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Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-5531-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically: <http://www.regulations.gov>

Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program

Dear Administrator Verma:

The American College of Radiology (ACR), representing nearly 40,000 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 the Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program Interim Final Rule (IFC). The College appreciates the added flexibilities during this unprecedented time which allow our members to care for patients in the most safe and efficient manner possible. We note in comments below, thoughts and concerns about extending some of these flexibilities beyond the duration of the public health emergency (PHE).

Scope of Practice

Supervision of Diagnostic Tests by Certain Nonphysician Practitioners

Interim Final Rule Policy

In December 2019, CMS issued a request for feedback in response to part of the President's Executive Order (EO) 13890 on "Protecting and Improving Medicare for Our Nation's Seniors," seeking stakeholders guidance in identifying additional Medicare regulations which contain more restrictive supervision requirements than existing state scope of practice laws, or which limit health professionals from practicing at the top of their license. In response to the request for feedback, physician assistants (PAs) and nurse practitioners (NPs) recommended regulatory changes that would allow them to supervise diagnostic tests because they are currently authorized to do so under State scope of practice rules. CMS received feedback



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from the radiology community that did not support making any changes to CMS regulations that would result in any inappropriate expansion of the role of non-physician practitioners (NPPs). Currently under CMS policy, only physicians are generally permitted to supervise diagnostic tests.

CMS is amending the regulation to specify in the basic rule that diagnostic tests must be furnished under the appropriate level of supervision by a physician during the PHE, by a NP, CNS, PA, and CNM. Also, CMS is amending regulation to allow diagnostic tests to be performed by a PA without physician supervision when authorized to perform the tests under applicable state law. Similarly, CMS is amending regulation regarding the levels of supervision, to also authorize NPs, CNSs, PAs, and CNMs during the PHE to provide the appropriate level of supervision assigned to diagnostic tests.

CMS is seeking public feedback indicating the number of states with more flexible scope of practice rules than federal regulations to help CMS understand the scope of impact of these changes.

ACR Perspective and Comments

ACR does not support the relaxation of supervision regulation to allow NP, CNS, PA, and CNMs supervise diagnostic tests. To prevent the spread of COVID-19 and provide the highest quality patient care, radiographic interpretations can be provided following appropriate social distancing measures via teleradiology. Allowing PA's and advanced practice registered nurses (APRNs) supervise diagnostics test would present unnecessary risks for patients and beneficiaries. These new policies would take major steps that move patient care away from a physician-led team and more towards allowing PAs and APRNS to work in independent practice. For radiological care, this could be very detrimental to patients. All NPPs should work under the direct supervision of a radiologist. Lastly, 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. Currently, at the state level there are many laws that allow for APRN's 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.

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 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 evaluation

¹ Munding, 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

and management (E/M) office visits.² With the marked reduction in elective outpatient procedures, and the slow reopening, there is an excess capacity for physician interpretation obviating need for NPP to provide such procedures.

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 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.

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 ACR does not support the relaxation of regulation to specify in the basic rule that diagnostic tests must be furnished under the appropriate level of supervision by a physician during the PHE, by a NP, CNS, PA, and CNM. ACR does not agree with CMS amending regulation to allow diagnostic tests to be performed by a PA without physician supervision when authorized to perform the tests under applicable state law.* The relaxation of these policies would result in reduced patient safety and quality care. *The ACR urges CMS to return to previous policy of physicians only being generally permitted to supervise diagnostic tests.*

Update to the Hospital Value-Based Purchasing (VBP) Program Extraordinary Circumstance Exception (ECE) Policy

Interim Final Rule Policy

CMS is modifying the Hospital VBP Program's ECE policy to allow CMS to grant ECE exceptions to hospitals which have not requested them when CMS determines that an extraordinary circumstance that is out of the hospitals control, such as an act of nature or PHE, which affects an entire region, in addition to

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



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retaining the individual ECE request policy. CMS is granting exceptions under their updated policy to all hospitals participating in the Hospital VBP Program with respect to certain 4th quarter 2019 measure data that hospitals would otherwise be required to report in April or May of 2020, and measure data that hospitals would otherwise be required to collect during the 1st and 2nd quarters of 2020.

ACR Perspective and Comments

ACR supports CMS in granting ECE exceptions to hospitals which have not requested them when CMS determines that an extraordinary circumstance that is out of the hospitals control, such as an act of nature or PHE.

Updating the Medicare Telehealth List

Interim Final Rule Policy

CMS is revising its regulation to allow the use of a subregulatory process to modify the services included on the Medicare telehealth list.

ACR Perspective and Comments

ACR supports CMS policy to update the Medicare Telehealth list through a subregulatory process during the COVID-19 PHE to ensure the Medicare Telehealth list is as updates as possible. ***The ACR urges CMS to ensure that payment of telehealth services should be resource based and follow CPT and RUC guidelines.***

Payment for Audio-Only Telephone Evaluation and Management Services

Interim Final Rule Policy

CMS received responses from providers after the issuance of the first COVID-19 IFC explaining that audio-only services are being furnished primarily as a replacement for care that would otherwise be reported as an in-person or telehealth visit using the office/outpatient E/M codes. Therefore, CMS is establishing new RVUs for the telephone E/M services based on crosswalks to the most analogous office/outpatient E/M codes, based on the time requirements for the telephone codes and the times assumed for valuation for purposes of the office/outpatient E/M codes. Specifically, CMS is crosswalking CPT codes 99212, 99213, and 99214 to 99441, 99442, and 99443 respectively. The Agency is finalizing, on an interim basis and for the duration of the COVID-19 PHE the following work RVUs: 0.48 for CPT code 99441; 0.97 for CPT code 99442; and 1.50 for CPT code 99443. It is also finalizing the direct PE inputs associated with CPT code 99212 for CPT code 99441, the direct PE inputs associated with CPT code 99213 for CPT code 99442, and the direct PE inputs associated with CPT code 99214 for CPT code 99443. CMS is not finalizing increased payment rates for CPT codes 98966-98968 as these codes describe services furnished by practitioners who cannot independently bill for E/Ms and so these telephone assessment and management services, by definition, are not furnished in lieu of an office/outpatient E/M service.



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ACR Perspectives and Comments

Given the need to minimize exposure to COVID-19, the ACR understands the great value of telehealth during the PHE. ***Once the PHE is over, the ACR urges CMS to consider how continued telehealth claims processing shall be administered in the future and how representative payments shall be determined. Specifically, the ACR asks that all payments for Medicare services should be resource based with appropriate work relative value units reflecting time and intensity, as well as appropriate practice expense inputs***

Medicare Shared Savings Program

Interim Final Rule Policy

CMS is modifying the Shared Savings Program to 1) allow ACOs whose current agreement periods expire on December 31, 2020 the option to extend 1 year, and allow ACOs in the BASIC track to maintain their current level of participation in PY2021, 2) clarify the program’s extreme and uncontrollable circumstances policy, 3) adjust calculations to mitigate the impact of COVID-19 on ACOs, and 4) expand the definition of primary care services for beneficiary assignment to include telehealth codes.

ACR Perspectives and Comments

The ACR appreciates CMS’ additional revisions to the Medicare Shared Savings Program. Specifically, the ACR appreciates CMS’ clarification that extreme and uncontrollable circumstances began in January 2020 for the PHE and will therefore be factored into reduction in shared losses calculations. The ACR also appreciates that CMS is revising its policy to exclude from Shared Savings Program calculations all Parts A and B fee-for-service payment amounts for an episode for care for treatment of COVID-19, remove COVID-19 related expenditures from determination of benchmarks and expenditures, and exclude affected months from total person years used in the per capita expenditure calculations.

The National Association of ACOs, along with the American Medical Association and other provider groups, sent a [letter](#) to the Administrator urging CMS to extend the deadline to terminate MSSP contracts from June 2020 to October 31, 2020, recommending that CMS adopt a policy to give ACOs an option to be protected from losses in exchange for a reduced shared savings rate, no less than 40 percent, that CMS should reverse its decision to cancel the 2021 MSSP application cycle, and that CMS should pay ACO shared savings payments and Advanced APM bonuses as soon as possible. **The ACR agrees with the recommendations put forth in this letter, specifically the recommendation to give ACOs an option to protect against shared losses by reducing their shared savings rate.**

The ACR appreciates the opportunity to provide comments on this IFC. We encourage CMS to continue to work with physicians and their professional societies to develop policies that allow physicians needed flexibilities to provide safe and efficient care during the PHE and to determine the best way to return to a



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“new normal” when the PHE has ended. The ACR looks forward to continued dialogue with CMS officials about this important issue in order to ensure continued Medicare beneficiary access to vital healthcare services. If you have any questions or comments on this letter or any other issues with respect to radiology or radiation oncology, please contact Kathryn Keysor at 800-227-5463 ext. 4950 or via email at kkeysor@acr.org.

Respectfully Submitted,

A handwritten signature in black ink, which appears to read "William T. Thorwarth, Jr." followed by a stylized flourish.

William T. Thorwarth, Jr, MD, FACR
Chief Executive Officer