July 22, 2016

David J. Shulkin, MD
Under Secretary for Health
Department of Veterans Affairs
810 Vermont Ave. NW, Room 1068
Washington, DC 20420

Re: RIN 2900–AP44-Advanced Practice Registered Nurses; Proposed Rule (May 25, 2016)

The undersigned physician organizations representing national specialty and state medical societies are writing to provide comments on the Veterans Health Administration's (VHA) Advanced Practice Registered Nurses (APRNs) Proposed Rule which, if finalized, would permit all VHA-employed APRNs to practice without the clinical supervision of physicians and without regard to state law.

Nurses are an integral part of physician-led health care teams that deliver high quality care to patients. They are often the first and last person to interact with a patient during an episode of care, and, in the case of APRNs, they are well equipped to play advanced roles in the health care team. However, APRNs are no substitute for physicians in diagnosing complex medical conditions, developing treatment plans that take into account patients' wishes and limited health care resources, and ensuring that the treatment plan is followed by all members of the health care team. Nowhere is this more important than in the VHA, which delivers highly complex medical care to disabled veterans, including those with traumatic brain injuries and other serious medical and mental health issues. Our nation's veterans deserve high quality health care that is overseen by physicians. For the reasons below, **the undersigned organizations strongly oppose the Proposed Rule and urge the VHA to consider policy alternatives that prioritize team-based care rather than independent nursing practice.**

Education and Training Matter

The key difference between medical and nursing education and training is the fact that medical students spend four years focusing on the entire human body and all of its systems—organ, endocrine, biomedical, and more—before undertaking three to seven years of residency training to further develop and refine their ability to safely evaluate, diagnose, treat, and manage a patient's full range of medical conditions and needs. And, by gradually allowing residents to practice those skills with greater independence, residency training prepares physicians for the independent practice of medicine. Combined, medical school and residency training total more than 10,000 hours of clinical education and training.

In contrast, a nurse generally must complete either a two- or three-year masters or doctoral degree program to become an APRN. While all baccalaureate nursing programs require a minimum 800 hours of patient care, advanced nursing degree programs have different patient care hour requirements with no common minimum standard. It has been estimated, for example, that nurse practitioners' training includes 500-720 patient care hours, and that nurse anesthetists complete approximately 2,500 hours of patient care. APRN education and training simply does not provide the same experience, and as such, independent practice is not appropriate.

The Proposed Rule Goes Against State Law and Trends

The VHA's proposal would undermine the 28 states that require nurse practitioners to collaborate with or be supervised by physicians. Currently only 22 states[1] and the District of Columbia allow nurse practitioners to practice completely independently, seven[2] of which allow nurse practitioners to practice independently only after the nurse practitioner has completed a certain amount of hours/years of clinical practice in collaboration with a physician. Another eight states[3] allow nurse practitioners to diagnose and treat independently, but require a collaborative agreement for purpose of prescribing. The remaining 20 states[4] require physician involvement for nurse practitioners to diagnose, treat, and prescribe. Even states that have granted independent practice in recent years have required transition periods that maintain the physician's oversight role for a certain amount of time.[5] Some states also created joint regulatory bodies (composed of members of the boards of medicine and nursing) that advise nursing boards on such issues as formularies and collaborative practice agreements or review nurse practitioner applications for independent practice. Taken together, these laws are a further indication that the Proposed Rule is misguided and out of step with state law and trends.

The Proposed Rule is also in conflict with the 21 states[6] that require nurse midwives to collaborate with or practice under the supervision of a physician, and six states[7] that require collaborative practice for purposes of a nurse midwife's prescriptive authority. Finally, the Proposed Rule is significantly out of step with 45 states and the District of Columbia, which require nurse anesthetists to practice with or be supervised by physicians.[8]

The Proposed Rule's Preemption Language Does not Accord with Federalism Policy

The Proposed Rule asserts that state or local laws relating to the practice of APRNs in the context of VHA employment are "without any force or effect," and that state and local governments "have no legal authority to enforce them." While the undersigned understand the Supremacy Clause justification cited in the preamble, the VHA's proposed regulatory preemption language is startlingly aggressive in light of both federal policy and the lack of underlying statutory preemption language in 38 U.S.C. 7301.

President Obama's preemption memorandum of May 20, 2009 specifically noted with approval that "state and local governments have frequently protected *health* [and] *safety* more aggressively than has the national government." The President's memorandum, therefore, announced that "preemption of state law

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[1] AK, AZ, CO, CT, HI, IA, ID, MD, ME, MN, MT, ND, NE, NH, NM, NV, OR, RI, VT, WA, WV, WY.
[2] CT, MD, MN, NE, ME, VT, WV.
[3] AR, KY, MA, NJ, OK, TX, UT.
[4] AL, CA, DE, FL, GA, IL, IN, KS, LA, MO, MS, NC, NY, OH, PA, SC, SD, TN, VA, WI.
[5] See CT Governor's Bill 36 (Session Year 2014); MD House Bill 999 (2015 Regular Session); MI Senate File 511 (88th Session); NB Legislative Bill 107 (2015-2016 Session); NV Assembly Bill 170 (77th Session); NY Assembly Bill 4846 (2013-2014 Regular Session); and WV House Bill 4334 (2016 Regular Session).
[6] AL, AR, CA, FL, GA, IL, IN, KS, LA, MD, MS, MO, NE, NM, NC, OH, PA, SC, SD, VA, WI.
[7] DE, KY, MI, OK, TN, TX, WV.
[8] Only ID, MT, NH, OH, and UT allow CRNAs to practice independently. While 18 states have "opted out" of the federal requirement that physicians supervise anesthesia care for purposes of Medicare repayment, opting out of this requirement does not supersede state scope of practice laws.

by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the states and with sufficient legal basis for preemption."[9]

Moreover, Executive Order 13132 of August 4, 1999 requires that "any regulatory preemption of state law shall be restricted to the *minimum level necessary* to achieve the objectives of the statute pursuant to which the regulations are promulgated."[10] We do not support the VHA's assertion in the preamble of the Proposed Rule that it complied with this requirement. Executive Order 13132 requires the VHA to "consult with state and local officials early in the process of developing the proposed regulation." While the VHA solicited input from state boards of nursing, there is no mention of any outreach to the state boards of medicine. We urge the VHA to consult with state boards of medicine and other physician stakeholders that do not support the Proposed Rule for legitimate patient safety reasons before adopting a policy that would subvert states' rights.

Comparison to DoD policy

The VHA tries to make the case that the Proposed Rule is neither "novel [n]or unexpected" by referring to other agencies, such as the Military Health Service, that "employ APRNs in independent practice without oversight from physicians." However, the VHA does not cite specific policies to support this claim and the Proposed Rule, which would permit all APRNs to practice "*without the clinical supervision or mandatory collaboration of physicians,*" is significantly and qualitatively different from employment policies that allow some APRNs to practice independently.

For example, the Air Force Medical Service (AFMS) states that privileged CRNAs "may act independently in areas of demonstrated competency within their designated scope of practice." However, the AFMS also explicitly states that (1) "CRNAs *will consult* with an anesthesiologist or any other medical specialty for patients who require such medical consultation based on acuity of the health condition or complexity of the surgical procedure;" (2) "a *collaborative relationship* is a key component for safe, quality healthcare;" (3) "CRNAs granted MTF [military treatment facility] privileges *must have physician consultation* (privileged to the same scope of practice) available either in person or by phone when they are performing direct patient care activities;" and (4) all privileged APRNs "*must have a physician supervisor available for consultation and collaboration*." Nowhere does the AFMS use language antithetical to team-based care like that employed in the Proposed Rule (e.g., "without the clinical supervision or mandatory collaboration of physicians"). In fact, the AFMS expressly requires the opportunity and availability for physician collaboration.[11]

The VA Under Secretary for Health was correct when he stated that "part of what any good health care professional does is know when it is time to seek help from more experienced professionals."[12] However, these best practices need to be built into policies and structures so that the framework for support is available when health care professionals need it. In its current iteration, the Proposed Rule stands in stark contrast to the team-based model by explicitly eschewing supervision and collaboration.

[9] 74 Fed. Reg. 24693-24694 (May 22, 2009).
[10] 64 Fed. Reg. 43255-43259 (August 10, 1999).
[11] Air Force Instruction 44-119, Medical Quality Operations (August 16, 2011).
[12] Lisa Rein, Top VA doc: if there aren't enough doctors, have nurses treat our vets, The Washington Post (June 2, 2016).

Existing data does not support the VHA's proposal

In September 2014, the VA published an evidence brief entitled, "The Quality of Care Provided by Advanced Practice Nurses."[13] The authors of this evidence synthesis found "scarce long-term evidence to justify" the position that "a large body of evidence shows that APRNs working independently provide the same quality of care as medical doctors."[14] The authors conclude that "strong conclusions or policy changes relating to the extension of autonomous APRN practice cannot be based solely on the evidence reviewed [in the brief.]" While the VHA cites this brief in supporting documents for the Proposed Rule, the evidence brief's conclusions do not support the VHA's proposal.

The VHA brief finds that APRNs deliver high quality care with a focus on protocol-driven care, thereby ensuring that physicians on the team can focus on more complex patients which uniquely require their expertise. However, it does not follow that APRNs should practice independently. The authors acknowledge as such, noting that studies that "do not explicitly define that autonomy of the nurses, compare non-autonomous nurses with physicians, or evaluate nurse-direct protocol-driven care for patients with specific conditions" are often used to support claims regarding the care independent APRNs provide compared to physicians.[15]

The evidence brief also found insufficient evidence to draw conclusions on APRN effect on quality of life and hospitalizations. The authors concluded that insufficient evidence exists to support "strong conclusions or policy changes relating to extension of autonomous APRN practice."[16]

Patients want and expect physician-led health care teams

Research shows patients value and rely upon the additional education and training that physicians receive and they want a physician in the decision-making process.[17] Patients understand the benefits of team-based care delivery which is why, according to a 2012 survey, patients overwhelmingly want a physician leading the health care team. Key findings include:

- 91 percent of respondents said that a physician's years of education and training are vital to optimal patient care, especially in the event of a complication or medical emergency.
- 86 percent of respondents said that patients with one or more chronic conditions benefit when a physician leads the primary health care team.
- 4 out of 5 patients prefer a physician to have primary responsibility for leading and coordinating their health care.
- 78 percent of respondents agreed that nurse practitioners should not be allowed to run their own medical practices without physician involvement.

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[13] McCleery E, Christensen V, Peterson K, Humphrey L, Helfand M. Evidence Brief: The Quality of Care Provided by Advanced Practice Nurses. VA-ESP Project #09-199; 2014.
[14] *Id*. at 1.
[15] *Id*. The authors also found insufficient information on whether the quality of care provided by APRNs varies by the practice setting or degree of autonomy.
[16] *Id*. at 19.
[17] Cite AMA PLT study.

- 79 percent of respondents agreed that nurse practitioners should not be able to practice independently of physicians, without physician supervision, collaboration, or oversight.

Enabling APRNs to practice independently dismisses clear patient preference for the physician-led model of care delivery and the undersigned reiterate their strong opposition to the VHA Proposed Rule. If the VHA moves forward with this proposal despite our opposition, VA beneficiaries and their surrogates should have all the information necessary to make informed health care decisions consistent with the current Administration's focus on transparency. This includes advance, clear, and conspicuous notification of whether the beneficiary will be seen by a doctor of medicine or osteopathy or by a non-physician provider. The right to opt out of the health care appointment and to reschedule with the preferred type of provider is critical to engaging patients in their health care choices and to providing veterans with the benefits they have so deservedly earned.

Conclusion

The undersigned believe that policymakers serve patients best by supporting team-based care that makes the most of the respective education and training of physicians and APRNs as part of a collaborative framework. Patients deserve to have a physician on their team, whether that is for the treatment and management of chronic conditions, or for surgery. Nowhere is this more important than in the VHA, which delivers highly complex medical care to our nation's veterans. To that end, **the undersigned urge the VHA to preserve the highest quality of care and protect the safety of our nation's veterans and not move forward with the proposed rule**.

Sincerely,

American Medical Association
Academy of Physicians in Clinical Research
Advocacy Council of the American College of Allergy, Asthma and Immunology
American Academy of Allergy, Asthma and Immunology
American Academy of Child and Adolescent Psychiatry
American Academy of Dermatology Association
American Academy of Family Physicians
American Academy of Ophthalmology
American Academy of Otolaryngic Allergy
American Academy of Otolaryngology—Head and Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Association for Geriatric Psychiatry
American Association of Clinical Endocrinologists
American Association of Clinical Urologists
American Association of Hip and Knee Surgeons
American Association of Neurological Surgeons
American Association of Neuromuscular & Electrodiagnostic Medicine
American Association of Orthopaedic Surgeons
American Association of Physicians of Indian Origin
American College of Allergy, Asthma & Immunology

American College of Emergency Physicians
American College of Mohs Surgery
American College of Occupational and Environmental Medicine
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Radiation Oncology
American College of Radiology
American College of Surgeons
American Orthopaedic Foot & Ankle Society
American Osteopathic Association
American Psychiatric Association
American Rhinologic Society
American Society for Clinical Pathology
American Society for Dermatologic Surgery Association
American Society for Gastrointestinal Endoscopy
American Society for Surgery of the Hand
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery
American Society of Dermatopathology
American Society of Echocardiography
American Society of Neuroradiology
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
American Academy of Ophthalmology
College of American Pathologists
Congress of Neurological Surgeons
Infectious Diseases Society of America
National Association of Medical Examiners
National Association of Spine Specialists
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society of Interventional Radiology
Spine Intervention Society

Medical Association of the State of Alabama
Alaska State Medical Association
Arizona Medical Association
Arkansas Medical Society
California Medical Association
Colorado Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia

Florida Medical Association Inc
Medical Association of Georgia
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Louisiana State Medical Society
Maine Medical Association
MedChi, The Maryland State Medical Society
Massachusetts Medical Society
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
Nevada State Medical Association
Medical Society of New Jersey
New Mexico Medical Society
Medical Society of the State of New York
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oklahoma State Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Carolina Medical Association
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Association
Vermont Medical Society
Medical Society of Virginia
Washington State Medical Association
West Virginia State Medical Association
Wisconsin Medical Society
Wyoming Medical Society