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July 7, 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."

The American College of Radiology (ACR) appreciates the opportunity to comment on the proposed Department of Veterans Affairs (VA) rule to expand the role of Advanced Practice Registered Nurses (APRNs). While we support the VA's efforts to address the challenges that exist within its health system, we are deeply concerned that the proposal to allow advanced practice nurses to practice independently of a physician's clinical oversight could seriously jeopardize the quality of care our veterans receive. We therefore oppose the adoption of this proposed rule.

Notwithstanding our general concerns that the proposal would undercut the physician-led, team-based models of care that best ensure efficient, safe, high quality patient care, our comments focus primarily on Section 17.415(d)(1)(i)(B) which would give Certified Nurse Practitioners (CNPs) full practice authority to: "Order, **perform, supervise, and interpret ... imaging studies.**" We understand that other nursing and medical specialties had advance notice of the proposed rulemaking. Indeed, the Supplementary Information accompanying the proposed rule even lists "external stakeholders" who were consulted in the development of the proposed rule. However, this list did not include any stakeholders representing the practice of medical imaging. The resultant proposed rule reflects that lack of input by medical imaging professionals, is misleading as it applies to medical imaging, and ignores critical factors that would advise against the adoption of Section 17.415(d)(1)(i)(B).

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CNPs do not have the specialized education, experience or skills required to order, interpret, supervise or perform imaging studies

Without question, nurses are an essential part of physician-led health care teams. Their education, training, and experience equip them to play an integral role in patient care, but it does not substitute for intensive and specialized training that radiologists receive. Including medical school, the vast majority of physician radiologists undergo 10 years of comprehensive training beyond their undergraduate degree. The four year medical school requirement is foundational to the practice of medicine in that it entails a comprehensive understanding of the human body, its systems, functions and disease processes. While in medical school, radiologists learn anatomy, physiology, pathology, pharmacology, and pathophysiology as is required of all graduating physicians. Medical school is followed by a one year clinical internship, and a four year residency program interpreting tens of thousands of imaging studies under the supervision of a practicing radiologist. Radiology residents typically spend at least four weeks (130 lecture hours) in an intensive Radiologic Pathology Correlation Course entailing a comprehensive review of all imaging modalities, the radiologic presentation of a broad range of diseases and pathologic basis from all organ systems, with emphasis on the principles of radiologic-pathologic correlation. Most radiologists elect to continue their training with a one- or two- year post-residency fellowship program in a radiology subspecialty to hone their diagnostic skills in a radiology subspecialty.

Near the end of residency and again after beginning practice, radiology residents must pass multiple sets of board-certifying examinations. An image-rich Core Examination offered after 36 months of residency training “tests knowledge and comprehension of anatomy, pathophysiology, all aspects of diagnostic radiology, and physics concepts important for diagnostic radiology.” The exam covers eighteen subspecialty and modality categories including: breast, cardiac, gastrointestinal, interventional, musculoskeletal, neuroradiology, nuclear, pediatric, reproductive/endocrinology, thoracic, urinary, vascular, computed tomography, magnetic resonance, radiography/fluoroscopy, ultrasound, physics, and safety. In addition, a portion of the Radioisotope Safety Exam (RISE), one of the requirements for Authorized User (AU) eligibility status, is included within the Core Exam. Physics questions are integrated into each category. Passing scores must be received in each category and overall in order to receive a passing result. Further, a 'maintenance of certification' process requires radiologists to commit to continuing medical education, practice quality improvement, and maintenance of certification exams to ensure continued proficiency and expertise in the rapidly-advancing field of medical imaging.

By contrast, training to become an APRN generally consists of a two- or three-year postgraduate masters or doctoral degree program. Irrespective of any additional imaging-specific training an APRN may receive, APRN education and training cannot provide the same foundational learning experience of medical school and specialized radiology residency and fellowship training. To be clear, the thorough training radiologists receive is not excessive; it is essential in equipping them to oversee/supervise and interpret imaging procedures, accurately diagnose patients, and minimize unnecessary tests. The extent to which referring physicians both outside and within the VA utilize the expertise of radiologists gives evidence to the value of radiologists' subspecialty training even with respect to other physicians. The ACR finds your proposal alarming that a VA APRN would be deemed competent to interpret images that ordering physicians in the VA commonly refer to radiology specialists. Simply put: proper interpretation of imaging exams by highly trained radiologist physicians is critical to the accurate diagnosis and treatment of disease and injury.

In addition to the requisite expertise of radiologists, registered radiologic technologists are similarly critical to the safety and quality of medical imaging. Under the supervision and in collaboration with radiologists, radiologic technologists operate imaging equipment to acquire images e.g., they “perform” medical imaging. The training and certification of Registered Radiological Technologists (many with modality specific certification such as CT and MRI) and Diagnostic Medical Sonographers (also often with subspecialty certification) is highly specialized and extensive. They have expertise in anatomic positioning, equipment protocols, and optimizing image acquisition to maximize image quality while minimizing radiation exposure. In contrast, CNP educational curricula is not tailored to the responsibilities of a radiologic technologist and cannot adequately equip them to perform highly technical procedures like conventional radiography, fluoroscopy, computed tomography, magnetic resonance imaging, nuclear medicine, vascular-interventional or bone densitometry. Utilizing insufficiently trained CNPs to perform imaging exams would endanger veterans both from the standpoint of radiation safety as well as the likelihood that poorly performed exams could lead to misdiagnosis or repeat exam necessity. (Additionally, given that CNP salaries are generally higher than RT salaries, it seems to ‘fly in the face’ of cost-effectiveness to utilize CNPs to perform RT job responsibilities.)

Moreover, lacking the competence to either perform or interpret imaging exams, APRNs should not be allowed to supervise diagnostic imaging. In order to ensure quality in diagnostic imaging, it is essential that the supervising professional be able to assess the quality of an image relative to the capability of the equipment and diagnostic demands, ensure diagnostic quality, and minimize unnecessary radiation exposure to the patient and personnel. In short, the safe and appropriate use of imaging (particularly given that many imaging tests require radiation safety expertise) are most appropriately conducted utilizing a physician-led team approach where expertly trained radiologists oversee radiological technologists (who are trained in radiation safety and image/acquisition techniques), along with other appropriately qualified clinicians.

Finally, research demonstrates that APRN’s, when seeing a diverse population of patients with a broad range of ailments will order diagnostic imaging approximately 30% more often than a physician. The ordering and performance of unnecessary imaging can expose patients to unnecessary radiation, delayed or missed diagnoses, and pointless follow-tests, while driving up the cost of their health care. Though we believe that this could be dramatically improved with the support of “Appropriate Use Criteria” provided through clinical decision support (CDS) as will soon be required for all ordering of advanced diagnostic imaging studies (ADIS) in the Medicare population, the oversight of a team leading physician in the assessment of need for and selection of appropriate studies with radiologist consultation available is still optimal care.

Using CNPs to order, interpret, supervise or perform imaging studies will jeopardize quality of care and thwart the goal of the rulemaking to decrease wait times in the VA healthcare system

Notwithstanding the purported goal of the rulemaking to decrease wait times in the VA healthcare system, ACR believes the proposed rule, if finalized, would actually exacerbate wait time problems. As noted above, patients who utilize advance practice registered nurses for their care are 30% more likely to have an imaging test ordered than if they were seen by a physician. In addition to causing delays in diagnosis and excessive radiation exposure for the patient, the ordering of unnecessary imaging can impede the availability of expensive diagnostic imaging equipment for patients who need it as well as the time of the personnel performing and interpreting unnecessary studies.

Moreover, misdiagnosis and missed diagnosis related to interpretation by less-qualified CNP's can lead to additional follow-up testing. If a problem that should have been picked up in an imaging exam is not diagnosed, the patient is likely to be subject to additional tests (imaging and non-imaging) that may not have been required otherwise. This in turn further taxes the VA healthcare system, increases waiting times, and results in additional cost associated with unnecessary exams.

VA should thoughtfully consider federal Radiation Protection Guidance for Diagnostic and Interventional Procedures (Federal Guidance Report No. 14)

Authority to provide radiation protection guidance to federal agencies was transferred to EPA in 1970. Under this authority, Federal Guidance Report No. 14 was developed to provide federal facilities that use diagnostic and interventional x-ray equipment with recommendations for keeping radiation doses to patients as low as reasonably achievable without compromising the quality of patient care. Although not binding on any federal agency or facility, the guidance was developed by an interagency working group on medical radiation made up of medical and radiation safety professionals from the EPA, Department of Veterans Affairs, Department of Defense, Department of Health and Human Services, the Occupational Safety and Health Administration. The guidance represents "best practices" for improving the safety of diagnostic and interventional imaging. As outlined in the guidance, "The goals of radiation dose management are to optimize radiation protection for patients, consistent with image quality requirements, and to keep worker radiation doses as low as reasonably achievable (ALARA)."

The 145 page guidance highlights the importance of using appropriately qualified and credentialed radiologic technologists and radiological medical practitioners, and referring practitioners who are knowledgeable in the appropriate ordering of radiologic imaging procedures and collaborate with radiologic medical practitioners.

Among its recommendations:

- "that a radiologist provide general supervision in facilities performing radiography."¹
- "that agencies ensure that the justification of medical exposure for an individual patient be carried out by the Referring Medical Practitioner in consultation with the Radiologic Medical Practitioner, when appropriate."²
- "Radiographic equipment should be operated under the general supervision of a physician."³
- "CT systems should only be operated by Radiologic Technologists registered by the ARRT or equivalent, preferably with advanced certification in CT, operating under the supervision of Radiological Medical Practitioners with appropriate training in CT Physics, radiation safety, and CT image interpretation."⁴

¹ Federal Guidance Report No. 14: Radiation Protection Guidance for Diagnostic and Interventional x-ray procedures (EPA-402-R-10003, November 2014, page 41.

² Id. At vii.

³ Id. At 40.

⁴ Id. At 61.

- “Performance of imaging examinations by incompletely trained personnel is not justified except for emergent or life-threatening circumstances, such as natural disasters.”⁵

The FRN overstates CNP’s authority related to medical imaging notwithstanding current state scope of practice laws

Twenty-two states⁶ and the District of Columbia allow nurse practitioners to practice completely independently; however, within the 22 states and DC, additional restrictions on practice exist within radiation protection statutes and regulations. More specifically, of the 22 states with independent practice for APRNs, eighteen⁷ states require radiographer licensure for operators of x-ray equipment. Examined in more detail, the radiation protection statutes and regulations also place restrictions on authorizing (ordering) of human exposure to radiation for medical purposes. In CO, CT, MD, RI, and WV where APRNs are granted independent practice privileges in scope of practice laws, a licensed practitioner/physician’s order is required for imaging procedures but nurse practitioners do not meet the definition of licensed practitioner or physician. And of the 22 states with independent practice, in CO, CT, MN, ND and NE an APRN does NOT have supervision privileges over ancillary personnel operating fluoroscopic equipment.

Currently 40⁸ states have standards for operators of ionizing radiation equipment (such as fluoroscopic machines), meaning an APRN cannot operate ionizing radiation emitting equipment unless they are also certified as a radiographer or unless they obtain a limited x-ray operator license offered in 33⁹ states. States without radiography standards in place¹⁰ require operators to be trained prior to operation of fluoroscopic equipment.

Extending APRN practice authority in the VA to encompass imaging is not consistent with the role of APRNs in the non-VA health care sector and contravenes VHA’s obligation to meet or exceed generally-accepted professional standards

The summary of the proposed rule contends, “[t]his rule would permit 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.” It further acknowledges that 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. However, notwithstanding state scope of practice laws, CNPs are not traditionally performing, supervising or interpreting imaging studies in the private sector. In addition to state scope of practice laws, medical practitioner practice can be limited by a number of other factors such as facility credentialing and privileging, the CNP’s desire to perform a particular service, the CNP’s belief in his/her own competence to perform the service, availability and cost of malpractice insurance, and a patient’s willingness to utilize a CNP for medical care, to name just a few. The truth is: CNP’s are not commonly performing, supervising, or interpreting imaging studies on a broad scale in the non-VA health care sector; as such, it is not clear

⁵ Id. At 24.

⁶ AK, AZ, CO, CT, HI, IA, ID, MD, ME, MN, MT, ND, NE, NH, NM, NV, OR, RI, VT, WA, WV, WY.

⁷ AZ, CO, CT, HI, IA, MD, ME, MN, MT, ND, NE, NM, OR, RI, VT, WA, WV, WY.

⁸ AZ, AR, CA, CO, CT, DE, FL, GA, HI, IL, IN, IA, KS, KY, LA, ME, MD, MA, MN, MS, MT, NE, NJ, NM, NY, ND, OH, OR, PA, RI, SC, TN, TX, UT, VT, VA, WA, WV, WI, WY.

⁹ AZ, AR, CA, CO, DE, FL, GA, IL, IN, IA, KY, ME, MA, MN, MS, MT, NE, NJ, NM, ND, OH, OR, PA, SC, TN, TX, UT, VT, VA, WA, WV, WI, WY.

¹⁰ AL, AK, ID, MI, MO, NV, NH, NC, OK, SD, DC.

that VA using them in such a capacity would “meet or exceed generally accepted professional standards.” Even to the extent CNPs are performing, supervising or interpreting imaging studies in the private sector, patients in the private sector have the option of selecting their own health care providers and can decide whether to seek care from a CNP or a physician.

Conclusion

Veterans, and all Americans, deserve ready access to high-quality physician-led, patient-centered care, particularly in regard to medical imaging. Accurate diagnosis and treatment of disease and injury commonly depends on proper interpretation of imaging exams by highly trained radiologist physicians. The safe and appropriate performance of imaging scans, many of which involve radiation, is also dependent on expert radiological technologists with oversight of uniquely trained radiologists. We therefore urge VHA to maintain the highest quality of care and safety our nation’s veterans deserve by not finalizing the proposed rule.

Sincerely,

A handwritten signature in cursive script that reads "James Brink". The signature is written in black ink and is positioned above the printed name.

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