell disease (*87*), for children undergoing surgical procedures (*88*), and for palliative care in adolescent and young adult patients with cancer (*89*).

Although some principles in this clinical practice guideline might be helpful in the management of pain related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care, some recommendations might not be relevant for pain management in these contexts. Other guidelines more specifically address pain management in these situations (*87*,*89*–*93*); therefore, this clinical practice guideline does not apply to patients experiencing pain associated with these conditions or types of care. This does not imply that any other types of pain are more or less worthy of effective treatment, only that clinicians are referred to existing clinical guidelines that more specifically address unique considerations for management of pain related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care.

This clinical practice guideline follows the Institute of Medicine's definition of palliative care as care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness (*94*). Palliative care can begin early in the course of treatment for any serious illness that requires advanced management of pain or other distressing symptoms (*94*). In this guideline, end-of-life care refers to care for persons in hospice care and others with a terminal illness or at high risk for dying in the near future in hospitals, receiving long-term services and supports (including institutional care and home- and community-based services), or at home. This clinical practice guideline does not apply to patients undergoing cancer-related pain treatment, palliative care, or end-of-life care because of the unique therapeutic goals, ethical considerations, opportunities for medical supervision, and balance of benefits and risks with opioid therapy in such care. For example, for many persons at the end of life, serious potential long-term opioid-related harms such as opioid use disorder might not be relevant.

Recommendations on pain management for patients with cancer and patients who have survived cancer are available in the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Adult Cancer Pain (*90*), NCCN Clinical Practice Guidelines in Oncology: Survivorship (*91*), and Management of Chronic Pain in Survivors of Adult Cancers: American Society of Clinical Oncology (ASCO) Clinical Practice Guideline (*92*). Because of unique considerations in management of pain related to sickle cell disease, which can change the balance of benefits and risks of the use of opioids, clinicians should refer to the American Society of Hematology (ASH) 2020 Guidelines for Sickle Cell Disease: Management of Acute and Chronic Pain (*87*). In 2018, NCCN and ASCO convened and led a meeting including representatives and guideline authors from NCNN, ASCO, ASH, and CDC to review existing pain management guidelines and guidelines then in development from these organizations (*56,87,90*–*92*). Meeting participants noted that these guidelines applied to different patient populations and target audiences but found no disagreement among

recommendations when applied to the appropriate patient and clinical situation (*95*).

Although this update includes content on pain management for patients with opioid use disorder and one recommendation on management of opioid use disorder as a complication of opioid use, recommendations on opioids used specifically as medications for opioid use disorder are not the focus of this clinical practice guideline. More detailed recommendations on management of patients with opioid use disorder are available in the American Society of Addiction Medicine (ASAM) National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update (*96*).

Clinical Practice Guideline Development Methods

Systematic Reviews and Evidence Sources

The 2016 CDC Opioid Prescribing Guideline was based on a systematic clinical evidence review sponsored by AHRQ on the effectiveness and risks of long-term opioid therapy for chronic pain (*47*,*97*), a CDC update to the AHRQ-sponsored review, and additional contextual questions (*56*,*98*). The systematic review addressed the effectiveness of long-term opioid therapy for outcomes related to pain, function, and quality of life; the comparative effectiveness of different methods for initiating and titrating opioids; the harms and adverse events associated with opioids; and the accuracy of risk prediction instruments and effectiveness of risk mitigation strategies on outcomes related to overdose, opioid use disorder, illicit drug use, and prescription opioid misuse. The CDC update to the AHRQ-sponsored review included literature published during or after 2015 and an additional question on the association between opioid therapy for acute pain and long-term use. The contextual evidence review addressed effectiveness of nonpharmacologic and nonopioid pharmacologic treatments, clinician and patient values and preferences, and information about resource allocation.

For this update to the 2016 CDC Opioid Prescribing Guideline, CDC funded AHRQ in 2018 and 2019 to conduct five systematic reviews (*7*–*11*). AHRQ's Evidence-based Practice Centers completed these reviews, which included new evidence related to the treatment of chronic and acute pain. The AHRQ review of opioids for chronic pain updated and expanded the evidence for the 2016 CDC review; studies were included on short-term (1 to <6 months), intermediate-term (6 to <12 months) and long-term (≥12 months) outcomes of therapy involving opioids, effects of opioid plus nonopioid combination therapy, effects of tramadol, effects of naloxone coprescription, risks of coprescribed benzodiazepines, risks of coprescribed gabapentinoids, and effects of concurrent use of cannabis (*7*). The systematic clinical evidence review on opioids for chronic pain (*7*) also included contextual questions on clinician and patient values and preferences, costs and cost-effectiveness of opioid therapy, and risk mitigation strategies. CDC considered four new complementary AHRQ reviews on the benefits and harms of nonpharmacologic treatments for chronic pain (*9*), nonopioid pharmacologic treatments for chronic pain (*8*), treatments for acute episodic migraine (*11*), and treatments for acute (nonmigraine) pain (*10*). A question on management of acute pain in the systematic clinical evidence review for the 2016 CDC Opioid Prescribing Guideline was included in the new review on therapies for acute pain (*10*). CDC also reviewed AHRQ-sponsored surveillance reports conducted in follow-up to the five systematic reviews for any new evidence that could potentially change systematic review conclusions. To supplement the clinical evidence reviews, CDC sponsored a contextual evidence review on clinician and patient values and preferences and resource allocation (costs) for the areas addressed in the four new reviews (*8*–*11*).

AHRQ Method for Evaluating Quality of Evidence

The reviews used the AHRQ approach to synthesize and grade the strength of evidence (*99*). The AHRQ approach is based on a systematic review of the evidence and provides an overall strength of evidence indicating the level of certainty (high, moderate, low, or insufficient); similar factors are considered in the Advisory Committee on Immunization Practices (ACIP) adapted (*100*,*101*) Grading of Recommendations Assessment, Development, and Evaluation (GRADE) (*102*) method. These factors include study limitations and risk for bias, consistency, directness, precision, and reporting bias. Large strength of association, dose response, and plausible confounders can strengthen observed findings. The primary clinical questions, detailed methods, and findings for the systematic and contextual evidence reviews are presented (Appendix).

ACIP Adapted GRADE Method for Evaluating Quality of Evidence

The GRADE method is predicated on a systematic review of scientific evidence and provides a transparent framework for grading the quality of evidence and strength of recommendations. GRADE has been adapted by ACIP (*100*,*101*), and CDC used the ACIP adaptation in this clinical practice guideline. Under the ACIP GRADE framework, each body of evidence is initially categorized using a hierarchy that reflects the degree of confidence in the effect of a clinical action

Commonwealth of Virginia

REGULATIONS

GOVERNING PRESCRIBING OF OPIOIDS AND BUPRENORPHINE

VIRGINIA BOARD OF MEDICINE

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

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

Revised Date: June 9, 2021

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TABLE OF CONTENTS

Part I
General Provisions

18VAC85-21-10. Applicability.

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

B. This chapter shall not apply to:

1. The treatment of acute or chronic pain related to (i) cancer, (ii) sickle cell, (iii) a patient in hospice care, or (iii) a patient in palliative care;

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

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

18VAC85-21-20. Definitions.

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

"Acute pain" means 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" means the Virginia Board of Medicine.

"Chronic pain" means nonmalignant 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" means drugs listed in The Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) in Schedules II through IV.

"FDA" means the U.S. Food and Drug Administration.

"MME" means morphine milligram equivalent.

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

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

18VAC85-21-21. Electronic prescribing.

A. Beginning July 1, 2020, a prescription for a controlled substance that contains an opioid shall be issued as an electronic prescription consistent with § 54.1-3408.02 of the Code of Virginia, unless the prescription qualifies for an exemption as set forth in subsection C of § 54.1-3408.02.

B. Upon written request, the board may grant a one-time waiver of the requirement of subsection A of this section for a period not to exceed one year due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances demonstrated by the prescriber.

Part II
Management of Acute Pain

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan, and the medication prescribed or administered to include the date, type, dosage, and quantity prescribed or administered.

Part III
Management of Chronic Pain

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

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

1. The nature and intensity of the pain;

2. Current and past treatments for pain;

3. Underlying or coexisting diseases or conditions;

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

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

6. A urine drug screen or serum medication level;

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

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

9. A request for prior applicable records.

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

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

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

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

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

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

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

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

C. Buprenorphine mono-product in tablet form shall not be prescribed for chronic pain.

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

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

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

A. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including pain relief and improved physical and psychosocial function, quality of life, and daily activities.

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

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

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

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

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

C. The treatment agreement shall include notice that the practitioner will query and receive reports from the Prescription Monitoring Program and permission for the practitioner to:

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

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

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

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

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

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

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

D. The practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and thereafter randomly at the discretion of the practitioner, but at least once a year.

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

18VAC85-21-110. Additional consultations.

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

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

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

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

1. The medical history and physical examination;

2. Past medical history;

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

4. Diagnostic, therapeutic, and laboratory results;

5. Evaluations and consultations;

6. Treatment goals;

7. Discussion of risks and benefits;

8. Informed consent and agreement for treatment;

9. Treatments;

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

11. Patient instructions; and

12. Periodic reviews.

Part IV
Prescribing of Buprenorphine for Addiction Treatment

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

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

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

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

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

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

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

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

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

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

1. When a patient is pregnant;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Patients younger than 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 that can be identified, quantified, and independently verified.

D. Practitioners shall (i) evaluate patients with medical comorbidities by history, physical exam, appropriate laboratory studies and (ii) 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. A patient who is determined by the prescriber to be psychiatrically unstable shall be referred for psychiatric evaluation and treatment prior to initiating medication-assisted treatment.

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

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

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

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

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

Next Meeting Date of the Executive Committee is

April 7, 2023

Please check your calendars and advise staff of any known conflicts that may affect your attendance.

The travel regulations require that "travelers must submit the Travel Expense Reimbursement Voucher **within 30 days after completion of their trip"**. (CAPP Topic 20335, State Travel Regulations, p.7). If you submit your reimbursement after the 30-day deadline, please provide a justification for the late submission and be aware that it may not be approved.

In order for the agency to be in compliance with the travel regulations, please submit your request for today's meeting no later than

January 2, 2023