Gift Tee
Director, Division of Practitioner Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C1-13-07, Room C1-09-07
Baltimore, MD 21244-1850

April 1, 2020

Re: Request to Revise CMS Guidance Regarding the Treating Physician Rule for Radiologists

Dear Mr. Tee:

The American College of Radiology (ACR) writes to request that the Centers for Medicare & Medicaid Services (CMS) revise a Medicare Benefit Policy manual provision that restricts the situations where radiologists may act as a "treating physician" and order Medicare covered diagnostic tests. ACR believes that this manual provision creates an unwarranted disparity in how radiologists are treated relative to primary care physicians and other physician specialties, and that this disparity is inhibiting high quality and efficient delivery of patient care, as well as radiologist transition into value based arrangements. ACR respectfully requests that CMS take action to remove this unwarranted limitation on radiologists. The need for action by CMS is made only more critical due to the current COVID-19 pandemic. Acting on ACR's request will allow radiologists most fully to utilize their deep expertise in the area of diagnostic testing to help patients (and other specialties of physicians) during a time period of unprecedented need and resource constraints, where the need for patient management by expert diagnosticians is at its most profound.

ACR is a professional organization that represents more than 39,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists. As a leading organization in the area of radiological care, ACR is at the forefront of radiology evolution. We are deeply committed to serving patients and society by empowering members to advance the practice, science, and professions of radiological care.

An area of long-standing importance to ACR is ensuring that patients have appropriate and readily available access to medically necessary diagnostic services (and non-diagnostic services) furnished by radiologists. ACR believes that CMS's current treating physician rule is an impediment to the equitable and efficient access to such care. CMS could remove this impediment by revisiting its manual guidance implementing the rule.

CMS created the treating physician rule through a regulation that interprets the circumstances where ordering diagnostic services are reasonable and necessary.[1] This regulation, at 42 C.F.R. § 410.32, states that diagnostic tests must be ordered by a treating physician, described as "the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem."[2]

In the Medicare Benefit Policy Manual, CMS has interpreted the treating physician regulation to impose an additional "radiologist-only" restriction. The manual states: "A radiologist performing a therapeutic interventional procedure is considered a treating physician. A radiologist performing a diagnostic interventional or diagnostic procedure is not considered a treating physician."[3]

ACR asks CMS to issue a transmittal revising the agency's manual guidance. Among other things, the manual's radiologist-only restriction is inconsistent with the purpose of the treating physician regulation and how the regulation is applied to other types of physicians.

CMS has explained that the purpose of the treating physician regulation "is to assure that the physician who orders the test is responsible for the management of some aspect of the patient's care."[4] CMS does not, however, require non-radiologist physicians to perform a therapeutic procedure in order to be considered responsible for the management of some aspect of patient care. When CMS first issued the treating physician regulation, primary care physicians (PCPs) commented that they primarily perform diagnostic services that lead to a *referral to a specialist* for actual therapeutic interventional procedures.[5] CMS took pains to explain that the treating physician rule was "*not* [intended] to preclude the ordering of tests by a [PCP] who refers the patient to a specialist . . . or by a specialist who is managing only one aspect of [a] patient's care."[6] Consistent with this preamble guidance, PCPs (and certain other specialists) frequently furnish only diagnostic services and order diagnostic tests, while referring the patient to a specialist for the actual therapeutic intervention.

ACR believes that radiologists should be treated in a manner consistent with PCPs and other similarly situated physicians. CMS therefore should revise its guidance to make clear that radiologists can order medically necessary tests where the radiologist manages an aspect of the patient's care, even if the radiologist (similar to a PCP) may refer the patient out for interventional procedures.

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1 *See* 62 Fed. Reg. 59,048, 59,057 (Oct. 31, 1997); *see also* Social Security Act (SSA) § 1862(a)(1)(A) (services are not covered by Medicare if they are not reasonable and necessary).

2 42 C.F.R. § 410.32(a)(1).

3 Medicare Benefit Policy Manual, ch. 15, § 80.6.1.

4 61 Fed. Reg. 59,490, 59,497–98 (Nov. 22, 1996).

5 *See Id.* at 59,497.

6 *Id.* at 59,497–98 (emphasis added).

Not only is it inequitable to impose unique restrictions exclusively on radiologists, ACR also believes that CMS's radiologist-only restriction is premised on an antiquated view of the role of radiologists in a patient's continuum of care. Presumably, CMS used its manual to impose a radiologist-only restriction because of a belief that, in decades past, radiologists often operated as referred-consultant specialists with limited interaction with patients. But the practice of radiology has evolved over time, and this assumption is not warranted. It also is not in the best interest of patient care.

An increasing number of radiology practices have the capability and desire to serve a much more active role in "managing [at least] one aspect of [a] patient's care."[7] ACR members have found that this can often make the most clinical and logistical sense. Radiologists have unique and specialized training in the optimal performance of radiological procedures and the interpretation of medical images. Having a radiologist directly manage aspects of certain patients' care can be an important way of helping to ensure the appropriate diagnosis, management, and treatment of patient ailments. The experience of ACR members also is supported by empirical research, which shows significant decreases in variability in follow-up imaging (and cost) when radiologist recommendations are followed.[8]

Having a radiologist (rather than a non-radiologist physician or a non-physician healthcare provider) manage aspects of a patient care is sometimes simply in the best interest of patients—especially where the nature of the patient's condition necessitates complex radiological procedures or significant follow-up implicating radiological care. Far too often, the wrong study is ordered by non-radiologist providers, who are not familiar with the next best imaging test (or that there is no value in additional imaging). This can lead to low value diagnostic exams, which in turn can trigger a downstream cascade of subsequent testing and intervention that could have been avoided if a radiologist had been appropriately engaged and allowed directly to manage the patient's care. As experts in imaging and evidence-based imaging guidelines, radiologists are uniquely positioned to manage follow-up with the most appropriate examination (or to know when to recommend no further follow-up based on a low probability of clinically significant pathology).[9] Empowering radiologists to actively manage diagnostic work-up scenarios will not

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7 *Id.*

8 *See, e.g.*, Rosenkrantz et al., *Downstream Costs Associated with Incidental Pulmonary Nodules Detected on CT*, 11 Acad. Radiology 798 (2018); Rosenkrantz et al., *Variation in Downstream Relative Costs Associated with Incidental Ovarian Cysts on Ultrasound*, 15 J. Am. College Radiology 958 (2018); Rosenkrantz et al., *Downstream Costs Associated With Incidental Pancreatic Cysts Detected at MRI*, 211 Am. J. Roentgenology 1278 (2018).

9 *See generally* Lumbreras et al., *Incidental Findings in Imaging Diagnostic Tests: A Systematic Review*, 83 British J. Radiolology, 276 (2010); Blagev et al., *Follow-up of Incidental Pulmonary Nodules and the Radiology Report*, 11 J Am. Coll. Radiology 378 (2014); Cho et al., *Follow-up Imaging After Urological Imaging Studies: Comparison of Radiologist Recommendation and Urologist Practice,* 184 J. Urol. 254 (2010); MacMahon et al., *Guidelines*

only minimize unnecessary and low value imaging studies, but it will also create avenues for assigning greater accountability to radiologists. This is in the best interest of patients—as well as the best interests of the Medicare program (and will, among other things, be vital to the specialty's ability to participate in alternative payment models that carry the promise of substantial new efficiencies for federal health care programs).

Ultimately, removing regulatory barriers that restrict the ability of radiologists to assume full ownership of and management over the process of ordering diagnostic tests will reduce the number of patients who are lost to follow-up.[10] To further introduce accountability for overutilization, ACR is also developing quality measures to ensure that follow-up recommendations are based on specific algorithms derived from evidence-based guidelines, white papers, and consensus statements such as those for pulmonary and thyroid nodules, renal masses, and ovarian lesions.[11]

ACR's proposed revisions also would further Administration policy priorities established by Executive Order 13890, which mandates that CMS "propose reforms to the Medicare program to enable providers to spend more time with patients by," among other things, eliminating burdensome regulatory restrictions that "limit professionals from practicing at the top of their professions" and ensuring appropriate Medicare payment "for time spent with patient by both primary and specialist health providers practicing in all types of health professions."[12]

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for Management of Small Pulmonary Nodules Detected on CT Scans: A Statement from the Fleischner Society, 237 Radiology 395 (2005); Frates et al., *Management of Thyroid Nodules Detected at US: Society of Radiologists in Ultrasound Consensus Conference Statement*, 237 Radiology 794 (2005); Berland et al., *Managing Incidental Findings on Abdominal CT: White Paper of the ACR Incidental Findings Committee*, 7 J. Am. Coll. Radiology 754 (2010); Levine et al., *Management of Asymptomatic Ovarian and Other Adnexal Cysts Imaged at US: Society of Radiologists in Ultrasound Consensus Conference Statement*, 256 Radiology 943 (2010).

[10] There is also a wealth of empirical support that shows the significant care gap associated with inadequate follow-up of incidental imaging findings. *See* Rosenkrantz et al., *Downstream Costs Associated with Incidental Pulmonary Nodules Detected on CT*, 11 Acad. Radiology 798. Up to two-thirds of patients whose radiology reports advise follow-up do not receive it. *See* Rosenkrantz et al., *Variation in Downstream Relative Costs Associated with Incidental Ovarian Cysts on Ultrasound*, 15 J. Am. College Radiology 958 (2018). These patients are at risk for delayed diagnosis, more invasive treatments, and increased downstream costs of care—which could all potentially be avoided if radiologists were given greater flexibility to directly manage and oversee patient care.

[11] *See* Rosenkrantz et al., *Downstream Costs Associated With Incidental Pancreatic Cysts Detected at MRI*, 211 Am. J. Roentgenology 1278.

[12] Executive Order 13890: Protecting and Improving Medicare for our Nation's Seniors § 5(a)–(b) (Oct. 3, 2019), *available at* https://www.govinfo.gov/content/pkg/FR-2019-10-08/pdf/2019-22073.pdf.

Consistent with the policy objectives of Executive Order 13890, ACR urges CMS to revise its guidance to clarify that a radiologist can act as a treating physician and order medically necessary diagnostic tests, where he or she is managing the treatment of an aspect of the patient's care, even if the radiologist is not directly furnishing a therapeutic interventional procedure. Doing so will ensure that radiologists are treated in a manner that is consistent with other physician specialists and categories. It also will eliminate unnecessary burdens and benefit patient care by giving radiologists greater flexibility when engaging in such management—e.g., by allowing radiologists to directly order tests as follow-up on incidental findings, where doing so is medically necessary and consistent with well-established guidelines.

We include a draft transmittal and revised manual language that could be used to implement these requested changes. We also would appreciate the opportunity to meet with you and your staff in the near future to discuss this issue further and to obtain agency feedback on ACR's request and its proposed revisions to CMS's guidance.

Thank you for your time and attention to this important matter. Please feel free to contact Cynthia Moran, ACR Executive Vice President at Cmoran@acr.org with any questions you might have. Thank you.

Respectfully Submitted,

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

cc: Cynthia Moran, ACR
Angela J. Kim, ACR
Kathryn Keysor, ACR

Enclosures

CMS Manual System	**Department of Health and Human Services (DHHS)**
Pub. 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal [XXX]	**Date: March [XX], 2020**
	Change Request [XXXX]

SUBJECT: Manual Update for Implementation on the Definition of Treating Physician as Applied to Radiologists

I. SUMMARY OF CHANGES: This change request (CR) revises the definition of treating physician to clarify that a radiologist may be considered a treating physician and order Medicare covered diagnostic tests if the radiologist uses the results of the diagnostic test as part of management of a beneficiary's specific medical problem, regardless of whether the radiologist performs a therapeutic interventional procedure or refers the performance of interventional procedures to a different physician specialist.

EFFECTIVE DATE: March [XX], 2020
*Unless otherwise specified, the effective date is the date of service

IMPLEMENTATION DATE: March [XX], 2020

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/80.6.1/Definitions

III. FUNDING:

For Medicare Administrative Contractors (MACs): The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does

not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment – Business Requirements

Pub. 100-02	Transmittal: [XX]	Date: March [XX], 2020	Change Request: [XXXX]

SUBJECT: Manual Update for Implementation on the Definition of Treating Physician as Applied to Radiologists

EFFECTIVE DATE: March [XX], 2020
*Unless otherwise specified, the effective date is the date of service

IMPLEMENTATION DATE: March [XX], 2020

I. GENERAL INFORMATION

A. Background: Medicare covered diagnostic tests must generally be ordered by a "treating physician." This transmittal revises the Medicare Benefit Policy manual definition of treating physician to make clear that a radiologist is considered a treating physician if the radiologist uses the results of the diagnostic test as part of management of a beneficiary's specific medical problem, regardless of whether the radiologist directly performs a therapeutic interventional procedure on the beneficiary or refers the performance of such procedure to a different type of physician specialist. CMS's manual revisions are intended to make clear that radiologists are subject to the same treating physician requirements as primary care physicians and other types of physician specialists. A radiologist therefore will be considered a treating physician if he or she is responsible for the management of an aspect of the patient's care, and diagnostic tests ordered by such a radiologist will be considered reasonable and necessary, so long as there is an appropriate medical need for the test given the patient's clinical circumstances and needs.

B. Policy: On October 31, 1997, CMS adopted regulations (62 Fed. Reg. 50,098) that requires all diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests to be ordered by a physician who is treating the beneficiary, that is, a physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. CMS historically has regarded primary care physicians and (non-radiologist) specialists as treating physicians if the physician is responsible for the management of some aspect of the patient's care, regardless of whether the physician directly furnishes an interventional procedure. CMS's manual historically has required radiologists to furnish an interventional procedure to be considered a treating physician, however. CMS is revising the Medicare Benefit Policy to eliminate this disparity, which CMS believes creates unwarranted inefficiencies in the delivery of care and disparities in the ability of radiologists to order Medicare covered diagnostic tests, relative to other types of similarly

situated physicians. Under CMS's revised policy, radiologists are considered treating physicians (and may order Medicare covered diagnostic tests), so long as the radiologist is responsible for the management of some aspect of the patient's care. A radiologist is not required to furnish an interventional procedure to be considered a treating physician, so long as the radiologist is responsible for managing an aspect of the patient's medical care and uses the diagnostic test as part of managing the patient's medical care.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
XXXXX – XX.X	Contractors shall be aware of the changes to Medicare Benefit Policy Manual – Chapter 15, section 80.6.1.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A
"Should" denotes a recommendation

X-Ref Requirement Number	Recommendations or other supporting information

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): [XXXX], [XXXXX]@cms.hhs.gov.

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Benefit Policy Manual
Chapter 15 – Covered Medical and Other Health Services

80.6.1 - Definitions

(Rev. 95, Issued: 03-[XX]-20, Effective: 03-[XX]-20, Implementation: 03-[XX]-20)

Diagnostic Test

A "diagnostic test" includes all diagnostic X-ray tests, all diagnostic laboratory tests, and other diagnostic tests furnished to a beneficiary.

Treating Physician

A "treating physician" is a physician, as defined in §1861(r) of the Social Security Act (the Act), who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results of a diagnostic test in the management of the beneficiary's specific medical problem.

A radiologist *is considered a treating physician if the radiologist uses the results of the diagnostic test as part of management of a beneficiary's specific medical problem, regardless of whether the radiologist directly performs a therapeutic interventional procedure or refers the performance of such interventional procedure to a different type of physician specialist.* ~~*performing a therapeutic interventional procedure is considered a treating physician. A radiologist performing a diagnostic interventional or diagnostic procedure is not considered a treating physician.*~~

Treating Practitioner

A "treating practitioner" is a nurse practitioner, clinical nurse specialist, or physician assistant, as defined in §1861(s)(2)(K) of the Act, who furnishes, pursuant to State law, a consultation or treats a beneficiary for a specific medical problem, and who uses the result of a diagnostic test in the management of the beneficiary's specific medical problem.

Testing Facility

A "testing facility" is a Medicare provider or supplier that furnishes diagnostic tests. A testing facility may include a physician or a group of physicians (e.g., radiologist, pathologist), a laboratory, or an independent diagnostic testing facility (IDTF).

Order

An “order” is a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. The order may conditionally request an additional diagnostic test for a particular beneficiary if the result of the initial diagnostic test ordered yields to a certain value determined by the treating physician/practitioner (e.g., if test X is negative, then perform test Y). An order may be delivered via the following forms of communication:

- A written document signed by the treating physician/practitioner, which is hand-delivered, mailed, or faxed to the testing facility; **NOTE:** No signature is required on orders for clinical diagnostic tests paid on the basis of the clinical laboratory fee schedule, the physician fee schedule, or for physician pathology services;
- A telephone call by the treating physician/practitioner or his/her office to the testing facility; and
- An electronic mail by the treating physician/practitioner or his/her office to the testing facility

If the order is communicated via telephone, both the treating physician/practitioner or his/her office, and the testing facility must document the telephone call in their respective copies of the beneficiary’s medical records. While a physician order is not required to be signed, the physician must clearly document, in the medical record, his or her intent that the test be performed.