

**Committee of Joint Boards of Nursing and Medicine  
and Advisory Committee of Joint Boards of Nursing and Medicine**

Department of Health Professions  
Perimeter Center - 9960 Mayland Drive, Conference Center, Suite 201, Henrico, Virginia 23233

**Business Meeting Agenda  
April 12, 2017 at 9:30 A.M. in Board Room 4**

**Call To Order** - Louise Hershkowitz, CRNA, MSHA; Chair

**Establishment of Quorum**

**Review of Minutes**

- February 8, 2017 Business Meeting
- February 8, 2017 Formal Hearing

**Public Comment**

**Dialogue with Agency Director**

**Old Business:**

- Nurse Practitioners Regulations on Pain Management and Prescribing of Buprenorphine – Ms. Yeatts
- Expert Witness – Ms. Barrett
- Final Report on 2017 General Assembly – Ms. Yeatts
- Update on Board Counsel review of Statutory limitations related to proposal of eliminating prescriptive authority license – Ms. Douglas/Ms. Mitchell
- CARA Waivers from SAMHSA - FYI

**New Business**

- Appointment of Joint Boards Advisory Committee Member, Dr. Thokozeni Lipato – Ms. Hershkowitz
- Report of the March 9, 2017 “*Addiction Disease Management*” training provided by Virginia Department of Health (VDH)– Ms. Hershkowitz
- Report of National Council State Board of Nursing (NCSBN) Advance Practice Registered Nurses (APRN) Roundtable on April 4, 2017 – Ms. Hershkowitz
- Board of Nursing Executive Director Report – Ms. Douglas
  - March 13-15, 2017 NCSBN Mid-Year Meeting
  - NURSYS Update
  - APRN Compact
  - Veterans Affairs New Rule
  - 2018 Proposed Meeting Dates

**Recommendations for Consideration** - Joint Board Members Only

- Ann McTernan, RN, LPN
- Traci Colley, RN, LNP

**Probable Cause Case Review** - Joint Board Members Only

**Adjourn**

**VIRGINIA BOARD OF NURSING  
COMMITTEE OF THE JOINT BOARDS OF NURSING AND MEDICINE  
BUSINESS MEETING MINUTES  
February 8, 2017**

**TIME AND PLACE:** The meeting of the Committee of the Joint Boards of Nursing and Medicine was convened at 9:00 A.M., February 8, 2017 in Board Room 2, Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 201, Henrico, Virginia.

**MEMBERS PRESENT:** Louise Hershkowitz, CRNA, MSHA; Chair  
Marie Gerardo, MS, RN, ANP-BC  
Rebecca Poston, PhD, RN, CPNP  
Wayne Reynolds, DO  
Kenneth Walker, MD

**MEMBERS ABSENT:** Lori D. Conklin, MD

**ADVISORY COMMITTEE MEMBERS PRESENT:**  
Joseph F. Borzelleca, Jr., MD, MPH  
Kevin E. Brigle, RN, NP  
Mark Coles, RN, BA, MSN, NP-C  
Wendy Dotson, CNM, MSN  
Cathy A. Harrison, DNAP, CRNA  
Sarah E. Hobgood, MD  
Stuart F. Mackler, MD

**STAFF PRESENT:** Jay P. Douglas, MSM, RN, CSAC, FRE; Executive Director; Board of Nursing  
Jodi P. Power, RN, JD; Deputy Executive Director; Board of Nursing  
Stephanie Willinger, Deputy Executive Director; Board of Nursing  
Huong Vu, Executive Assistant; Board of Nursing

**OTHERS PRESENT:** Erin Barrett, Assistant Attorney General; Board Counsel  
David Brown, DC; Director; Department of Health Professions  
Elaine Yeatts, Senior Policy Analyst, Department of Health Professions  
William L. Harp, MD, Executive Director; Board of Medicine

**IN THE AUDIENCE:** W. Scott Johnson, Medical Society of Virginia (MSV)  
Julie Galloway, Medical Society of Virginia (MSV)  
Lynn Poole, FNP-BC  
Joyce A. Hahn, PhD, RN, NEA-BC, FNAP, Board of Nursing President  
Mary Duggan, American Association of Nurse Practitioners (AANP) State Representative  
Caroline Perrin, MWC  
Sarah Heisler, Virginia Hospital and Healthcare Association (VHHA)  
Letha Fisher, RN, Public Health Nursing Director; Virginia Department of Health (VDH)  
Hughes Melton, MD, MBA, FAAFP, FABAM, Chief Deputy Commissioner, Office of the Commissioner, Virginia Department of Health (VDH)

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**INTRODUCTIONS:** Committee members, Advisory Committee members and staff members introduced themselves.

Dr. Borzelleca stated that he will be retiring soon and asked the Committee of the Joint Boards to consider the nomination of Tholozeni Lipato, MD as his replacement. Ms. Hershkowitz said the Committee will consider this matter at its next meeting and thanked Dr. Borzelleca for his service.

**ESTABLISHMENT OF A QUORUM:**

Ms. Hershkowitz called the meeting to order and established a quorum was present.

**REVIEW OF MINUTES:** The minutes of December 7, 2016 was reviewed. Ms. Gerardo moved to accept the minutes as presented. The motion was seconded and carried unanimously.

**PUBLIC COMMENT:** There was no one present that wished to address the Board.

**DIALOGUE WITH  
AGENCY DIRECTOR:**

**Opioid Crisis** – Dr. Brown reported that the fatalities from opioid overdose in 2016 are closed to 1100 and over prescribing is the major part of the problem. Dr. Reynolds asked what percentage of the fatalities in 2016 was due to heroin overdose. Dr. Brown said he did not have the breakdown but he could ask.

Dr. Brown stated that there are many bills providing guidelines on controlled substance prescribing and treating opioid addiction that the current General Assembly is considering.

**OLD BUSINESS:**

**Revision of Guidance Document (GD) 90-56 (Practice Agreements):**

Ms. Yeatts noted that Ms. Douglas prepared the GD 90-56 time line which includes modification by Board of Medicine, revision by Committee of the Joint Boards of Nursing and Medicine at its last meeting, and amendment by Board of Nursing at its January 2017 meeting. She added that the current version includes changes in highlighted languages as suggested by Wendy Dotson, representing the Virginia Affiliate of the American College of Nurse Midwives, and is presented to the Committee of Joint Boards of Nursing and Medicine for consideration. She noted that it will be presented to the Board of Medicine at its February meeting for adoption.

Dr. Reynolds moved to adopt the GD as presented. The motion was seconded and passed unanimously.

**Board of Medicine FAQ's related to Controlled Substances CE requirements for Nurse Practitioners:**

Ms. Douglas referred to Dr. Harp for clarification. Dr. Harp stated that the FAQ's was sent to all practitioners who prescribe controlled substances to notify them of CE requirements. He noted that over 1,000 inquiries were made of which maybe

three were from Nurse Practitioners. He added that this is also posted at Board of Medicine website.

NEW BUSINESS:

**The Opioid Public Health Crisis and the CARA Act, Implications for Virginia:**

Dr. Melton, Chief Deputy Commissioner, Office of the Commissioner, VDH, provided three handouts regarding Virginian's Plan for Well-Being Measures and the Role of the Nurse in Addiction Disease Management. He commented that:

- Substance use disorder (SUD) diagnosis of members enrolled in Medicaid is spread across Virginia
- Southwest area is reported having largest Hepatitis C population with SUD diagnosis
- Distribution of treatment resources in Virginia is not uniform

Ms. Fisher, Public Health Nursing Director, VDH, said that addiction is treated as chronic disease. She noted that recovery of chronic illness management is a long process and relapse is expected. Ms. Fisher added that the American Nurses Association (ANA) encourages comprehensive pharmacology education for nurses practicing in all settings to ensure safe and appropriate prescription of drugs.

Dr. Melton stated that CARA 2016 makes it possible for physician assistants (PA) and nurse practitioners (NP) to obtain a waiver to use buprenorphine to treat opioid addiction. PA's and NP's must complete 24 hours of education on buprenorphine and obtain a waiver from the Substance Abuse Mental Health Service Administration (SAMHSA) before treating patients. Dr. Melton added that currently there are 28 educational sessions scheduled throughout Virginia and 800 practitioners have signed up already. He noted that he will provide the detail of the training sessions to Ms. Douglas.

Ms. Dotson asked if certified nurse midwives are included in the training sessions. Dr. Melton said that he will check and communicate with Ms. Douglas regarding the findings.

Ms. Hershkowitz commented that she received the training email from VDH and has signed up for the training session.

Dr. Walker asked if the training session is qualified for the required two CE hours. Dr. Melton said yes.

Dr. Harrison commented appreciation for the information provided.

Dr. Hahn, Board of Nursing President, asked if these training sessions are available to NP students. Dr. Melton replied yes.

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Ms. Hershkowitz suggested the Advisory members to pass on the information to respective associations.

RECESS: The Committee recessed at 9:43 A.M.

RECONVENTION: The Committee reconvened at 9:57 A.M.

**Regulatory Update and 2017 General Assembly Report:**

Ms. Yeatts reviewed the Bills that are currently considered by the General Assembly including:

**HB 1885 (Opioids; limit on amount prescribed)** – requiring a prescriber to obtain information from PMP at the time of initiating a new course of treatment that includes the prescribing of opioids anticipated to last more than seven consecutive days.

**HB 2119 (Laser hair removal; limits practice)** – adding nurse practitioners.

**HB 2164 (Drugs of concern; gabapentin)** – adding any material, compound, mixture, or preparation containing any quantity of gabapentin, including any of its salts, to the list of drugs of concerns.

**SB 848 (Naloxone; dispensing for use in opioid overdose reversal, etc.)** – allowing a person who is authorized by the Department of Behavioral Health and Developmental Services (DBHDS) to train individuals on the administration of naloxone for use in opioid overdose reversal.

**SB 1020 (Registration of peer recovery specialist and qualified mental health professionals)** – authorizing the registration of peer recovery specialists and qualified mental professionals by the Board of Counseling at the DHP. It is collaboration between DHP, DBHDS, and Department of Medical Assistance Services (DMAS).

**SB 1180 (Opioids and Buprenorphine; Board of Dentistry (BOD) and Board of Medicine (BOM) to adopt regulations for prescribing)** – directing BOD and BOM to adopt regulations for the prescribing of opioids and products containing Buprenorphine. BOM is working on regulations of two hours mandated continuing education (CEs) for opioid prescribing.

**SB 1230 (Opiate prescriptions; electronic prescriptions)** - requiring a prescription for any controlled substance containing an opiate to be issued as an electronic prescription and prohibits a pharmacist from dispensing a controlled substance that contains an opiate unless the prescription is issued as an electronic prescription, beginning July 1, 2020. Ms. Yeatts added that this is the Governor's Bill and there will be a work group to discuss how to implement.

**SB 1232 (Controlled substances; limits on prescription containing opioids)** – prohibiting a prescriber from providing treatment for a patient in an emergency department of a corporation, facility, or institution licensed, owned, or operated

by the Commonwealth to provide health care from prescribing a controlled substance containing an opioid in a quantity greater than a three-day supply. This bill is also applied to a pharmacist who dispenses.

**Emergency Regulations for Nurse Practitioners with Prescriptive Authority: Pain Management, Opioid Treatment, use of Buprenorphine:**

Ms. Yeatts stated that on November 21, 2016, the Commissioner of Health declared a statewide Public Health Emergency for Virginia as a result of the opioid addiction epidemic. The Board of Medicine (BOM) convened a Regulatory Advisory Panel (RAP) with four addiction specialists to draft regulations for prescribing of opioids and buprenorphine. The proposed amendments to prescriptive authority regulations in the agenda package are virtually identical to the regulations recommended by the BOM Legislative Committee which will be adopted as emergency regulations by the BOM on February 16<sup>th</sup>.

Ms. Yeatts noted that once the emergency regulations are adopted, there is no public comment required and the regulations remain in effective for up to 18 months during which the permanent regulations must be prepared for adoption.

Ms. Yeatts said the task today is for the Committee to review and to make changes to the draft regulations as presented. The draft regulations will be presented at the BON meeting in March 2017 for adoption and are forwarded to BOM Executive Committee for adoption in April 2017.

Ms. Yeatts then went through the proposed amendments to prescriptive authority regulations noting the Committee comments and suggestions:

**18VAC90-40-150. Evaluation of the patient for acute pain –**

**Section A** – Ms. Gerardo asked if homecare patients can be added to this section. Ms. Yeatts said that she will check.

**Part VI. Management of Chronic Pain** – Dr. Walker stated that too many requirements for primary providers to treat patient with chronic pain, it is better to refer to a specialist. Ms. Gerardo stated that urine tests on elderly patients are prone to more infection. Dr. Reynolds stated that the requirement of urine test every three months is a burden.

Dr. Brown asked Committee members to provide more specific suggestions that will promote good practices and deter bad practices. Ms. Barrett reminded Committee members that this is a chance for the Committee to provide input.

Dr. Harp suggested requiring urine test every three months for the first year then requiring twice or once per year after that. Ms. Yeatts asked Committee members to send her comments before February 16<sup>th</sup>. Ms. Barret asked that comments are sent to Ms. Yeatts only and not copied others.

**Part VII. Prescribing of Buprenorphine –**

**18VAC90-40-260.D** – Ms. Douglas suggested adding other practitioners (QMHP, CNS, CSAC) who can provide counseling other than licensed mental health professional for counseling.

**18VAC90-30-220(8) and (9)** – these languages should be added to 18VAC90-40-130 also.

Ms. Dotson asked if the public will be educated regarding the new requirements and available training. Dr. Brown stated that the Virginia Department of Health is taking the lead on this task and media campaign discussion is at state level.

Ms. Hershkowitz said that consistency between regulations are valuable and asked the Committee members to send comments to Ms. Yeatts as soon as possible. Ms. Hershkowitz asked if the Committee wishes to meet after the BOM meeting on February 16<sup>th</sup> and prior to BON March meeting. The consensus was no. Ms. Hershkowitz thanked Ms. Yeatts for the information.

**Information Only Materials:**

- NCSBN CARA Implementation: Educational Opportunities for Meeting Federal Requirements
- DEA Advisory regarding renewal of DEA numbers
- Changes in name of certifying body AANPCP to AANPCB
- NCSBN Annual APRN Certification Examination Report Data
- NCSBN APRN Roundtable Meeting, April 4, 2017, in Rosemont, IL – Ms. Hershkowitz attending
- Veterans Administration APRN Revised Rules – Ms. Hershkowitz notes that the rules include changes to APRN supervising language and did not include CRNA

Ms. Hershkowitz reminded available Board Members that assistance was needed with probable cause review following the meeting.

ADJOURNMENT:

As there was no additional business, the meeting was adjourned at 11:26 A.M.

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Jay P. Douglas, MSM, RN, CSAC, FRE  
Executive Director

**VIRGINIA BOARD OF NURSING  
COMMITTEE OF THE JOINT BOARDS OF NURSING AND MEDICINE  
FORMAL HEARING MINUTES  
February 8, 2017**

**TIME AND PLACE:** The meeting of the Committee of the Joint Boards of Nursing and Medicine was convened at 12:55 P.M., February 8, 2017 in Board Room 2, Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 201, Henrico, Virginia.

**CHAIR:** Louise Hershkowitz, CRNA, MSHA; Chair

**COMMITTEE OF THE JOINT BOARDS OF NURSING AND MEDICINE MEMBERS PRESENT:**  
Marie Gerardo, MS, RN, ANP-BC, Board of Nursing, Joint Board Member  
Rebecca Poston, PhD, RN, CPNP, Board of Nursing, Joint Board Member  
Wayne Reynolds, DO, Board of Medicine, Joint Board Member  
Kenneth Walker, MD, Board of Medicine, Joint Board Member

**BOARD OF NURSING MEMBERS PRESENT:**  
Guia Caliwagan, RN, MAN, EdS  
Joyce Hahn, PhD, RN, NEA-BC, FNAP  
William Traynham, LPN, CSAC

**STAFF PRESENT:** Jay P. Douglas, MSM, RN, CSAC, FRE; Executive Director; Board of Nursing  
Jodi P. Power, RN, JD; Deputy Executive Director  
Darlene Graham, Senior Discipline Specialist; Board of Nursing

**OTHERS PRESENT:** Erin Barrett, Assistant Attorney General; Board Counsel  
Amy Weiss, Adjudication Specialist (joined later)

**CONSIDERATION OF AGENCY SUBORDINATE RECOMMENDATION:**

**CLOSED MEETING:** Dr. Poston moved that the Committee of the Joint Board of Nursing and Medicine convene a closed meeting pursuant to §2.2-3711(A)(27) of the *Code of Virginia* at 1:00 P.M., for the purpose of consideration of agency subordinate recommendations. Additionally, Dr. Poston moved that Ms. Douglas, Ms. Power, Ms. Graham and Ms. Barrett attend the closed meeting because their presence in the closed meeting is deemed necessary and their presence will aid the Board in its deliberations. The motion was seconded and carried unanimously.

**RECONVENTION:** The Board reconvened in open session at 1:20 P.M.

Dr. Poston moved that the Committee of the Joint Board of Nursing and Medicine certify that it heard, discussed or considered only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion by which the closed meeting was convened. The motion was seconded and carried unanimously.



**Cherish Van Schaik, LNP 0024-171314; Prescriptive Authority 0017-141362**  
Ms. Schaik did not appear.

Ms. Gerardo moved that the Committee of the Joint Boards of Nursing and Medicine modify the recommended decision of the agency subordinate to reprimand Cherish Van Schaik and to place her on probation with terms for at least one year of active employment as a nurse practitioner in the Commonwealth of Virginia. The motion was seconded and carried unanimously.

**Lee Caswell Hughes, LNP 0024-169677; Prescriptive Authority 0017-140240**  
Ms. Hughes did not appear.

Dr. Walker moved that the Committee of the Joint Boards of Nursing and Medicine accept the recommended decision of the agency subordinate to reprimand Lee Caswell Hughes, to assess a monetary penalty of \$500.00 to be paid to the Board within 90 days from the date of entry of the Order, and to order Ms. Hughes to undergo a chemical dependency evaluation conducted by a Committee-approved specialist who holds an unrestricted license, and have a written report of the evaluation, including a diagnosis, recommended course of therapy, prognosis, and any other recommendations sent to the Committee, within 90 days of the entry of the Order. The motion was seconded and carried unanimously.

Ms. Power left at 1:30 P.M.

Ms. Weiss joined the hearing at 1:32 P.M.

**ESTABLISHMENT OF  
A QUORUM:**

With five members of the Committee of the Joint Boards present, a quorum was established. Additionally there were three members of Board of Nursing present with two members of the Board of Nursing serving in dual capacity.

**FORMAL HEARING:**

**Julie Maria Hall Megaro, RN 0001-217867; LNP 00024-0024168815**  
Ms. Megaro appeared accompanied by Kristin Paudling, Esquire.

Amy Weiss, Adjudication Specialist, represented the Commonwealth. Ms. Barret was legal counsel for the Committee of Joint Boards and Board of Nursing. Mary Tretar, court reporter from Crane Snead and Associates, recorded the proceedings.

Lane Raker, Senior Investigator, Department of Health Professions, and Amy Vinson, Office Manager, OB/GYN Physicians Inc., were present and testified

**CLOSED MEETING:**

Dr. Poston moved that the Committee of the Joint Boards of Nursing and Medicine and panel of the Board of Nursing convene a closed meeting pursuant to §2.2-3711(A)(28) of the *Code of Virginia* at 2:57 P.M., for the purpose to reach a

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decision in the matter of Ms. Megaro. Additionally, Dr. Poston moved that Ms. Douglas, Ms. Graham and Ms. Barrett attend the closed meeting because their presence in the closed meeting is deemed necessary and their presence will aid the Board in its deliberations. The motion was seconded and carried unanimously.

RECONVENTION: The Board reconvened in open session at 3:34 P.M.

Dr. Poston moved that the Committee of the Joint Boards of Nursing and Medicine and panel of the Board of Nursing certify that it heard, discussed or considered only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion by which the closed meeting was convened. The motion was seconded and carried unanimously.

ACTION: Mr. Traynham moved that the Board of Nursing accept the findings of fact and conclusions of law as presented by Ms. Weiss and amended by the Board.

Dr. Hahn moved that the Board of Nursing reprimand Julie Maria Hall Megaro and place her on probation with terms for a period of not less than two years of active employment as a professional nurse in the Commonwealth of Virginia. The motion was seconded and carried unanimously.

Ms. Gerardo moved that the Committee of the Joint Boards of Nursing and Medicine accept the findings of fact and conclusions of law as presented by Ms. Weiss.

Dr. Walker moved that the Committee of the Joint Boards of Nursing and Medicine reprimand Julie Maria Hall Megaro and place her on probation with terms for a period of not less than two years of active employment as a nurse practitioner in the Commonwealth of Virginia. The motion was seconded and carried unanimously.

ADJOURNMENT: The meeting was adjourned at 3:38 P.M.

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Jay P. Douglas, MSM, RN, CSAC, FRE  
Executive Director

**BOARDS OF NURSING AND MEDICINE**

**Prescribing of opioids**

Part IV

Disciplinary Provisions

**18VAC90-30-220. Grounds for disciplinary action against the license of a licensed nurse practitioner.**

The boards may deny licensure or relicensure, revoke or suspend the license, or take other disciplinary action upon proof that the nurse practitioner:

1. Has had a license or multistate privilege to practice nursing in this Commonwealth or in another jurisdiction revoked or suspended or otherwise disciplined;
2. Has directly or indirectly represented to the public that the nurse practitioner is a physician, or is able to, or will practice independently of a physician;
3. Has exceeded the authority as a licensed nurse practitioner;
4. Has violated or cooperated in the violation of the laws or regulations governing the practice of medicine, nursing or nurse practitioners;
5. Has become unable to practice with reasonable skill and safety to patients as the result of a physical or mental illness or the excessive use of alcohol, drugs, narcotics, chemicals or any other type of material;
6. Has violated or cooperated with others in violating or attempting to violate any law or regulation, state or federal, relating to the possession, use, dispensing, administration or distribution of drugs; or

7. Has failed to comply with continuing competency requirements as set forth in [18VAC90-30-105](#);

8. Has willfully or negligently breached the confidentiality between a practitioner and a patient. A breach of confidentiality that is required or permitted by applicable law or beyond the control of the practitioner shall not be considered negligent or willful; or

9. Has engaged in unauthorized use or disclosure of confidential information received from the Prescription Monitoring Program.

## Part I

### General Provisions

#### **18VAC90-40-10. Definitions.**

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

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

"Boards" means the Virginia Board of Medicine and the Virginia Board of Nursing.

"Certified nurse midwife" means an advanced practice registered nurse who is certified in the specialty of nurse midwifery and who is jointly licensed by the Boards of Medicine and Nursing as a nurse practitioner pursuant to § 54.1-2957 of the Code of Virginia.

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

"Committee" means the Committee of the Joint Boards of Nursing and Medicine.

“FDA” shall mean the U. S. Food and Drug Administration.

“MME” shall mean morphine milligram equivalent.

"Nonprofit health care clinics or programs" means a clinic organized in whole or in part for the delivery of health care services without charge or when a reasonable minimum fee is charged only to cover administrative costs.

"Nurse practitioner" means an advanced practice registered nurse who has met the requirements for licensure as a nurse practitioner as stated in 18VAC90-30.

"Practice agreement" means a written or electronic agreement jointly developed by the patient care team physician and the nurse practitioner for the practice of the nurse practitioner that also describes the prescriptive authority of the nurse practitioner, if applicable. For a nurse practitioner licensed in the category of certified nurse midwife, the practice agreement is a statement jointly developed with the consulting physician.

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

“SAMHSA” means the Substance Abuse and Mental Health Services Administration.

### **Part V. Management of Acute Pain.**

#### **18VAC90-40-150. Evaluation of the patient for acute pain.**

A. The requirements of this part shall not apply to:

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

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

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

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

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

**18VAC90-40-160. Treatment of acute pain with opioids.**

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

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

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

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

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

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

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

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

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

**18VAC90-40-170. 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 VI. Management of Chronic Pain.**

**18VAC90-40-180. Evaluation of the chronic pain patient.**

A. The requirements of this part shall not apply to:

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

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

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

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

1. The nature and intensity of the pain;

2. Current and past treatments for pain;

3. Underlying or coexisting diseases or conditions;

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

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

6. A urine drug screen or serum medication level;

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

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

9. A request for prior applicable records.

C. Prior to initiating opioid analgesia for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment 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.

**18VAC90-40-190. Treatment of chronic pain with opioids.**

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

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

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

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

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

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

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

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

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

**18VAC90-40-200. Treatment plan for chronic pain.**

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

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

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

**18VAC90-40-210. Informed consent and agreement for treatment of chronic pain.**

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

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

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

1. Obtain urine drug screen 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.

**18VAC90-40-220. Opioid therapy for chronic pain.**

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

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

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

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

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

**18VAC90-40-230. Additional consultation.**

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

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

**18VAC90-40-240. Medical records.**

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

1. The medical history and physical examination;
2. Past medical history;
3. Applicable records from prior treatment providers and/or any documentation of attempts to obtain;
4. Diagnostic, therapeutic and laboratory results;
5. Evaluations and consultations;
6. Treatment goals;
7. Discussion of risks and benefits;
8. Informed consent and agreement for treatment;
9. Treatments;
10. Medications (including date, type, dosage and quantity prescribed and refills).
11. Patient instructions; and
12. Periodic reviews.

**Part VII. Prescribing of Buprenorphine.**

**18VAC90-40-250. General provisions.**

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

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

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

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

**18VAC90-40-260. Patient assessment and treatment planning.**

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

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

**18VAC90-40-270. Treatment with buprenorphine.**

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

1. When a patient is pregnant;

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

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

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

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

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

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

F. During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on a dosage of 8 mg. of buprenorphine per day. The patient shall be seen by the prescriber at least once a week.

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

H. Practitioners shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, urine drug screens or serum

medication levels, pill counts and checks of the Prescription Monitoring Program. The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

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

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

**18VAC90-40-280. Special populations.**

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

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

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

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

E. Practitioners shall not undertake buprenorphine treatment with a patient who has psychiatric comorbidities and is not stable. 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.

**18VAC90-40-290. 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.



### **Expert admissibility standards to consider:**

#### **Traditional Virginia Standard:**

To qualify to serve as an expert witness, an individual:

must possess sufficient knowledge, skill, or experience regarding the subject matter of the testimony to assist the trier of fact in the search for the truth. Generally, a witness possesses sufficient expertise when, through experience, study or observation the witness acquires knowledge of a subject beyond that of persons of common intelligence and ordinary experience.

#### **Virginia Medical Malpractice Standard:**

To qualify to serve as an expert witness, an individual:

[a]ny health care provider who is licensed to practice in Virginia shall be presumed to know the statewide standard of care in the specialty or field of practice in which he is qualified and certified....A witness shall be qualified to testify as an expert on the standard of care if he demonstrates expert knowledge of the standards of the defendant's specialty and of what conduct conforms or fails to conform to those standards and if he has had active clinical practice in either the defendant's specialty or a related field of medicine within one year of the date of the alleged act or omission forming the basis of the action.

## Committee of the Joint Boards of Nursing and Medicine

### Report of the 2017 General Assembly

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#### **HB 1609 Nurse practitioner as expert witness; scope of activities.**

*Chief patron:* Leftwich

**Nurse practitioner as expert witness; scope of activities.** References the specific Code section outlining the scope of a nurse practitioner's activities in the context of the current provision that authorizes a nurse practitioner to testify as an expert witness within the scope of his activities.

#### **HB 2119 Laser hair removal; limits practice.**

*Chief patron:* Keam

**Practice of laser hair removal.** Limits the practice of laser hair removal to a properly trained person licensed to practice medicine or osteopathic medicine or licensed as a physician assistant or nurse practitioner or to a properly trained person under the direction and supervision of a licensed doctor of medicine or osteopathic medicine or physician assistant or nurse practitioner.

#### **HB 2153 Durable Do Not Resuscitate Orders; reciprocity.**

*Chief patron:* Rasoul

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

#### **HB 2164 Drugs of concern; drug of concern.**

*Chief patron:* Pillion

**Drugs of concern; gabapentin.** Adds any material, compound, mixture, or preparation containing any quantity of gabapentin, including any of its salts, to the list of drugs of concern. This bill contains an emergency clause.

EMERGENCY

#### **HB 2470 Drug Control Act; Schedule II and Schedule V.**

*Chief patron:* Jones

**Drug Control Act; Schedule II and Schedule V.** Adds thiafentanil to Schedule II of the Drug Control Act and brivaracetam to Schedule V of the Drug Control Act.

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

*Chief patron:* Wexton

**Dispensing of naloxone.** Allows a person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for use in opioid overdose reversal and who is acting on behalf of an organization that provides services to individuals at risk of experiencing opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a controlled substances registration from the Board of Pharmacy pursuant to § 54.1-3423 to dispense naloxone to a person who has completed a training program on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber, (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, and (iii) without charge or compensation. The bill also provides that dispensing may occur at a site other than that of the controlled substance registration, provided that the entity possessing the controlled substance registration maintains records in accordance with regulations of the Board of Pharmacy. The bill further provides that a person who dispenses naloxone shall not be liable for civil damages of ordinary negligence for acts or omissions resulting from the rendering of such treatment if he acts in good faith and that a person to whom naloxone has been dispensed pursuant to the provisions of the bill may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. The bill contains an emergency clause. This bill is identical to HB 1453.

EMERGENCY

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

*Chief patron:* Stanley

**Charity health care services; liability protection for administrators.** Provides that persons who administer, organize, arrange, or promote the rendering of services to patients of certain clinics shall not be liable to patients of such clinics for any civil damages for any act or omission resulting from the rendering of such services unless the act or omission was the result of such persons' or the clinic's gross negligence or willful misconduct. This bill is identical to HB 1748.

**SB 1009 Telemedicine, practice of; prescribing controlled substances.**

*Chief patron:* Dunnivant

**Practice of telemedicine; prescribing.** Provides that a health care practitioner who performs or has performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment, for the purpose of establishing a bona fide practitioner-patient relationship may prescribe Schedule II through VI controlled substances to the patient, provided that the prescribing of such controlled substance is in compliance with federal requirements for the practice of telemedicine. The bill also authorizes the Board of Pharmacy to register an entity at which a patient is treated by the use of instrumentation and diagnostic equipment for the purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II through VI controlled substances to possess and administer Schedule II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration. The bill contains an emergency clause. This bill is identical to HB 1767.

## EMERGENCY

### **SB 1020 Peer recovery specialists and qualified mental health professionals; registration.**

*Chief patron:* Barker

**Registration of peer recovery specialists and qualified mental health professionals.** Authorizes the registration of peer recovery specialists and qualified mental health professionals by the Board of Counseling. The bill defines "qualified mental health professional" as a person who by education and experience is professionally qualified and registered by the Board of Counseling to provide collaborative mental health services for adults or children. The bill requires that a qualified mental health professional provide such services as an employee or independent contractor of the Department of Behavioral Health and Developmental Services or a provider licensed by the Department of Behavioral Health and Developmental Services. The bill defines "registered peer recovery specialist" as a person who by education and experience is professionally qualified and registered by the Board of Counseling to provide collaborative services to assist individuals in achieving sustained recovery from the effects of addiction or mental illness, or both. The bill requires that a registered peer recovery specialist provide such services as an employee or independent contractor of the Department of Behavioral Health and Developmental Services, a provider licensed by the Department of Behavioral Health and Developmental Services, a practitioner licensed by or holding a permit issued from the Department of Health Professions, or a facility licensed by the Department of Health. The bill adds qualified mental health professionals and registered peer recovery specialists to the list of mental health providers that are required to take actions to protect third parties under certain circumstances and notify clients of their right to report to the Department of Health Professions any unethical, fraudulent, or unprofessional conduct. The bill directs the Board of Counseling and the Board of Behavioral Health and Developmental Services to promulgate regulations to implement the provisions of the bill within 280 days of its enactment. This bill is identical to HB 2095.

### **SB 1024 Doctor of medicine, etc.; reporting disabilities of drivers to DMV, not subject to civil liability.**

*Chief patron:* Dunnivant

**Health care practitioners; reporting disabilities of drivers.** Provides that any doctor of medicine, osteopathy, chiropractic, or podiatry or any nurse practitioner, physician assistant, optometrist, physical therapist, or clinical psychologist who reports to the Department of Motor Vehicles the existence, or probable existence, of a mental or physical disability or infirmity of any person licensed to operate a motor vehicle that the reporting individual believes affects such person's ability to operate a motor vehicle safely is not subject to civil liability or deemed to have violated the practitioner-patient privilege unless he has acted in bad faith or with malicious intent. This bill is identical to HB 1514.

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

*Chief patron:* Marsden

**Cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide.** Authorizes a pharmaceutical processor, after obtaining a permit from the Board of Pharmacy (the Board) and under the supervision of a licensed pharmacist, to manufacture and provide cannabidiol oil and THC-A oil to be used for the treatment of intractable epilepsy. The bill sets limits on the number

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

EMERGENCY

**SB 1178 Buprenorphine without naloxone; prescription limitation.**

*Chief patron:* Chafin

**Prescription of buprenorphine without naloxone; limitation.** Provides that prescriptions for products containing buprenorphine without naloxone shall be issued only (i) for patients who are pregnant, (ii) when converting a patient from methadone to buprenorphine containing naloxone for a period not to exceed seven days, or (iii) as permitted by regulations of the Board of Medicine or the Board of Nursing. The bill contains an emergency clause and has an expiration date of July 1, 2022. This bill is identical to HB 2163.

EMERGENCY

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

*Chief patron:* Chafin

**Boards of Dentistry and Medicine; regulations for the prescribing of opioids and buprenorphine.** Directs the Boards of Dentistry and Medicine to adopt regulations for the prescribing of opioids and products containing buprenorphine. The bill requires the Prescription Monitoring Program at the Department of Health Professions to annually provide a report to the Joint Commission on Health Care and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health on the prescribing of opioids and benzodiazepines in the Commonwealth that includes data on reporting of unusual patterns of prescribing or dispensing of a covered substance by an individual prescriber or dispenser or on potential misuse of a covered substance by a recipient. The bill contains an emergency clause.

EMERGENCY

**SB 1230 Opiate prescriptions; electronic prescriptions.**

*Chief patron:* Dunnavant

**Opiate prescriptions; electronic prescriptions.** Requires a prescription for any controlled substance containing an opiate to be issued as an electronic prescription and prohibits a pharmacist from dispensing a controlled substance that contains an opiate unless the prescription is issued as an electronic prescription, beginning July 1, 2020. The bill defines electronic prescription as a written prescription that is generated on an electronic application in accordance with federal regulations and is transmitted to a pharmacy as an electronic data file. The bill requires the Secretary of Health and Human Resources to convene a work group of interested stakeholders to review actions necessary for the implementation of the bill's provisions, to evaluate hardships on prescribers and the inability of prescribers to comply with the deadline for electronic prescribing, and to make recommendations for any extension or exemption processes relative to compliance or disruptions due to natural or manmade disasters or technology gaps, failures, or interruptions of services. The work group shall report on the work group's progress to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2017, and a final report to such Chairmen by November 1, 2018.

**SB 1232 Opioids; limit on amount prescribed, extends sunset provision.**

*Chief patron:* Dunnivant

**Limits on prescription of controlled substances containing opioids.** Requires a prescriber registered with the Prescription Monitoring Program (the Program) to request information about a patient from the Program upon initiating a new course of treatment that includes the prescribing of opioids anticipated, at the onset of treatment, to last more than seven consecutive days and exempts the prescriber from this requirement if the opioid is prescribed as part of treatment for a surgical or invasive procedure and such prescription is for no more than 14 consecutive days. Current law requires a registered prescriber to request information about a patient from the Program upon initiating a new course of treatment that includes the prescribing of opioids anticipated, at the onset of treatment, to last more than 14 consecutive days and exempts the prescriber from this requirement if the opioid is prescribed as part of a course of treatment for a surgical or invasive procedure and such prescription is not refillable. The bill extends the sunset for this requirement from July 1, 2019, to July 1, 2022.

**SB 1403 Controlled substances; use of FDA-approved substance upon publication of final rule, etc.**

*Chief patron:* Dunnivant

**Board of Pharmacy to deschedule or reschedule controlled substances.** Authorizes the Board of Pharmacy (Board) to designate, deschedule, or reschedule as a controlled substance any substance 30 days after publication in the Federal Register of a final or interim final order or rule designating such substance as a controlled substance or descheduling or rescheduling such substance. Under current law, the Board may act 120 days from such publication date. The bill also provides that a person is immune from prosecution for prescribing, administering, dispensing, or possessing pursuant to a valid prescription a substance approved as a prescription drug by the U.S. Food and Drug Administration on or after July 1, 2017, in accordance with a final or interim final order or rule despite the fact that such substance has not been scheduled by the Board. The immunity provided by the bill remains in effect until the earlier of (i) nine months from the date of the publication of the interim final order or rule or, if published within nine months of the interim final order or rule, the final order or rule or (ii) the substance is scheduled by the Board or by law. This bill is identical to HB 1799.

**SB 1484 Prescription Monitoring Program; disclosure of information to certain physicians or pharmacists.**

*Chief patron:* Hanger

**Prescription Monitoring Program.** Provides that the information in the possession of the Prescription Monitoring Program disclosed by the Director of Health Professions about a specific recipient who is a member of a Virginia Medicaid managed care program to a physician or pharmacist employed by the Virginia Medicaid managed care program may be disclosed to such physician's or pharmacist's clinical designee who holds a multistate licensure privilege to practice nursing or a license issued by a health regulatory board within the Department of Health Professions and is employed by the Virginia Medicaid managed care program.

## Vu, Huong (DHP)

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**From:** Maureen Cahill <MCahill@ncsbn.org>  
**Sent:** Friday, February 24, 2017 9:57 AM  
**To:** Advanced Practice Knowledge Network  
**Subject:** C.A.R.A. waivers from SAMHSA  
**Attachments:** qualifying-other-practitioner-noi-21017.doc

SAMHSA has announced its waiver process for CNPs who have completed the 24 hours of required education for medication assisted treatment of substance abuse under the C.A.R.A. legislation. Please see below. The locator for physicians able to prescribe medication assisted treatment is located at: <https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator> I expect a similar process for CNPs holding a waiver. The new DEA indicator must be on all the scripts and pharmacists will check that they are authorized in the SAMHSA/DEA system.

### **DATA 2000 Waiver NOI <https://www.samhsa.gov/medication-assisted-treatment/qualify-nps-pas-waivers>**

NPs and PAs who have completed the 24 hours of required training may seek to obtain a DATA 2000-waiver for up to 30 patients may apply by completing a hardcopy of the [Notification of Intent \(NOI\) \(DOC | 64 KB\)](#) and sending to [infobuprenorphine@samhsa.hhs.gov](mailto:infobuprenorphine@samhsa.hhs.gov) (link sends e-mail), along with copies of their training certificate(s). Starting February 27, 2017 SAMHSA will only accept electronic submissions of the NOI. These waiver applications are forwarded to the DEA, which will assign the NP or PA a special identification number. DEA regulations require this number to be included on all buprenorphine prescriptions for opioid dependency treatment, along with the NP's or PA's regular DEA registration number.

SAMHSA shall review waiver applications within 45 days of receipt. If approved, NPs and PAs will receive a letter via email that confirms their waiver and includes their prescribing identification number.

Last Updated: 02/21/2017

Please let me know any questions I can help with and I provide updates as I receive them.

Maureen

Maureen Cahill [Senior Policy Advisor] 312.525.3646 (D) [mcahill@ncsbn.org](mailto:mcahill@ncsbn.org)

National Council of State Boards of Nursing (NCSBN) 111 E. Wacker Drive, Ste 2900, Chicago, IL 60601-4277

312.279.1032 (F) [www.ncsbn.org](http://www.ncsbn.org)

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**Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Qualifying Other Practitioner" under 21 USC § 823(g)(2)**

To Complete Online Go To: <http://buprenorphine.samhsa.gov/pls/bwns/waiver>

Form Approved: XXXX-XXXX

Date: XX/XX/XXXX

See OMB Statement Below

DATE OF SUBMISSION

Note: Notification is required by § 303(g)(2), Controlled Substances Act (21 USC § 823(g)(2)). See instructions on reverse.  
**PLEASE DON'T FORGET TO SIGN AND DATE THIS FORM (ITEM 9)**

**I A. NAME OF PRACTITIONER**

**I B. State Health Professional License Number**

**I C. Professional Discipline**

**I D. DEA Registration Number**

**2. ADDRESS OF PRACTICE LOCATION (Include Zip Code) (See instruction below)**

**3. TELEPHONE NUMBER (Include Area Code)**

**4. FAX NUMBER (Include Area Code)**

**5. EMAIL ADDRESS (Required)**

**2A. Is this location a FQHC? Yes  No**

**6. PURPOSE OF NOTIFICATION (See instruction below)**

New Notification  New Notification, with the intent to immediately facilitate treatment of an individual (one) patient

Second notification of need and intent to treat up to 100 patients

**7. CERTIFICATION OF USE OF NARCOTIC DRUGS UNDER THIS NOTIFICATION**

When providing maintenance or detoxification treatment, I certify that I will only use Schedule III, IV, or V drugs or combinations of drugs that have been approved by the FDA for use in maintenance or detoxification treatment and that have not been the subject of an adverse determination.

**8. Certification of Qualifying Criteria**

I certify that I am either an advanced practice nurse or physician assistant who satisfies the definition of a "qualifying other practitioner" under 21 U.S.C. § 823(g)(2)(G)(iv), as amended by the Comprehensive Addiction and Recovery Act of 2016, and that I am aware that 'qualifying other practitioners' will be included in the definition of a "qualifying practitioner" under 21 U.S.C. § 823(g)(2)(G)(iii) until October 1, 2021.

I certify that I am licensed to prescribe Schedule III, IV, or V medications for the treatment of pain under State law. (To verify Mid-Level Practitioners Authorization by State please visit [https://www.deaddiversion.usdoj.gov/drugreg/practioners/mlp\\_by\\_state.pdf](https://www.deaddiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf))

I certify that I am NOT required by State law to be supervised by and work in collaboration with a qualifying physician to prescribe Schedule III, IV, or V medications.

or

I certify that I am required by State law to be supervised by and work in collaboration with a qualifying physician to prescribe III, IV, or V medications.

Supervisory Physician Name: \_\_\_\_\_

Supervisory Physician Phone Number: \_\_\_\_\_

I certify that I have completed the required 24 hours of training for the treatment and management of opioid-dependent patients and am therefore a qualifying other practitioner.

Name of organization approved for training: \_\_\_\_\_

Please Provide Date of Completion: \_\_\_\_\_

**9. Certification of Capacity**

I certify that I have the capacity to provide patients with appropriate counseling and other appropriate ancillary services, either directly or by referral.

I certify that I have the capacity to all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention.

**10. Certification of Maximum Patient Load (select one)**

I certify that I will not exceed 30 patients for maintenance or detoxification treatment at one time.

**11. CONSENT** (Read instruction 11 below before answering)

I consent to the release of my name, primary address, and phone number to the SAMHSA Treatment Locators.

I do not consent to the release of my name, primary address, and phone number to the SAMHSA Treatment Locators.

**12. I certify that the information presented above is true and correct to the best of my knowledge. I certify that I will notify SAMHSA at the address below if any of the information contained on this form changes. Note: Any false, fictitious, or fraudulent statements or information presented above or misrepresentations relative thereto may violate Federal laws and could subject you to prosecution, and/or monetary penalties, and or denial, revocation, or suspension of DEA registration. (See 18 USC § 1001; 31 USC §§ 3801–3812; 21 USC § 824.)**

X \_\_\_\_\_

X \_\_\_\_\_

**Signature**

**Date**

Substance Abuse and Mental Health Services Administration,  
Division of Pharmacologic Therapies

Please submit form electronically to:  
<http://buprenorphine.samhsa.gov/pls/bwns/waiver>

For questions, please call  
1-866-287-2728 (1-866-BUP-CSAT)

This form is intended to facilitate the implementation of the provisions of 21 USC § 823(g)(2). The Secretary of DHHS will use the information provided to determine whether practitioners meet the qualifications for waivers from the separate registration requirements under the Controlled Substances Act (21 USC § 823(g)(1)). If such qualifications are met, the Drug Enforcement Administration will assign an identification number to qualifying practitioners and the number will be included in the practitioner's registration under 21 USC § 823(f). This form may be completed and submitted electronically (including facsimile) to facilitate processing.

1. The practitioner must identify the DEA registration number issued under 21 USC § 823(f) to prescribe substances controlled in Schedules III, IV, or V.

2. Only one address should be specified. For the practitioner to dispense the narcotic drugs or combinations to be used under this notification, the primary address listed here must be the same primary address listed in the practitioner's registration under § 823(f).

**7. Purpose of notification:**

New Notification - an initial notification for a waiver submitted for the purpose of obtaining an identification number from DEA for inclusion in the registration under 21 USC § 823(f).

New Notification, with the intent to immediately facilitate treatment of an individual (one) patient - an initial notification submitted for the purpose described above, with the additional purpose of notifying the Secretary and the Attorney General of the intent to provide immediate opiate addiction treatment for an individual (one) patient pending processing of this waiver notification.

Increase to 100 Notification - For physicians who submitted a new notification not less than one year ago and intend and need to treat up to 100 patients.

11. The SAMHSA Buprenorphine Physician and Treatment Program Locator Web site is publicly accessible at [http://buprenorphine.samhsa.gov/bwns\\_locator/](http://buprenorphine.samhsa.gov/bwns_locator/). The Locator Web site lists the names and practice contact information of physicians with DATA waivers, which allow them to treat opioid addiction with Schedule III, IV, and V opioid medications, who agree to be listed on the site. The Locator Web site is used by the treatment-seeking public and health care professionals to find physicians with DATA waivers. The Locator Web site additionally provides links to many other sources of information on substance abuse. No physician listings on the SAMHSA Buprenorphine Physician and Treatment Program Locator Web site will be made without the express consent of the physician.

**Privacy Act Information**

Authority: Section 303 of the Controlled Substances Act of 1970 (21 USC § 823(g)(2)). Purpose: To obtain information required to determine whether a practitioner meets the requirements of 21 USC § 823(g)(2). Routine Uses: Disclosures of information from this system are made to the following categories of users for the purposes stated:

- A. Medical specialty societies to verify practitioner qualifications.
  - B. Other federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
  - C. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
  - D. Persons registered under the Controlled Substance Act (PL 91-513) for the purpose of verifying the registration of customers and practitioners.
- Effect: This form was created to facilitate the submission and review of waivers under 21 USC § 823(g)(2). This does not preclude other forms of notification.

**Paperwork Reduction Act Statement**

Public reporting burden for completing this form is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the completed form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0234. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer; Paperwork Reduction Project (0930-0234); 5600 Fishers Lane, Rockville, MD 20857

## **PERSONAL INFORMATION**

Name: Thokozeni Lipato  
Title: Assistant Professor  
Institution Name: Virginia Commonwealth University  
Business Address 1: Theater Row, Room 436; 730 East Broad Street; PO BOX 980306  
City, State, Zip: Richmond, VA 23298-0306  
Business Phone: (804) 628-3628  
Business Fax: (804) 828-4862  
Business Email: thokozeni.lipato@vcuhealth.org

## **PROFESSIONAL SUMMARY**

Primary Departmental Program Area: General Internal Medicine  
Areas of expertise and interest: Sickle cell disease, Addiction Medicine and chronic pain management

## **EDUCATION**

### **POSTGRADUATE**

07/2002 – 06/2004 University of Minnesota, Minneapolis, MN Internal Medicine Residency  
07/2001 – 06/2002 University of Minnesota, Minneapolis, MN Internal Medicine Internship

### **GRADUATE**

06/1997 – 06/2001 University of Alabama School of Medicine, Birmingham, AL M.D.

### **UNDERGRADUATE**

06/1993 – 05/1997 Alabama A&M University, Normal, AL B.S.  
Honors: Summa cum laude, 1997; Dean's List, 1993 – 1997

## **CERTIFICATION AND LICENSURE**

### **LICENSURE or REGISTRATION**

Virginia medical license; 0101254004; issued /22/2013

USMLE Step 1 – 6/21/1999

USLME Step 2 – 8/15/2000

USLME Step 3 – 12/3/2002

### **CERTIFICATION**

The American Board of Internal Medicine, # 228477, Expires in 2024

## HOSPITAL APPOINTMENTS

Virginia Commonwealth University Medical Center

## ACADEMIC APPOINTMENT HISTORY

Department of Internal Medicine, School of Medicine, Virginia Commonwealth University, Richmond, Virginia, Assistant Professor. September 2013 – present.

Department of Internal Medicine, School of Medicine, University of Minnesota, Minneapolis, Minnesota, Assistant Professor. July 2009 through June 2013.

## EMPLOYMENT HISTORY INCLUDING SIGNIFICANT WORK EXPERIENCE

Staff Physician, Division of General Internal Medicine, Virginia Commonwealth University Medical Center, Richmond, Virginia. September 2013 – present.

Staff Physician, Division of General Internal Medicine, University of Minnesota Medical Center and Community University Healthcare Center, Minneapolis, Minnesota. July 2009 through June 2013.

Medical Director of Barbara McInnis House, Boston Healthcare for the Homeless Program, Boston, Massachusetts. May 2008 through May 2009.

Primary care physician, Boston Healthcare for the Homeless Program, Boston, Massachusetts. August 2005 through May 2009.

Hospitalist (per-diem), Northeast Health System, Beverly, Massachusetts. August 2005 through May 2009.

Primary care physician, Minneapolis VA Medical Center, Minneapolis, Minnesota. July 2004 through July 2005.

## SPECIAL AWARDS AND HONORS

Minnesota Veteran's Research Institute's Zieve Award. 2004

2014 – 2015 Research and External Funding (REF) Fellow. The REF academy is supported by the Division for Inclusive Excellence, the Office of Research and Innovation and the Office of the Provost, and is designed to increase external funding opportunities for underrepresented ethnic minority faculty.

## MEMBERSHIP IN SCIENTIFIC OR PROFESSIONAL SOCIETIES

Society of General Internal Medicine. 2014

**SCIENTIFIC AND SCHOLARLY ACTIVITIES**

**GRANTS AND CONTRACTS: ACTIVE**

1. Phase 1B, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of PF-04447943, Co-Administered with and without Hydroxyurea in subjects with Sickle Cell Disease, B0401016, Wally Smith, Sponsored by Pfizer, Inclusive dates: 03/2015 – 03/2016, Total Direct Costs: \$175,255, Sub I, Percent Effort: 0%
2. Project Title: Enhancing Use of Hydroxyurea in SCD using Patient Navigators R18, HM14641, PI Name: Wally Smith, Source of Funds: NIH/NHLBI sponsored, Inclusive dates: 8/2012-7/2017, Total funding: \$3,000,000.00, Role on Project: Clinical Investigator, Percent Effort: 2%
3. Title: Subjective Responses and Metabolic State During Exercise in Sickle Cell Anemia. PI: Ameringer, Suzanne W. Sponsor: National Institute of Nursing Research/NIH/DHHS. Index: 540645. Award Period: 09/25/2015-07/31/2017. Clinical investigator, Percent Effort: 2%
4. Title: Center for the Study of Tobacco Products. PI: Eissenberg, Thomas E. Sponsor/Award #: National Institute on Drug Abuse/NIH/DHHS - PDA036105B. Index: 548795. Banner Title: 4P50DA036105 04 Proj 3 Internal Med. Award Period: 09/30/2013-08/31/2017. Medically responsible investigator
5. Title: Center for the Study of Tobacco Products. PI: Eissenberg, Thomas E. Sponsor/Award #: National Institute on Drug Abuse/NIH/DHHS - PDA036105A. Index: 548691. Banner Title: 5P50DA036105 03 Proj 2 Internal Med Award Period: 09/30/2013-08/31/2017. Medically responsible investigator
6. Title: Behavior and Toxicant Exposure Among Dual Users of Cigarettes and E-Cigarettes. PI: Cobb, Caroline O. Sponsor/Award #: National Cancer Institute/NIH/DHHS - RCA184634A Index: 545610. Banner Title: 5R21CA184634 02 Internal Med Sub. Award Period: 09/16/2014-08/31/2017. Total award amount: & 419,352. Medical Responsible Investigator

**GRANTS AND CONTRACTS: PAST**

1. Title: Evaluation of Purified Poloxamer 188 in Vaso-Occlusive Crisis of Sickle Cell Disease (EPIC): A Phase 3, Randomized, Double Blind, Placebo-Controlled Multicent Clinical Trail of

MST-188 (purified poloxamer 188) Injection in Subjects with Sickle Cell Disease. PI: Lipato, Thokozeni Sponsor/Award #: Mast Therapeutics, INC. Index: 512726 - Evaluation of Purified Poloxamar 18 Award Period: 08/13/2014-08/12/2016. Total funding: \$169,768, PI, Percent Effort: 4%

2. Enhancing Adherence to Prescribed Opiates in Sickle Cell Disease, Org Code #: 450018, Thokozeni Lipato, Quest Innovation Fund Award, Inclusive dates: 4/2014 – 6/2016, Total funding: \$49, 556,PI, Percent Effort: 9%
3. The role of N-acetyl-L-cysteine (NAC) as an Adjuvant to Opioid Treatment in Patients with Chronic Neuropathic Pain, ClinicalTrials.gov, NCT01840345, Dace Svikis, Inclusive Dates: 12/2013 – 2016, Medical Responsible Investigator, Percent Effort: 0%

#### RESEARCH ADVISING AND MENTORING

Daniel Sop. Department of Engineering, VCU on a research project - Enhancing Adherence to Prescribed Opiates in Sickle Cell Disease. Earned MS degree in May 2016.

#### EXTRAMURAL PRESENTATIONS

##### LOCAL

December 2013. Clinicopathologic Conference. Virginia Commonwealth University, Department of Internal Medicine.

May 2015. Grand Rounds. *Responsible Prescribing of Opioids*. Virginia Commonwealth University, Department of Obstetrics and Gynecology.

May 2016. Grand Rounds. *Sickle Cell Disease*. Virginia Commonwealth University, Department of Surgery.

#### TEACHING, ADVISING AND MENTORING

July 2009 – June 2013, Attending Physician, Inpatient Service (1 resident, 2 interns, 2 M-3s) University of Minnesota; 8 hours per day, 10 weeks per year.

July 2009 – June 2013, Clinic attending, Primary Care Clinic; University of Minnesota; 4 hours per week.

September 2013 - present, Attending Physician, Inpatient Service (1 resident, 2 interns, 2 M-3s); Virginia Commonwealth University; 8 hours per day, 8 weeks per year.

September 2013 – present, Clinic attending, Primary Care Clinic; Virginia Commonwealth University; 8 hours per week.

Sickle Cell Anemia Case Presentation for First Year Medical Students. 2014 - Present.

Internal Medicine Core Conference. May 2016. *Chronic pain management; Buprenorphine pharmacology.*

September 2016 – December 2016, Nurse Practitioner student preceptor, Primary Care Clinic: Virginia Commonwealth University; 4 hours per week.

### **SERVICE ACTIVITIES**

#### **CLINICAL SERVICE**

##### **1. Outpatient Activities**

- a. September 2013 to present; Primary care physician in Faculty Clinic, Ambulatory Care Center, VCU Medical Center
- b. September 2013 to present; Staff physician in Sickle Cell Clinic, Ambulatory Care Center, VCU Medical Center

##### **2. Inpatient Activities**

- a. September 2013 to present; Attending physician, VCU Medical Center. 8 weeks per academic year

##### **3. Miscellaneous Activities**

- a. Informal consultations with VCU Medical Center inpatient teams regarding management of Sickle Cell Disease

#### **SERVICE TO THE UNIVERSITY**

2015 Search Committee for Director of Pain Clinic

#### **SERVICE TO THE DEPARTMENT**

July 2015 – Present Medical Director of Internal Medicine Subspecialty Clinic

May 2015 – Present Co-chair of Ambulatory Pain Committee

October 2013 – Present Pain Management Committee; member

## **PUBLICATIONS**

### **PAPERS PUBLISHED IN PEER REVIEWED JOURNALS**

Sawhney MS, **Lipato T**, Nelson DB, Lederle FA, Rector TS, Bond JH. *Should Patients with Anemia and Low Normal and Normal Ferritin Undergo Colonoscopy?* American Journal of Gastroenterology. 2007; 102(1): 82 – 88

Ramoa CP, Hiler MM, Spindle TR, Lopez AA, Karaoghlanian N, **Lipato T**, Breland AB, Shihadeh A, Eissenberg T. *Electronic cigarette nicotine delivery can exceed that of combustible cigarettes: a preliminary report.* Tobacco Control, 2015.

Soule EK, **Lipato T**, Eissenberg T. *Waterpipe tobacco-smoking: a new smoking epidemic among the young?* Current Pulmonology Reports, September 2015.

Lopez AA, Hiler MM, Soule EK, Ramoa CP, Karaoghlanian NV, **Lipato T**, Breland AB, Shihadeh AL, Eissenberg T. *Effects of Electronic Cigarette Liquid Nicotine Concentration on Plasma Nicotine and Puff Topography in Tobacco Cigarette Smokers: A Preliminary Report.* Nicotine Tob Res. 2015 Sep 16.

### **PAPERS PUBLISHED IN JOURNALS THAT ARE NOT PEER REVIEWED**

**Lipato T.** *Improving the Health of the Homeless.* Minnesota Medicine. 2012; 95 (2): 45 – 50



**From:** Maureen Cahill <[MCahill@ncsbn.org](mailto:MCahill@ncsbn.org)>

**Date:** March 8, 2017 at 4:06:09 PM EST

**To:** Elliot Vice <[evice@ncsbn.org](mailto:evice@ncsbn.org)>, MB Executive Officers <[execoffs@ncsbn.org](mailto:execoffs@ncsbn.org)>, Board of Directors <[bod@ncsbn.org](mailto:bod@ncsbn.org)>

**Cc:** David Benton <[dbenton@ncsbn.org](mailto:dbenton@ncsbn.org)>, Maryann Alexander <[malexander@ncsbn.org](mailto:malexander@ncsbn.org)>, Nicole Livanos <[nlivanos@ncsbn.org](mailto:nlivanos@ncsbn.org)>, Rebecca Fotsch <[rfotsch@ncsbn.org](mailto:rfotsch@ncsbn.org)>

**Subject:** RE: NCSBN Legal Memo - VHA Full Practice Authority Implementation Issues

Nicely done, Elliot!  
Maureen

**From:** Elliot Vice

**Sent:** Wednesday, March 8, 2017 2:13 PM

**To:** MB Executive Officers <[execoffs@ncsbn.org](mailto:execoffs@ncsbn.org)>; Board of Directors <[bod@ncsbn.org](mailto:bod@ncsbn.org)>

**Cc:** David Benton <[dbenton@ncsbn.org](mailto:dbenton@ncsbn.org)>; Maryann Alexander <[malexander@ncsbn.org](mailto:malexander@ncsbn.org)>; Maureen Cahill <[MCahill@ncsbn.org](mailto:MCahill@ncsbn.org)>; Nicole Livanos <[nlivanos@ncsbn.org](mailto:nlivanos@ncsbn.org)>; Rebecca Fotsch <[rfotsch@ncsbn.org](mailto:rfotsch@ncsbn.org)>

**Subject:** NCSBN Legal Memo - VHA Full Practice Authority Implementation Issues

Dear Executive Officers,

As many of you know, the Department of Veterans Affairs (VA) released an [interim final rule](#) on December 14, 2016 that grants full practice authority to APRNs (excluding CRNAs) employed by the Veterans Health Administration (VHA). This regulation went into effect January 13, 2017, but has not yet been implemented. The VA is in the process of drafting implementation guidelines for VHA facilities. The VA has decided not to make implementation of this rule mandatory, so individual VHA facilities will choose whether or not to implement full practice authority. The VA has identified several VHA facilities that will be "early adopters" of full practice authority for their APRN workforce. A list of "early adopter" VHA facilities is attached for your reference. The VA hopes these facilities can begin implementation in the next 90 – 120 days, or faster if possible.

Over the past month, NCSBN staff has been working with VA staff to help identify potential issues that may arise with facilities seeking to implement APRN full practice authority. Through these meetings, the VA sought clarification on how state licensing boards, particularly in states that have not adopted APRN full practice authority, might address new issues their APRN workforce and VHA facilities face after implementing the rule. For example, VA staff inquired how state licensing boards would handle renewal of a VA APRN's license in a non-full practice authority state if that state requires a collaborating or supervising physician to be listed on an APRN's license renewal application. To gain a better understanding of this issue's legal precedent, NCSBN staff asked Vedder Price, NCSBN's legal counsel, to produce a legal memorandum, which is attached for your reference. Ultimately, Vedder Price determined "that a state may not deny a licensee's application for licensure renewal based on the licensee's failure to maintain a collaborative agreement, otherwise required by state law, where the licensee practices exclusively as an appointed APRN at VA facilities pursuant to 38 CFR Part 17."

NCSBN is also working with the VA to develop strategies that ensure state boards of nursing are notified which VHA facilities have granted their APRNs full practice authority and which specific APRNs have been given this authority. The VA has also shared potential options for how they could verify an APRN's

employment at a VHA facility that has implemented full practice authority, which may be necessary for APRNs seeking renewal of a license from a non-full practice authority state.

The VA would like to continue working closely with NCSBN and state boards of nursing to ensure a smooth implementation process. If issues arise, both the VA and NCSBN have committed to work together to find solutions that are mutually agreeable for the long term needs of all involved parties. If you have questions or would like to connect with the VA to discuss state-specific implementation issues, please let us know.

Best,

Elliot Vice

Elliot Vice | Director, Government Affairs  
National Council of State Boards of Nursing (NCSBN)  
202.530.4830 (D) | [evice@ncsbn.org](mailto:evice@ncsbn.org)  
1110 Vermont Ave NW, Suite 1000  
Washington, DC 20005

NCSBN – *Leading in nursing regulation* – [www.ncsbn.org](http://www.ncsbn.org)

**Our Mission**

*The National Council of State Boards of Nursing (NCSBN) provides education, service and research through collaborative leadership to promote evidence-based regulatory excellence for patient safety and public protection.*

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issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. Therefore, no economic impact analysis under Section 6(a)(3)(C) of Executive Order 12866 has been prepared. For the same reason, and because no notice of proposed rulemaking has been published, no statement is required under Section 202 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532. In any event, this rulemaking is procedural and interpretive in nature and is thus not expected to have a significant economic impact. Finally, this rule does not have "federalism implications." The rule does not have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government" and therefore is not subject to Executive Order 13132 (Federalism).

#### VI. Regulatory Flexibility Analysis

The notice and comment rulemaking procedures of Section 553 of the APA do not apply "to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. 553(b)(A). Rules that are exempt from APA notice and comment requirements are also exempt from the Regulatory Flexibility Act (RFA). See SBA Office of Advocacy, A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act, at 9; also found at: <https://www.sba.gov/advocacy/guide-government-agencies-how-comply-regulatory-flexibility-act>. This is a rule of agency procedure, practice, and interpretation within the meaning of 5 U.S.C. 553; and, therefore, the rule is exempt from both the notice and comment rulemaking procedures of the APA and the requirements under the RFA. Nonetheless OSHA, in the IFR, provided interested persons 60 days to comment on the procedures applicable to retaliation complaints under MAP-21 and considered the one comment pertinent to the IFR that it received in deciding to finalize without change the procedures in the IFR.

#### List of Subjects in 29 CFR Part 1988

Administrative practice and procedure, Automobile dealers, Employment, Investigations, Motor vehicle defects, Motor vehicle manufacturers, Part suppliers, Reporting and recordkeeping requirements, Whistleblower.

### PART 1988—PROCEDURES FOR HANDLING RETALIATION COMPLAINTS UNDER SECTION 31307 OF THE MOVING AHEAD FOR PROGRESS IN THE 21ST CENTURY ACT (MAP-21)

■ For the reasons set out in the preamble, the interim final rule adding 29 CFR part 1988, which was published at 81 FR 13976 on March 16, 2016, is adopted as a final rule without change.

Signed at Washington, DC, on December 8, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2016-29914 Filed 12-13-16; 8:45 am]

BILLING CODE 4510-28-P

### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2016-1044]

#### Drawbridge Operation Regulation; Sacramento River, Sacramento, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the Tower Drawbridge across the Sacramento River, mile 59.0, at Sacramento, CA. The deviation is necessary to allow the community to participate in the New Year's Eve fireworks. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period.

**DATES:** This deviation is effective from 8:30 p.m. on December 31, 2016 to 12:15 a.m. on January 1, 2017.

**ADDRESSES:** The docket for this deviation, [USCG-2016-1044], is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510-437-3516, email [David.H.Sulouff@uscg.mil](mailto:David.H.Sulouff@uscg.mil).

**SUPPLEMENTARY INFORMATION:** California Department of Transportation has requested a temporary change to the

operation of the Tower Drawbridge, mile 59.0, over Sacramento River, at Sacramento, CA. The vertical lift bridge navigation span provides a vertical clearance of 30 feet above Mean High Water in the closed-to-navigation position. The draw operates as required by 33 CFR 117.189(a). Navigation on the waterway is commercial and recreational.

The drawspan will be secured in the closed-to-navigation position from 8:30 p.m. on December 31, 2016 to 12:15 a.m. on January 1, 2017, to allow the community to participate in the New Year's Eve fireworks. This temporary deviation has been coordinated with the waterway users. No objections to the proposed temporary deviation were raised.

Vessels able to pass through the bridge in the closed position may do so at any time. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: December 9, 2016.

D.H. Sulouff,

District Bridge Chief, Eleventh Coast Guard District.

[FR Doc. 2016-29986 Filed 12-13-16; 8:45 am]

BILLING CODE 9110-04-P

### DEPARTMENT OF VETERANS AFFAIRS

#### 38 CFR Part 17

RIN 2900-AP44

#### Advanced Practice Registered Nurses

AGENCY: Department of Veterans Affairs.

ACTION: Final rule with comment period.

**SUMMARY:** The Department of Veterans Affairs (VA) is amending its medical regulations to permit full practice authority of three roles of VA advanced practice registered nurses (APRN) when they are acting within the scope of their VA employment. Certified Registered Nurse Anesthetists (CRNA) will not be included in VA's full practice authority

under this final rule, but comment is requested on whether there are access issues or other unconsidered circumstances that might warrant their inclusion in a future rulemaking. The final rulemaking establishes the professional qualifications an individual must possess to be appointed as an APRN within VA, establishes the criteria under which VA may grant full practice authority to an APRN, and defines the scope of full practice authority for each of the three roles of APRN. The services provided by an APRN under full practice authority in VA are consistent with the nursing profession's standards of practice for such roles. This rulemaking increases veterans' access to VA health care by expanding the pool of qualified health care professionals who are authorized to provide primary health care and other related health care services to the full extent of their education, training, and certification, without the clinical supervision of physicians, and it permits VA to use its health care resources more effectively and in a manner that is consistent with the role of APRNs in the non-VA health care sector, while maintaining the patient-centered, safe, high-quality health care that veterans receive from VA.

**DATES:** This final rule is effective January 13, 2017. Comments on full practice authority for CRNAs must be received by VA on or before January 13, 2017.

**ADDRESSES:** Written comments may be submitted: Through <http://www.Regulations.gov>; by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; by fax to (202) 273-9026. Comments should indicate that they are submitted in response to "RIN 2900-AP44-Advanced Practice Registered Nurses." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Call (202) 461-4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at <http://www.Regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** David J. Shulkin, M.D., Under Secretary for Health, (202) 461-7000 or Linda M. McConnell, Office of Nursing Services, (202) 461-6700, 810 Vermont Avenue

NW., Washington, DC 20420. (These are not toll-free numbers.)

**SUPPLEMENTARY INFORMATION:** In a document published in the *Federal Register* on May 25, 2016 (81 FR 33155), VA proposed to amend its medical regulations in part 17 of Title 38, Code of Federal Regulations (CFR) to permit full practice authority of four roles of VA advanced practice registered nurses (APRN) when they were acting within the scope of their VA employment. We provided a 60-day comment period, which ended on July 25, 2016. We received 223,296 comments on the proposed rule.

The Office of the Federal Register has prepared a document, *A Guide to the Rulemaking Process*, that states that an agency is not permitted to base its final rule on the number of comments received in support of the rule over those in opposition to it or vice versa. The document further states that an agency must base its reasoning and conclusions on the rulemaking record, which consists of the comments received, scientific data, expert opinions, and facts accumulated during the pre-rule and proposed rule stages. This final rule adheres to the guidance established by the Office of the Federal Register.

Section 7301 of title 38 United States Code (U.S.C.) establishes the Veterans Health Administration (VHA) within VA, and establishes that its primary function is to "provide a complete medical and hospital service for the medical care and treatment of veterans, as provided in this title and in regulations prescribed by the Secretary pursuant to this title." To allow VA to carry out its medical care mission, Congress also established a comprehensive personnel system for certain medical employees in VHA, independent of the civil service rules. See Chapters 73 and 74 of title 38, U.S.C. As an integrated Federal health care system with the responsibility to provide comprehensive care under 38 U.S.C. 7301, it is essential that VHA wisely manage its resources and fully utilize the skills of its health care providers to the full extent of their education, training, and certification.

By permitting the three APRN roles, Certified Nurse Practitioner (CNP), Clinical Nurse Specialist (CNS), or Certified Nurse-Midwife (CNM), throughout the VHA system with a way to achieve full practice authority in order to provide advanced nursing services to the full extent of their professional competence, VHA furthers its statutory mandate to provide quality health care to our nation's veterans.

This regulatory change to nursing policy permits three roles of APRNs to practice to the full extent of their education, training and certification, without the clinical supervision or mandatory collaboration of physicians.

Standardization of APRN full practice authority, without regard for individual State practice regulations, helps to ensure a consistent delivery of health care across VHA by decreasing the variability in APRN practice that currently exists as a result of disparate State practice regulations. Certified Registered Nurse Anesthetists (CRNA) will not be included in VA's full practice authority under this final rule, but comment is requested on whether there are access issues or other unconsidered circumstances that might warrant their inclusion in a future rulemaking.

Standardization of full practice authority to the three APRN roles also aids VA in making the most efficient use of VHA APRN staff capabilities, which increases VA's capacity to provide timely, efficient, and effective primary care services, as well as other services. This increases veteran access to needed VA health care, particularly in medically-underserved areas and decreases the amount of time veterans spend waiting for patient appointments. In addition, standardizing APRN practice authority enables veterans, their families, and caregivers to understand more readily the health care services that VA APRNs are authorized to provide. This preemptive rule increases access to care and reduces the wait times for VA appointments utilizing the current workforce already in place. VA's position to not include the CRNAs in this final rule does not stem from the CRNAs' inability to practice to the full extent of their professional competence, but rather from VA's lack of access problems in the area of anesthesiology.

To ensure that VA would have available highly qualified medical personnel, Congress mandated the basic qualifications for certain health care positions, including registered nurses. Sections 7401 through 7464 of title 38, U.S.C., grant VA authority to regulate the professional activities of such personnel. To be eligible for appointment as a VA employee in a health care position (other than Director) covered by section 7402(b), of title 38, U.S.C., a person must, among other requirements, be licensed, registered, or certified to practice their profession in a State. The standards prescribed in section 7402(b) establish only the basic qualifications necessary "[t]o be eligible for appointment" and

do not limit the Secretary or Under Secretary for Health from establishing other qualifications for appointment, or additional rules governing such personnel. In particular, 38 U.S.C. 7403(a)(1) provides that appointments under Chapter 74 “may be made only after qualifications have been established in accordance with regulations prescribed by the Secretary, without regard to civil-service requirements.” As the head of VHA, the Under Secretary for Health has the duty to “prescribe all regulations necessary to the administration of the Veterans Health Administration,” subject to approval by the Secretary. See 38 U.S.C. 7304; see also 38 U.S.C. 501. Pursuant to this authority, the Under Secretary for Health is authorized to establish the qualifications and clinical practice standards of VHA’s nursing personnel and to otherwise regulate their professional conduct.

To continue to provide high quality health care to veterans, this final rule will allow three roles of APRNs to practice to the full extent of their education, training, and certification when acting within the scope of their VA employment, regardless of State restrictions that limit such full practice authority, except for applicable State restrictions on the authority to prescribe and administer controlled substances.

The proposed rule stated that VA was proposing to grant full practice authority to four APRN roles. We received 104,256 comments against granting full practice authority to VA CRNAs. The American Society of Anesthesiologists lobbied heavily against VA CRNAs having full practice authority. They established a Web site that would facilitate comments against the CRNAs, which went as far as providing the language for the comment. These comments were not substantive in nature and were akin to votes in a ballot box. The main argument against the VA CRNAs was that by granting CRNAs full practice authority VA would be eliminating the team based concept of care in anesthesia, which is currently established in VA policy via VHA Handbook 1123, Anesthesia Service. Team based care was not addressed in the proposed rule because we consider it to be an integral part in addressing all of a veteran’s health care needs. Establishing full practice authority to VA APRNs, including CRNAs, would not eliminate any well-established team based care. The second argument posed against granting full practice authority to VA CRNAs was that there is “no shortage of physician anesthesiologists in VA and the current system allows for sufficient flexibility to address the

needs of all VA hospitals.” Again, most of these comments were not substantiated by evidence, though as discussed further below, VA does believe that evidence exists that there is not currently a shortage of anesthesiologists that critically impacts access to care, and therefore VA agrees with the sentiment of this argument.

We similarly received 45,915 comments in support of full practice authority for APRNs as a whole without specific mention of CRNAs. We received 9,613 comments in support of full practice authority for CRNAs. The CRNA-specific commenters stated that “CRNAs currently exercise their full scope of practice in 17 states and in the Army, Navy, Air Force, Combat Support Hospitals, Forward Surgical Teams, and the Indian Health Services, even in some VAs where CRNAs are the only anesthesia providers. Evidence shows that APRN provided care increases access, improves quality, and reduces costs for all Americans. By extending Full Practice authority to CRNAs and other APRNs at the VHA, we can help end delays to high-quality, safe, and cost-effective care for America’s Veterans. Implement this well researched policy change promptly.” The commenters also stated that “APRN’s and CRNAs practicing in a manner which they have been educated and trained to provide expert care has been backed by decades of research.” Several other commenters stated “Over 900 CRNAs provide every type of anesthesia care, as well as chronic pain management services, for our Veterans in the VHA. The safety of CRNA services has long been recognized by the VHA and underscored by peer-reviewed scientific studies, including a major study published in Health Affairs which found that anesthesia care by CRNAs was equally safe with or without physician supervision.” VA agrees with these comments, but has chosen not to include CRNAs in this final rule due to VA’s lack of access problems in the area of anesthesiology.

Commenters raised anesthesia issues related to the RAND Assessment, which the public can view at [http://www.va.gov/opa/choiceact/documents/assessments/Assessment\\_B\\_Health\\_Care\\_Capabilities.pdf](http://www.va.gov/opa/choiceact/documents/assessments/Assessment_B_Health_Care_Capabilities.pdf). Specifically, the Department of Veterans Affairs Independent Assessment B, Appendix E–I reported on qualitative interviews with Chiefs of Staff at VA facilities; fourteen comments discussed lack of anesthesia service/support as a barrier to providing care, including for urgent and non-urgent cardiovascular surgeries (three comments), as well as colon cancer/gastrointestinal services such as

endoscopy and colonoscopy (eleven comments).<sup>1</sup> As discussed further below, VA understands that there are difficulties hiring and retaining anesthesia providers, but generally believes that this situation is improving. VA reviewed the qualitative interviews with Chiefs of Staff at VA facilities contained in the RAND Assessment but did not determine that data supported granting FPA to CRNAs to solve access issues. Nonetheless, VA is requesting further comments on whether advanced practice authority for CRNAs would bring further improvements.

We reviewed the Veterans Health Administration payroll data revealed that, as of August 31, 2016, VHA employs 940 Physician Anesthesiologists (physicians), 5,444 Nurse Practitioners, 937 CRNAs, and 386 Nurse Specialists. Nurse Practitioner is currently #3 in the top 5 difficult to recruit and retain nurse specialties. Additional workforce trend data is available in the Regulatory Impact Analysis.

In a 2015 independent survey of VA general facility Chief of Staffs conducted by the Rand Corporation, approx. 38% (43 of 111) reported problems *recruiting or hiring* advanced practice providers, such as Nurse Practitioners, and 50% reported problems recruiting or hiring nurses such as clinical specialists.<sup>2</sup> The most commonly reported barriers to recruitment and hiring for these medical experts were: Non-competitive wages (72% of 43 responses for advanced practice providers; 64% of 56 responses percent for nurses), Human Resources process (42% for advanced practice providers; 45% for nurses), geographic location of facility (35% for advanced practice providers; 23% for nurses), and lack of qualified applicants (26% for advanced practice providers; 32% for nurses).<sup>3</sup>

Similarly, nearly 30% (33 of 111) of Chiefs of Staffs reported problems *retaining* advanced practice providers, such as NPs, and almost half reported problems retaining nurses, such as clinical specialists.<sup>4</sup> The most commonly reported reasons for problems with retention of these medical experts were; Dissatisfaction

<sup>1</sup> VA Independent Assessment, Appendices E–I, [http://www.va.gov/opa/choiceact/documents/assessments/Assessment\\_B\\_Health\\_Care\\_Capabilities\\_Appendices\\_E-I.pdf](http://www.va.gov/opa/choiceact/documents/assessments/Assessment_B_Health_Care_Capabilities_Appendices_E-I.pdf).

<sup>2</sup> RAND, Independent Assessment B, Appendix G.1.1 Chief of Staff, 2015 Survey of VA Capabilities and Resources, G–5.

<sup>3</sup> *Id.* at G–6. (Totals greater than 100 due to option to select the two most important factors affecting recruiting and hiring. Only respondents who reported problems recruiting specific personnel categories were asked to respond.)

<sup>4</sup> *Id.* at G–7.

with supervision/management support (61% of 31 responses for advanced practice providers; 57% of 49 responses for nurses) and dissatisfaction with pay (36% of advanced practice providers; 27% of nurses).<sup>5</sup> Chiefs of Staff rarely selected lack of opportunity for professional growth/promotion as a top two reason for retention problems, only 6% selected this option for advanced practice providers and 8% for nurses. Lack of professional autonomy was also not viewed as a significant contributor to retention issues (3% for advanced practice providers, 0% for nurses).

In fiscal years 2011 through 2015, CRNAs were in the top 10 VHA Occupations of Critical Need, but dropped to 12th place in FY 2015. Despite the challenges discussed above, within VHA the occupation has grown approximately 27% between FY 2010 and FY 2014 (166 employees). Total loss rates decreased from 6.6% in FY 2013 to 6.2% in FY 2014, but have ranged from 9.4% to 6.2% between FY 2009 and FY 2014. Voluntary retirements decreased from 3.2% in FY 2013 to 2.7% in FY 2014. Quits increased from 1.9% in FY 2013 to 2.6% in FY 2014. VA has taken steps to improve recruitment of CRNAs, including partnering with the U.S. Army to educate interested and qualified VA registered nurses in the field of nurse anesthesia.<sup>6</sup> Also, as previously stated in this rulemaking, VA CRNAs are a crucial part of the team based anesthesia care. VHA Handbook 1123, Anesthesia Service, states in paragraph 4.a. "In facilities with both anesthesiologists and nurse anesthetists, care needs to be approached in a team fashion taking into account the education, training, and licensure of all practitioners."

Anesthesiology is not in the top 5 difficult to recruit and retain physician specialties. However, in a 2015 independent survey of VA general facility Chief of Staffs conducted by the Rand Corporation, 25% (27 of 111) reported problems *recruiting or hiring* anesthesiologists.<sup>7</sup> The most commonly reported barriers to recruitment and hiring for these medical experts were: Non-competitive wages (78% of 27 respondents), Human Resources process (25%), and geographic location of

facility (22.2%).<sup>8</sup> Nearly 10% of Chiefs of Staff (11/111) reported difficulties *retaining* anesthesiologists.<sup>9</sup> The most commonly reported reason for staff retention problems for these medical experts were: Dissatisfaction with supervision/management support (27%) and dissatisfaction with pay (55%).<sup>10</sup> Despite these challenges, over the past 5 years, the number of anesthesiologists VHA hired increased from 87 in FY11 to 149 in FY15. The FY15 turnover rate for anesthesiologists is slightly lower than the turnover rate for physicians overall. VHA has had recent successes in hiring or contracting for Anesthesiology services.

Recruiting, hiring, and retention challenges, as reported by VA facility Chiefs of Staffs struggling with these issues, are similar among advanced practice or specialist nurses and anesthesiologists. These managers did not view lack of advancement opportunity or practice autonomy as significant barriers to retention, which may indicate that increased use of advanced practice authority is unlikely to fully resolve this challenge—both because it may not address the root causes of these problems and because similar challenges constrain hiring of both doctors and nurses. On the other hand, the perceptions of potential applicants and staff may not be fully reflected by a survey of facility management. Further, it is possible that resources might be available to address some of these underlying issues if efficiencies were realized as a result of advanced practice nursing authority. VA welcomes comment on whether lack of advanced practice authority is a hiring, recruitment, or retention barrier for CRNAs, as well as on the extent to which advanced practice authority could help to resolve these issues either directly or indirectly.

Based on this analysis, VHA believes that VA does not have immediate and broad access problems in the area of anesthesia care across the full VA health care system that require full practice authority for all CRNAs.

However, VA requests comment on the question of whether there are current anesthesia care access issues for particular states or VA facilities and whether permitting CRNAs to practice to the full extent of their advanced authority would resolve these issues. VA also requests comment on potential future anesthesia care access issues, particularly in light of projected

increases in demand for VA care, including surgical care, in coming years.

We will, therefore, not finalize the provision including CRNAs in the rule as one of the APRN roles that may be granted full practice authority at this time. However, we request comment on this decision. If we learn of access problems in the area of anesthesia care in specific facilities or more generally that would benefit from advanced practice authority, now or in the future, or if other relevant circumstances change, we will consider a follow-up rulemaking to address granting full practice authority to CRNAs.

VA CRNAs that have already been granted full practice authority by their State license will continue to practice in VA in accordance with their State license and subject to credentialing and privileging by a VA medical facility's medical executive committee. VA will not restrict or eliminate these CRNAs' full practice authority.

This final rule uses the term "full practice authority" to refer to the APRN's authority to provide advanced nursing services without the clinical oversight of a physician when that APRN is working within the scope of their VA employment. Such full practice authority is granted by VA upon demonstrating that the advanced educational, testing, and licensing requirements established in this rulemaking are met and upon the recommendation and approval of the medical executive committee when the provider is credentialed and privileged.

In this rulemaking, VA is exercising Federal preemption of State nursing licensure laws to the extent such State laws conflict with the full practice authority granted to VA APRNs while acting within the scope of their VA employment. Preemption is the minimum necessary action for VA to allow APRNs full practice authority. It is impractical for VA to consult with each State that does not allow full practice authority to APRNs to change their laws regarding full practice authority.

The campaign in support of the proposed rule was not as extensive as the campaign against granting full practice authority to CRNAs. The main lobbyists in support of the proposed rule were the American Nurses Association and the American Association of Nurse Practitioners, who supported a letter campaign. We received 45,915 comments in support of the proposed rule. Of these 45,915, we received specific support of individual APRN roles as follows: 9,613 in support of CRNAs, 1,079 in support of CNM, and 495 in support of CNPs. These

<sup>5</sup> *Id.* at G-9.

<sup>6</sup> VA, Patient Care Services, Nurse Anesthetist Education Program, available at: [http://www.patientcare.va.gov/CRNA\\_Education/Pages/Certified\\_Registered\\_Nurse\\_Anesthetists.asp](http://www.patientcare.va.gov/CRNA_Education/Pages/Certified_Registered_Nurse_Anesthetists.asp) (last accessed Oct. 18, 2016).

<sup>7</sup> RAND, Independent Assessment B, Appendix G.1.1 Chief of Staff, 2015 Survey of VA Capabilities and Resources, G-5.

<sup>8</sup> *Id.* at G-6.

<sup>9</sup> *Id.* at G-8.

<sup>10</sup> *Id.* at G-9.

commenters agreed that the proposed rule aligns with the Institute of Medicine (IOM) of the National Academy of Sciences 2010 IOM Report in that the rule removes scope-of-practice barriers and increases access to VA care. The commenters also agreed that the APRNs are highly skilled in their particular APRN role, as demonstrated by their education and hours of skilled training. Several commenters stated that "APRNs will deliver care to the full scope of their education and training and ensure that the VA has the flexibility to utilize all providers within the healthcare team, maximizing the effective use of resources and providing optimal care for the men and women who have served our country in uniform." Other commenters supported the proposed rule by stating "this proposal supports the VHA team model of care and promotes efficiency in healthcare delivery by making smarter use of the 6,000 APRNs" that are employed by VA. "Most importantly, this proposal has the ability to make real and significant improvements to the availability of high-quality care for millions of Veterans." The commenters also stated that "APRN full practice authority within the VA would create nationwide consistency, thereby improving upon the current patchwork of state regulations and making the most effective use of these health care professionals." We thank the commenters for their support of the proposed rule.

We received a comment in support of the proposed rule from the Federal Trade Commission (FTC). The FTC focuses on the "impact of regulation on competition in the private sector and, ultimately, on consumers." The FTC's main interest in the proposed rule was "the extent that the VA's actions may encourage entry into health care service provider markets, broaden the availability of health care services outside the VHA system, as well as within it, and yield information about new models of health care delivery." The FTC believes that its experience "may inform and support the VA's endeavor." The FTC staff supports the granting of full practice authority to APRNs, which will benefit "VA's patients and the institution itself, by improving access to care, containing costs, and expanding innovation in health care delivery." VA's actions could also spur competition among "health care providers and generate additional data in support of safe APRN practice," which could also spill into the private health care sector. We thank

the FTC for their support of the proposed rule and make no edits based on this comment.

Several commenters stated that they were concerned with proposed § 17.415(d)(1)(i)(B), where we stated that a Certified Nurse Practitioner (CNP) may order, perform, or supervise laboratory studies. The commenters stated that the proposed language does not "adequately appreciate the levels of complexity involved in laboratory testing" and that there are rigid standards for laboratory tests that require rigorous academic and practical training, which are not part of the training for APRNs. Another commenter stated, "While the VHA uses the word 'interpret' in reference to laboratory and imaging studies," the commenter ". . . infers that the VA's intent is to grant the ability for CNPs to interpret laboratory and imaging results, not to interpret or report raw images or data." The commenter suggested that VA amend the term "'interpret' and recommends instead to use 'integrate results into clinical decision making,' or some other phrase" in order to avoid confusion between the duties of an APRN and those of a laboratory specialist. We agree with the commenter in that the proposed language might be construed as allowing CNPs the ability to perform laboratory studies. It is not VA's intent to have APRNs take over the role of laboratory specialists. These specialists perform a crucial role at VA medical facilities and are skillfully trained in performing the various testing techniques that allow health care professionals to properly treat a veteran's medical condition. We are amending proposed § 17.415(d)(1)(i)(B) to now state that a CNP may be granted full practice authority to "Order laboratory and imaging studies and integrate the results into clinical decision making."

Other commenters were similarly concerned with the language in proposed § 17.415(d)(1)(i)(B), but as it refers to ordering, performing, supervising and interpreting imaging studies. The commenters stated that only trained radiologists, who undergo 10 years of comprehensive training to accurately interpret high-tech imaging exams and safely account for the radiation used in many scans should perform these duties. The commenters further stated that imaging exams should only be performed by registered radiological technologists. It is not VA's intent to replace our highly qualified radiologists or radiological technologists. VA is committed to providing high quality health care for our nation's veterans and is proud of the outstanding work performed by

radiologists in our system. We note, however, that during the course of care, other health care providers may review radiology exams and make evaluations based upon the radiologist's findings. These health care providers include providers in emergency departments, primary care clinics, and specialty clinics throughout the VA health care system. All radiology studies are formally performed and read by individuals who are credentialed in radiology. This rulemaking will not change this practice. In order to avoid confusion, we are amending § 17.415(d)(1)(i)(B) by removing performing, supervising, and interpreting imaging studies and replacing it with "Order laboratory and imaging studies and integrate the results into clinical decision making."

Some commenters were also concerned that CNPs "may order more imaging studies, which increases the total cost and the radiation dose to the patient." One commenter cited a study that indicated that CNPs may order imaging more frequently than primary care physicians. However, the study defined advanced practice clinicians to include CNPs and physician assistants, and did not differentiate between these two different types of health care providers in the study. This rulemaking only addresses APRNs, and it is unclear how the study was influenced by including physician assistants. It's also unclear whether there is actually a significantly higher rate of ordering imaging among these groups. We found no other significant evidence provided by the commenters to support the claim that CNPs order more imaging studies than physicians. For these reasons, we make no changes based on this comment.

Several commenters were concerned that the value of team-based care would be undermined by granting full practice authority to APRNs. They stated that physicians and other members of a health care team bring unique value to patient care that is based on the individual member's education, skill, and training. The commenters argued that by eliminating team-based care, patients would be placed at risk. Team-based care is an integral part of VA health care and is used in a wide range of settings, which include polytrauma care, nutrition support, and primary care. VA will continue to provide the already established team-based care to properly treat the veteran's individual health care needs. The proposed rule only addressed the granting of full practice authority to APRNs and does not address team-based care. Any change to current VA team-based health

care is beyond the scope of this rulemaking. We are not making any edits based on these comments.

Other commenters questioned an APRN's years of training versus those of a physician, citing an American Medical Association statement that "physicians typically receive a combined total of over 10,000 hours of training and patient experience prior to beginning practice, whereas the typical APRN receives less than 1,000 hours of training and patient experience." The commenters added that trained physicians should be taking care of the veterans' medical needs as opposed to a nurse who has not received the same training and education as physicians. APRN education is competency based and APRNs must demonstrate that they have integrated the knowledge and skill to provide safe patient care. Entry into APRN practice is predicated on the requirement to attain national certification. APRNs are held to the same standard as physicians in measuring patient outcomes for safe and effective care. VHA acknowledges the fact there are differences in physician and APRN educational and training models and is not planning on replacing physicians with APRNs in any health care setting within VHA.

APRNs are valuable members of VA's health care system and provide a degree of much needed experience to alleviate the current access problems that are affecting VA. APRNs, like physicians, are required to maintain their State license and their health care skills are continuously assessed through the privileging process. As we stated in the proposed rule "APRNs would not be authorized to replace or act as physicians or to provide any health care services that are beyond their clinical education, training, and national certification" and an APRN will require approval of their credentials and privileges by the VA medical facility's medical executive committee. An APRN will refer patients to a physician for care that goes beyond that of the APRN's training. We will not make any edits based on these comments.

Several commenters stated that they would like all veterans to receive the best and safest medical care in VA and do not believe that granting APRNs full practice authority will lead to such care. As previously stated in this final rule, VHA's primary function is to "provide a complete medical and hospital service for the medical care and treatment of veterans" under 38 U.S.C. 7301(b). We also stated in the proposed rule that in carrying out this function, VHA has an obligation to ensure that patient care is appropriate and safe and its health care

practitioners meet or exceed generally-accepted professional standards for patient care. The general qualifications for a person to be appointed as a VA nurse are found in 38 U.S.C. 7402(b)(3). In addition to these general qualifications, the proposed rule stated that APRNs would now be required to have "successfully completed a nationally-accredited, graduate-level educational program that prepares the advanced practice registered nurse in one of the four APRN roles; and to possess, and maintain, national certification and State licensure in that APRN role." VA believes that these additional qualifications for APRNs ensure that VA has highly qualified health care personnel to provide safe health care to veterans. In addition, the VA medical facility's medical executive committee will be responsible for the quality and oversight of the health care provider. Additionally, the IOM Report states that "the contention that APRNs are less able than physicians to deliver care that is safe, effective, and efficient is not supported by the decades of research that has examined this question (Brown and Grimes, 1995; Fairman, 2008; Groth et al., 2010; Hatem et al., 2008; Hogan et al., 2010; Horrocks et al., 2002; Hughes et al., 2010; Laurant et al., 2004; Mundinger et al., 2000; Office of Technology Assessment, 1986). No studies suggest that care is better in states that have more restrictive scope-of-practice regulations for APRNs than in those that do not." We will not make any edits based on these comments.

Several commenters stated that the proposed rule would undermine the State requirement that CNPs need to collaborate with or be supervised by physicians. They were also concerned that the rule would eliminate local control of licensing and regulation of physicians and health care providers, which would result in lower standard of care. We note that there may be discrepancies between State practice acts and this final rule which is why this regulation preempts conflicting state and local law. As we stated in the proposed rule, "In circumstances where there is a conflict between Federal and State Law, Federal law prevails in accordance with Article VI, clause 2, of the U.S. Constitution (Supremacy Clause)." We also stated "where there is conflict between State law and Federal law with regard to full practice authority of APRNs working within the scope of their federal VA employment, this regulation would control." Again, we emphasize that this rule only preempts State law for VA employees practicing within the scope of their VA

employment, and that as a result, any such infringement upon State authority would be limited. Further, this final rule does not eliminate the APRN's need to possess a license from a State licensing board in one of the recognized APRN roles. This is a requirement in proposed § 17.415(a)(3). Proposed § 17.415(a)(4) also requires an APRN to maintain both the national certification and licensure. In addition to these requirements, an APRN must demonstrate the knowledge and skills necessary to provide the services described in proposed § 17.415(d) without the clinical oversight of a physician, and is thus qualified to be privileged for such scope of practice by the medical executive committee. These measures will ensure that patients receive care from an APRN that is credentialed and privileged to perform the specified tasks and will promote patient safety. We will not make any edits based on these comments.

Several commenters were concerned that APRNs would be at a higher risk of malpractice, especially when the APRN's State license does not grant full practice authority. A commenter asserted that the APRN's defense would be diminished when the "state in which the APRN is practicing in deems an act beyond the provider's scope of practice, but the Federal government has given all APRNs the broadest rights available." Under the Federal Tort Claims Act, 28 U.S.C. 1346(b), 2401(b), 2671–2680, and the Westfall Act, 28 U.S.C. 2679(b)–(d), employees furnishing medical care or services in the exercise of their duties for VHA are immune from personal liability for malpractice in the scope of their employment; the rule clarifies the intent of VA that APRNs will be acting within the scope of employment when performing their duties in the capacities set forth herein. The commenters further stated that the preemption of State law would create a discrepancy with VA policy in that VA states in the proposed rule that an APRN must be licensed by a State. As previously stated in this rulemaking, where there is conflict between State law and Federal law with regard to full practice authority of APRNs working within the scope of their Federal employment, this regulation would control. In doing so, VA is better able to protect the APRNs against any challenge of their State license when practicing within the scope of their VA employment. VA does not see a disconnect between preemption and the requirement that an APRN must have a State license. Such requirement is established in statute



under 38 U.S.C. 7402 for the qualifications of appointment as a health care provider in VA. As we stated in the proposed rule, we are establishing “additional professional qualifications an individual must possess to be appointed as an APRN within VA.” These additional requirements go beyond the requirements of some State licenses and ensure consistency for health care provided within VA. We are not making any edits to the rule based on these comments.

One commenter indicated that the proposed rule stated “Section 4 of Executive Order 13132 requires that when an agency proposes to act through rulemaking to preempt state law, ‘the agency shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such conflict.’” [Emphasis added.] The commenter further stated that “VA did not provide affected state and local officials with such notice.” Specifically, “no state medical boards (whether osteopathic or allopathic) were consulted. By the very nature of the Notice of Proposed Rule Making (NPRM), these state medical boards, who are charged with overseeing independent medical practice and assuring patient safety, are ‘affected State officials.’” Initially, we note that section 1(d) of the Executive Order defines State and local officials as including only *elected* officials, and we do not believe the officials overseeing State medical boards are elected. Additionally, section 4 of the Executive Order, as cited by the commenter, states that the “agency shall consult, to the extent practicable” with affected State and local officials (emphasis added). Because advanced practice registered nurses, particularly NPs, are typically regulated by state Boards of Nursing rather than by State medical board we believe they are most affected by this rule.<sup>11</sup> Although VA did not specifically engage State medical boards, VA reached out to several medical associations, including the American College of Surgeons, American Academy of Family Practice Physicians, American Society of Anesthesiologists, American Medical Association, Association of American Medical Colleges, and, although not a medical association, The Joint Commission—Office of Accreditation and Certification. VA consulted with elected State officials, as required by Executive Order 13132, when it received

numerous calls and correspondence from State and local officials in support of this proposed rule. Such State and local officials included State Senators from Georgia and Illinois, State Representatives from Florida, Ohio, Vermont, North Carolina, Georgia, and Illinois, County Commissioners from Nevada, Ohio, and North Carolina, and the State Comptroller and Secretary of State from Illinois, to name a few. We also consulted with the National Council of State Boards of Nursing. We believe that VA’s efforts to consult with State and local officials meet the requirements of section 4(d) of Executive Order 13132. Furthermore, the proposed rule encouraged any comments regarding the granting of full practice authority, which afforded the “affected State and local officials notice and an opportunity for appropriate participation in the proceedings.” As we state in the Federalism paragraph in this rule, at least twelve States responded to VA’s outreach efforts prior to publication of the proposed rule. It would have been impracticable for VA to have consulted with all State medical boards as an outreach effort prior to publication of the proposed rule. We are not making edits based on this comment.

Another commenter stated that the proposed rule “will directly affect many individuals and will directly affect small entities.” The commenter further stated that the rule should not be exempt from the initial regulatory flexibility analysis as stated in the Regulatory Flexibility Act (5 U.S.C. 603 and 604), will not maximize net benefits and equity and will raise novel and legal policy issues. Another comment emphasizes only that “some private-sector anesthesiology services” are provided by small physician practices, which “may” include nurse anesthetists. It further notes that in a “limited” number of states, there is a “possibility” that private sector anesthetists could be induced to work at VA instead of in the private sector. None of these claims demonstrate that the regulation would have a significant economic effect on a substantial number of small entities; VA found no such effect would result in its proposed rule, and certified this finding as required by 5 U.S.C. 605(b). We further note that private sector providers are not subject to the proposed regulation, which would only regulate the activities of VA employees, and hence would be outside the scope of a required analysis under the Regulatory Flexibility Act. See, e.g., *Mid-Tex Electric Cooperative v. FERC*, 773 F.2d 327, 342–3 (D.C. Cir. 1985);

*Cement Kiln Recycling Coalition v. EPA*, 255 F.3d 855, 868–9 (D.C. Cir. 2001); and *Aeronautical Repair Station Ass’n v. F.A.A.*, 494 F.3d 161, 174–7. We are not making any edits based on these comments.

Another commenter was in support of the proposed rule, but had concerns regarding prescriptive authority, namely that in some States the prescriptive authority regulations “are linked to scope of practice laws which would create confusion in VA facilities operating within those states.” The commenter further stated that “collaborative agreements may limit the scope of practice of the advanced practice registered nurse and inhibit full practice authority.” VA understands that the proposed change could create confusion, and as a result, VA will train and educate its APRNs in their authorities based upon this rule to reduce the potential for confusion and to ensure they can practice to the full extent of their authority. We make no edits based on this comment.

A commenter stated a belief that there is a distinction “between the ability of APRNs to perform tasks autonomously and their ability to practice independently. The former is a well-established practice, while the latter is controversial.” The commenter distinguished “‘autonomy’ from ‘independence,’ the latter referring to practitioners acting alone and not in a team-based model.” The commenter stated that they support “highly trained APPs who are part of a care team practicing autonomously within the scope and ability of their licensure. This is generally accomplished with collaborative practice between a collaborating physician and APPs on the care team.” We previously stated in this final rule that team-based care was not addressed in the proposed rule. Team-based care is an integral part of VA health care, and we will continue to adhere to the already established team-based models of care within VA. We are not making any edits based on this comment.

Several commenters stated that VA should include physician assistants (PA) in the final rule and grant them full practice authority as well. Other commenters were opposed to the granting of full practice authority to PAs. We similarly received comments requesting that we include pharmacist practitioners in the rule. The granting of full practice authority to PAs and pharmacist practitioners was not addressed in the proposed rule and granting such authority in this final rule is beyond the scope of the proposed rule. VA would only be able to address

<sup>11</sup> Carolyn Buppert, *Nurse Practitioner’s Business Practice and Legal Guide*, Appendix 3–A (5th Ed. 2015). (Delaware and Alabama, with joint oversight authority, are rare exceptions to this general rule.)

the granting of full practice authority to PAs and pharmacist assistants in a future rulemaking.

One commenter opposed the proposed rule and urged VA “to instead focus on ways to improve access to care provided to veterans in community settings through the Choice Program. This would reduce wait times for appointments for all veterans, and free up VA clinicians to care for sicker and more complex patients in VA facilities prepared to address their unique needs.” The Veterans Choice Program is authorized by section 101 of the Veterans Access, Choice, and Accountability Act of 2014. The program is implemented in 38 CFR 17.1500 through 17.1540. The proposed rule did not address the Veterans Choice Program, and in no way affects the Veterans Choice Program. This comment is beyond the scope of this rulemaking. We are not making any edits based on this comment.

One commenter suggested that VA amend its application process for hiring physicians citing that there are delays in the *usajobs.gov* job portal that often leads physicians to remove themselves from job contention. The application process for physician positions was not addressed in the proposed rule, and this issue is beyond the scope of this rulemaking. We are not making any edits based on this comment.

VA received many comments that expressed general support or opposition to this rulemaking and raised various issues related to administration of the VA health care system or VA benefits that are beyond the scope of this rulemaking. We make no changes based on these comments.

We are making a minor typographical edit by adding a comma in proposed § 17.415(e) to correct an error in the proposed rule. We are also amending the last sentence of the paragraph to now read “Any State or local law, or regulation pursuant to such law, is without any force or effect on, and State or local governments have no legal authority to enforce them in relation to, activities performed under this section or decisions made by VA under this section.” The proposed rule inadvertently did not include the phrase “activities performed under”. We are now adding this clarifying language.

Based on the rationale set forth in the Supplementary Information to the proposed rule and in this final rule, VA is amending the proposed rule with the edits stated in this final rule.

#### **Executive Order 13132, Federalism**

Section 4 of Executive Order 13132 (titled “Federalism”) requires an agency

that is publishing a regulation that preempts State law to follow certain procedures. Section 4(b) of the Executive Order requires agencies to “construe any authorization in the statute for the issuance of regulations as authorizing preemption of State law by rulemaking only when the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute or there is clear evidence to conclude that the Congress intended the agency to have the authority to preempt State law.” Section 4(d) of the Executive Order requires that when an agency proposes to act through rulemaking to preempt State law, “the agency shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such a conflict.” Section 4(e) of the Executive Order requires that when an agency proposes to act through rulemaking to preempt State law, “the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.”

Section 6(c) of Executive Order 13132 states that “no agency shall promulgate any regulation that has federalism implications and that preempts State law, unless the agency, prior to the formal promulgation of the regulation, (1) consulted with State and local officials early in the process of developing the proposed regulation; (2) in a separately identified portion of the preamble to the regulation as it is to be issued in the *Federal Register*, provides to the Director of the Office of Management and Budget a federalism summary impact statement, which consists of a description of the extent of the agency’s prior consultation with State and local officials, a summary of the nature of their concerns and the agency’s position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met; and (3) makes available to the Director of the Office of Management and Budget any written communications submitted to the agency by State and local officials.”

Because this regulation addresses preemption of certain State laws, VA conducted prior consultation with State officials in compliance with Executive Order 13132. Such State officials include State Senators from Georgia and Illinois, State Representatives from Florida, Ohio, Vermont, North Carolina, Georgia, and Illinois, County Commissioners from Nevada, Ohio, and North Carolina, and the State Comptroller and Secretary of State from Illinois, to name a few. Although not

necessarily required by the Executive Order, VA sent a letter to the National Council of State Boards of Nursing to state VA’s intent to allow full practice authority to VA APRNs and for the National Council of State Boards of Nursing (NCSBN) to notify every State Board of Nursing of VA’s intent and to seek feedback from such Boards of Nursing. In response to its request for comments, VA received correspondence from the Executive Director and other relevant staff members within NCSBN, which agreed with VA’s position that this rulemaking properly identifies the areas in VA regulations that preempt State laws and regulations.

VA additionally engaged other relevant external groups on the proposed changes in this rulemaking, including the American Association of Nurse Anesthetists, American Association of Nurse Practitioners, American College of Surgeons, American Academy of Family Practice Physicians, American Society of Anesthesiologists, American Medical Association, Association of American Medical Colleges, The Joint Commission-Office of Accreditation and Certification, American Association of Retired Persons, American Legion, Blinded Veterans Association, Vietnam Veterans of America, American Women Veterans, Disabled American Veterans, Paralyzed Veterans of America, and Veterans of Foreign Wars. VA also engaged the Senate and House Veterans’ Affairs Committees and the Senate and House Armed Services Committees.

Many external stakeholders expressed general support for VA’s positions taken in the proposed rule, particularly with respect to full practice authority of APRNs in primary health care. However, we also received comments opposing full practice authority for CRNAs when providing anesthetics. To aid in VA’s full consideration to this issue, VA encouraged any comments regarding the proposed full practice authority. In this way, VA provided all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.

VA’s promulgation of this regulation complies with the requirements of Executive Order 13132 by (1) in the absence of explicit preemption in the authorizing statute, identifying where the exercise of State authority conflicts with the exercise of Federal authority under Federal statute; (2) limiting the preemption to only those areas where we find a conflict exists; (3) restricting the regulatory preemption to the minimum level necessary to achieve the objectives of the statute; (4) receiving and considering input from State and

local officials as indicated above; and (5) providing opportunity for comment through this rulemaking.

#### Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

#### Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

#### Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule directly affects only individuals and would not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

#### Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment,

public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined to be a significant regulatory action under Executive Order 12866 because it is likely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. VA's impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at <http://www.va.gov/orpm/>, by following the link for “VA Regulations Published From FY 2004 Through Fiscal Year to Date.”

#### Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule has no such effect on State, local, and tribal governments, or on the private sector.

#### Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are: 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA

Homeless Providers Grant and Per Diem Program.

#### Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert D. Snyder, Chief of Staff, Department of Veterans Affairs, approved this document on September 2, 2016, for publication.

#### List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Dated: December 8, 2016.

Jeffrey Martin,

Office Program Manager, Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set forth in the preamble, we amend 38 CFR part 17 as follows:

#### PART 17—MEDICAL

■ 1. The authority citation for part 17 is revised to read as follows:

**Authority:** 38 U.S.C. 501, and as noted in specific sections.

Section 17.415 is also issued under 38 U.S.C. 7301, 7304, 7402, and 7403.

■ 2. Add an undesignated center heading immediately after § 17.410 and add new § 17.415 to read as follows:

#### Nursing Services

##### § 17.415 Full practice authority for advanced practice registered nurses.

(a) *Advanced practice registered nurse (APRN)*. For purposes of this section, an advanced practice registered nurse (APRN) is an individual who:

(1) Has completed a nationally-accredited, graduate-level educational program that prepares them for one of the three APRN roles of Certified Nurse Practitioner (CNP), Clinical Nurse Specialist (CNS), or Certified Nurse-Midwife (CNM);

(2) Has passed a national certification examination that measures knowledge in one of the APRN roles described in paragraph (a)(1) of this section;

(3) Has obtained a license from a State licensing board in one of three recognized APRN roles described in paragraph (a)(1) of this section; and

(4) Maintains certification and licensure as required by paragraphs (a)(2) and (3) of this section.

(b) *Full practice authority.* For purposes of this section, full practice authority means the authority of an APRN to provide services described in paragraph (d) of this section without the clinical oversight of a physician, regardless of State or local law restrictions, when that APRN is working within the scope of their VA employment.

(c) *Granting of full practice authority.* VA may grant full practice authority to an APRN subject to the following:

(1) Verification that the APRN meets the requirements established in paragraph (a) of this section; and

(2) Determination that the APRN has demonstrated the knowledge and skills necessary to provide the services described in paragraph (d) of this section without the clinical oversight of a physician, and is thus qualified to be privileged for such scope of practice.

(d) *Services provided by an APRN with full practice authority.* (1) Subject to the limitations established in paragraph (d)(2) of this section, the full practice authority for each of the three APRN roles includes, but is not limited to, providing the following services:

(i) A CNP has full practice authority to:

(A) Take comprehensive histories, provide physical examinations and other health assessment and screening activities, diagnose, treat, and manage patients with acute and chronic illnesses and diseases;

(B) Order laboratory and imaging studies and integrate the results into clinical decision making;

(C) Prescribe medication and durable medical equipment;

(D) Make appropriate referrals for patients and families, and request consultations;

(E) Aid in health promotion, disease prevention, health education, and counseling as well as the diagnosis and management of acute and chronic diseases.

(ii) A CNS has full practice authority to provide diagnosis and treatment of health or illness states, disease management, health promotion, and prevention of illness and risk behaviors among individuals, families, groups,

and communities within their scope of practice.

(iii) A CNM has full practice authority to provide a range of primary health care services to women, including gynecologic care, family planning services, preconception care (care that women veterans receive before becoming pregnant, including reducing the risk of birth defects and other problems such as the treatment of diabetes and high blood pressure), prenatal and postpartum care, childbirth, and care of a newborn, and treating the partner of their female patients for sexually transmitted disease and reproductive health, if the partner is also enrolled in the VA healthcare system or is not required to enroll.

(2) The full practice authority of an APRN is subject to the limitations imposed by the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and that APRN's State licensure on the authority to prescribe, or administer controlled substances, as well as any other limitations on the provision of VA care set forth in applicable Federal law and policy.

(e) *Preemption of State and local law.* To achieve important Federal interests, including but not limited to the ability to provide the same comprehensive care to veterans in all States under 38 U.S.C. 7301, this section preempts conflicting State and local laws relating to the practice of APRNs when such APRNs are working within the scope of their VA employment. Any State or local law, or regulation pursuant to such law, is without any force or effect on, and State or local governments have no legal authority to enforce them in relation to, activities performed under this section or decisions made by VA under this section.

[FR Doc. 2016-29950 Filed 12-13-16; 8:45 am]

BILLING CODE 9320-01-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 81

[EPA-R06-OAR-2016-0275; FRL-9956-08-Region 6]

#### Determination of Nonattainment and Reclassification of the Houston-Galveston-Brazoria 2008 8-hour Ozone Nonattainment Area; Texas

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is determining that the Houston-Galveston-Brazoria, Texas 2008

8-hour ozone nonattainment area (HGB area) failed to attain the 2008 8-hour ozone national ambient air quality standard (NAAQS) by the applicable attainment deadline of July 20, 2016, and thus is classified by operation of law as "Moderate". In this action, EPA is also determining January 1, 2017 as the deadline by which Texas must submit to the EPA the State Implementation Plan (SIP) revisions that meet the Clean Air Act (CAA) statutory and regulatory requirements that apply to 2008 ozone NAAQS nonattainment areas reclassified as Moderate.

**DATES:** This rule is effective December 14, 2016.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA-R06-OAR-2016-0275. All documents in the docket are listed on the <http://www.regulations.gov> Web site. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202-2733.

**FOR FURTHER INFORMATION CONTACT:** Ms. Nevine Salem, (214) 665-7222, [salem.nevine@epa.gov](mailto:salem.nevine@epa.gov).

**SUPPLEMENTARY INFORMATION:** Throughout this document "we," "us," and "our" means the EPA.

### I. Background

The background for this action is discussed in detail in our September 27, 2016, (81 FR 66240) proposal. In that document, we proposed to determine that the HGB area failed to attain the 2008 ozone NAAQS by the applicable attainment deadline of July 20, 2016,<sup>1</sup> and to reclassify the area as Moderate. We also proposed that Texas must submit to us the SIP revisions to address the Moderate ozone nonattainment area requirements of the CAA section 182(b), as interpreted by 40 CFR part 51 Subpart AA, by January 1, 2017. We received comments on the proposal

<sup>1</sup> The attainment date of July 20, 2016, was established for the Houston-Galveston-Brazoria, TX 2008 ozone Marginal nonattainment area in EPA's final rule, *Determinations of Attainment by the Attainment Date, Extensions of the Attainment Date, and Reclassification of Several Areas for the 2008 Ozone National Ambient Air Quality Standards*, 81 FR 26697, May 4, 2016.



# COMMONWEALTH of VIRGINIA

David E. Brown, D.C.  
Director

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To: Committee of the Joint Boards of Nursing and Medicine  
Advisory Committee

From: Jay P. Douglas, Executive Director, Board of Nursing

Subject: Proposed 2018 Meeting Dates

Please mark your calendars for the following dates in **2018**:

Wednesday, February 7, 2018	9:00 AM	Board room 2
Wednesday, April 11, 2018	9:00 AM	Board room 2
Wednesday, June 13, 2018	9:00 AM	Board room 2
Wednesday, October 10, 2018	9:00 AM	Board room 2
Wednesday, December 5, 2018	9:00 AM	Board room 4

Please note business meetings will be scheduled from 9:00 AM to 12:00 P.M. Disciplinary proceedings will be scheduled following the meeting if there are cases to schedule.

cc: Charis Mitchell  
William Harp  
Elaine Yeatts  
Jim Banning  
Anne Joseph