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Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Feedback on Scope of Practice of Physician Assistant's and Advanced Practice Registered Nurses

The American College of Radiology (ACR), representing more than 39,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) on Scope of Practice based on the President's Executive Order (EO) #13890 on Protecting and Improving Medicare for Our Nation's Seniors.

The ACR previously submitted comments on CMS's proposals related to scope of practice, supervision requirements, and licensure requirements within the calendar year (CY) 2020 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule and the CY 2020 Medicare Physician Fee Schedule (MPFS) proposed rule. The ACR continues to believe that physician assistants (PAs), and other non-physician practitioners (NPPs) are valuable members of physician-led health teams. However, the ACR has concerns that loosening the national physician supervision requirements for NPPs will lead to reductions of patient safety and quality of care for Medicare beneficiaries who receive radiology services. Below, we outline our concerns surrounding implemented policies put forth by CMS and possible implications of further loosening scope of practice for NPP's.

CMS finalized its proposal from the CY 2020 HOPPS proposed rule that changed the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and critical access hospitals (CAHs). CMS finalized these policies in the CY 2020 HOPPS final rule that was published on November 12, 2019.

CMS included a similar proposal within the CY 2020 MPFS proposed rule to revise the regulation that establishes physician supervision requirements for PAs. CMS finalized this proposal in the CY 2020 MPFS final rule published on November 15, 2019. This policy changed where statutory physician supervision requirements for PA services would be met when a PA provides their services in accordance with state law and the state scope of practice rules for the PAs in the state in which the services are provided. Physicians would provide medical direction and appropriate supervision as directed by state law in which the services are performed. In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to working with physicians in providing their services. Under the general supervision requirement, PA services must be provided under a physician's overall direction. However, the physician does not have to be on site when the service is being provided.

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These two new policies take major steps that move patient care away from a physician-led team and more towards allowing PAs and advanced practice registered nurses (APRNs) to work in independent practice. For radiological care, this could be very detrimental to patients. Three major principles apply to NPPs, which includes registered radiologist assistants (RRA) working in radiology practices. All NPPs should work under the direct supervision of a radiologist. Finally, no NPP should ever be allowed to interpret images and none are meant to be trained to work in independent practice. Loosening CMS' national policies on the supervision of NPPs and more broadly deferring to state law and scope of practice could detract from quality patient care. For example, at the state level there are many laws that allow for APRNs to perform and interpret X-rays under general supervision. From a medical training and malpractice perspective, this is a dangerous path to take regarding quality patient care and patient safety.

Educational Differences

The ACR recognizes that APRNs, PAs, and other non-physician providers play a vital role in providing care to patients. However, these NPPs are not interchangeable with radiologists or other physicians. Physicians are highly educated and must complete between 10,000 and 16,000 hours of clinical education. In comparison, most APRNs are only required to complete between 500 and 720 hours of clinical training. Physician Assistants are required to complete 2,000 hours of clinical training after a two year graduate level program. Both APRNs' and PAs' education and clinical training pale in comparison to the rigors of a fully trained physician.

Including medical school, the vast majority of physician radiologists undergo 10 years of comprehensive training beyond their undergraduate degree. 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 residency includes extensive training and hundreds of lecture hours in an intensive Radiologic Pathology Correlation Course including 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.

By contrast, training to become a PA generally consists of a two- or three-year postgraduate masters or doctoral degree program. PA education and training cannot provide the same foundational learning experience of medical school. The thorough training physicians receive is essential for equipping them to oversee/supervise patient care, and in the case of radiologists, selecting the most appropriate radiology examination for the patient, interpreting and performing radiology procedures, accurately diagnosing patients, and minimizing unnecessary tests. 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, RRAs and registered radiologic technologists are similarly critical to the safety and quality of radiology. Under the supervision, and in collaboration with radiologists, RRAs and radiologic technologists operate imaging equipment to acquire images (e.g., they "perform" diagnostic radiology procedures under radiologist supervision). The training and certification of RRAs and 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.

PA's and APRNs' educational curricula are not tailored to the responsibilities of a radiologic technologist and cannot adequately equip them to perform and interpret highly technical procedures like conventional radiography, fluoroscopy, computed tomography, magnetic resonance imaging, nuclear medicine, vascular-interventional or bone densitometry. APRN's also include those who have completed a doctorate level program, a Doctor of Nursing Practice (DNP). Roughly, 85% of 533 DNP programs have a nonclinical focus.[1] Nonclinical programs offer administrative or leadership focus, not on patient care. Furthermore, there is a lack of certification of clinical knowledge as the primary certification exam has only been completed by 100 DNPs. With this discrepancy in education and lack of testing of medical knowledge, it is impossible to guarantee a DNP's medical knowledge. Utilizing lesser trained NPPs to perform imaging exams would endanger Medicare beneficiaries especially from the standpoint of radiation safety. For instance, the performance of imaging exams by lesser-trained NPP's could increase the likelihood that poorly performed exams by resulting in patients undergoing costly additional radiology tests and procedures or, possibly, misdiagnosis.

Patient Safety, Diagnostic Imaging, and the Interpretation of Images

CMS should prioritize patient safety. To ensure that, APRNs and PAs should continue to work alongside physicians under physician-led teams. Within the specialty of radiology, it should be a radiologist-led team.

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. NPP's have been found to order more imaging services as compared to primary care physicians (PCPs) during E&M office visits.[2] The safe and appropriate use of imaging is most appropriately conducted utilizing a physician-led team approach where expertly trained radiologists oversee RRAs and radiological technologists (who are trained in radiation safety and image/acquisition techniques), along with other appropriately qualified clinicians.

Malpractice Implications

Proper interpretation of imaging exams should be conducted by highly trained radiologists to ensure accurate diagnosis and treatment of disease and injury. If CMS defers to state laws and scope of practice for APRN's and PAs, they very well may be allowed to practice independently, allowing them to perform, supervise and interpret images for Medicare patients. APRNs and PAs would, under independent practice scenarios, need to assume primary responsibility for such care, particularly potential medical malpractice liability. Additionally, APRNs and PAs would fail to meet state laws that require a physician receive informed consent

[1] Mundinger, M.O. Carter, M.A. (2019). Potential Crisis in Nurse Practitioner Preparation in the United States. *Policy, Politics, and Nursing Practice, 20*(2), 57-63

[2] Hughes, D. Jiang, M. Duszak, R. (2015). A Comparison of Diagnostic Imaging Ordering Patterns Between Advanced Practice Clinicians and Primary Care Physicians Following Office-Based Evaluation and Management Visits. *JAMA Internal Medicine, 175*(1), 101-107

from patients regarding their health care services. Medicare patients deserve better care than allowing NPPs to serve as the primary providers of their imaging services. Insufficient attention to radiation dose and proper imaging diagnosis not only lowers the quality of care offered to Medicare patients but puts them in jeopardy of misdiagnosis of their imaging studies by an unqualified APRNs or PA. This may result in increased cost to the Medicare program because it might require treatment of more advanced disease due to lack of early detection or misdiagnosis. The ACR made these critical points in 2016 to the Veterans Administration, which agreed in its rulemaking that radiology interpretations and radiation dose should be the responsibility of radiologists and not APRNs.

Conclusion

To ensure safety and quality standards, NPPs should practice under direct supervision of a physician. NPPs offer value in providing quality patient care. However, 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 RRAs and radiological technologists with oversight by uniquely and highly trained radiologists. CMS should not compromise quality patient care and safety by deferring solely to state law and scope of practices which vary widely from state-to-state.

We hope these comments provide valuable input for your consideration. If you have any questions, please contact Christina Berry at cberry@acr.org**.**

Respectfully Submitted,

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