American College of Radiology™

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Russell Vought
Director
Office of Management and Budget
Office of Information and Regulatory Affairs
725 17th Street NW, Washington, DC 20503

Mailbox: MBX.OMB

RE: Executive Office of the President, Office of Management and Budget (OMB), Request for Information: Deregulation

Dear Mr. Vought:

The American College of Radiology (ACR) – a professional association representing more than 40,000 physicians practicing diagnostic radiology, interventional radiology, radiation oncology, and nuclear medicine (NM), as well as medical physicists - appreciates the opportunity to provide comments on the request for information on deregulation. There are many regulations within the field of medicine that add administrative burden to physician practices and impact Americans' access to care.

The ACR wishes to address the following issues in these comments:

- Treating Physician Rule
- Supervision of Contrast Administration
- Merit-based Incentive Payment System (MIPS)
- Protecting Access to Medicare Act (PAMA) Imaging Appropriate Use Criteria
- No Surprises Act Independent Dispute Resolution (IDR) Process

Treating Physician Rule
The ACR requests that the Centers for Medicare and Medicaid Services (CMS) take action to remove the burdensome limitation on radiologists in CMS's regulations on treating physicians (42 C.F.R. § 410.32). CMS created the treating physician rule through a regulation that defines the circumstances in which ordering diagnostic services is reasonable and necessary.[1] This arbitrary, bureaucratic decision has disrupted and delayed patient care for years and must be eliminated.

[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).

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This regulation 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] The Medicare Benefit Policy 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]

Changing the treating physician rule would allow radiologists to track important findings and help reduce the exploding data burden on primary care physicians and non-physician providers (NPPs). **Removing the requirement that a radiologist bill an E&M service to be qualified as the treating physician would help alleviate these barriers and allow radiologists to fully utilize their deep expertise in diagnostic testing to support patients and physicians in other specialties.** The ACR believes CMS's policy is based on an antiquated, inaccurate view of the role of radiologists in a patient's continuum of care.

Inaccurate and unnecessary advanced imaging utilization is a significant and growing national problem that can be attributed, in significant part, to the increased use of NPPs. NPPs order more imaging services than other physician providers.[4] Radiologists have extensive expertise in the selection and timing of appropriate imaging studies. To provide the best care to patients, radiologists should be able to change an order to a more appropriate study or less extensive imaging procedure when necessary. Research shows significant decreases in variability and costs in follow-up imaging when radiologist recommendations are followed.[5]

CMS should revise its guidance to clarify that radiologists can order medically necessary tests to manage certain aspects of a patient's care. CMS should not impose unique and deleterious restrictions on radiologists in the care of their patients.

Direct Supervision for Contrast Administration

The ACR has requested that CMS make permanent the rule adopted during the COVID-19 public health emergency to allow virtual direct supervision of level 2 diagnostic tests via real time audio/video communications. In 2024 and 2025 rulemaking, the ACR commented in support of CMS's decision to revise regulatory text to allow the virtual presence of the physician (or other practitioner) through audio/video real-time communications technology (excluding audio-only) through December 31, 2025. The ACR continues to believe remote direct supervision for level 2 diagnostic imaging tests is appropriate and will ensure patients have access to timely and safe diagnostic imaging.

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2 42 C.F.R. § 410.32(a)(1).

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

4 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

5 *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).

Making the presence of and "immediate availability" through real-time audio and visual interactive telecommunications a permanent part of the definition of direct supervision will help ensure afterhours access to radiology services. Additionally, virtual supervision will enable better access in rural and underserved areas, where imaging access issues are greater, while still ensuring patient safety.

Merit-based Incentive Payment System (MIPS)
Despite CMS's efforts, quality programs, particularly the Merit-based Incentive Payment System (MIPS) authorized under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Pub. L. No. 114-10, § 101(c), 129 Stat. 87 (2015), are highly complex and involve many regulations, policies, and guidance that change annually. The complicated rules of the MIPS program require continual, extensive, ongoing efforts by clinicians to maintain program compliance and avoid substantial decreases of up to 9% in reimbursement for Medicare services. Small, rural, and underserved radiology practices face disproportionate penalties due to limited resources to support and fund their efforts to successfully participate in MIPS.

Despite the MACRA aim to streamline this value-based payment program and reduce participation burdens for clinicians billing for Medicare part B services, the complex web of CMS regulations has done the opposite by failing to demonstrate better patient outcomes or avoid unnecessary spending. Regulatory simplification is essential to reduce this outsized burden on the teams of providers caring for Medicare patients.

In 2015, MACRA legislation consolidated several physician quality reporting programs into a single system, MIPS, designed to offer simplified and flexible participation options. Outdated or redundant existing measures were removed, and registry measure use was promoted with the intent to streamline reporting.

This change has disproportionately impacted radiology, leaving few clinically relevant measures for radiologists to meet MIPS reporting requirements. CMS formalized this process in the CY 2019 PFS Final Rule (83 FR 59452) and codified it in 42 CFR § 414.1330(c), allowing frequent and unpredictable updates, which placed increased administrative and financial strain on medical practices.

Practices invest years building systems, processes, and training around specific measures. When measures are removed, these investments are lost. Practices must annually reevaluate workflows, retrain staff, and update templates. A 2023 ACR analysis estimated the average annual cost of MIPS compliance at $12,881 per physician and 200 staff hours. For practices with 15 to 30 radiologists, costs rise to $193,215–$386,430 annually.

Ultimately, the complexity and cost of MIPS now outweigh its benefits, particularly for resource-limited, specialty-driven practices.

Protecting Access to Medicare Act of 2014 (PAMA) Imaging Appropriate Use Criteria
Section 218(b) of PAMA required CMS to establish a program mandating consultation of physician-developed appropriate use criteria (AUC) by ordering physicians and NPPs prior to referring Medicare Part B beneficiaries for advanced diagnostic imaging services beginning on January 1, 2017. CMS Coverage and Analysis Group (CAG) staff worked with stakeholders,

including the ACR, through the Medicare Physician Fee Schedule rulemaking process to develop and implement the PAMA AUC program. CMS encountered difficulties implementing the program, however. In the 2024 Medicare Physician Fee Schedule final rule, CMS estimated implementation of the PAMA imaging provisions would save Medicare approximately $700,000,000 annually. Despite these potential savings, CMS staff decided to suspend all work to implement this statutory mandate.

The AUC program is an effective, evidence-based program founded on physician-developed guidelines. AUCs are intended to optimize patient care by guiding providers to order the most appropriate advanced imaging study. Programs that utilize AUC within an Electronic Medical Record via clinical decision support (CDS) technology have demonstrated improvement in ordering the correct imaging study in hundreds of institutions over many years. Use of these AUC programs has also shown reductions in unnecessary utilization of imaging studies, producing savings to both payers and patients.

The ACR has proposed that CMS revisit the PAMA AUC program by making the following technical changes to the original program.

- **In lieu of the requirement to report AUC consultation information on each claim for advanced diagnostic imaging services prospectively, ordering providers would instead self-attest to this consultation. Qualified clinical decision support mechanisms would then collect the AUC consultation information (as was previously required of the mechanism).**
- **This information would then be provided to CMS for retrospective review and audit as needed.**
- **The current language should be amended to exempt small and rural practices and practices participating in clinical trials.**

The ACR feels CMS has the authority to make these changes. Thus, with minimal effort, the PAMA program could finally be implemented. We believe this technology will evolve and improve with use, can be applied to other services besides imaging, and will generate significant savings to the Medicare program.

No Surprises Act Independent Dispute Resolution (IDR) Process

The No Surprises Act (NSA) was signed into law by President Trump in 2020 to protect patients from unexpected medical bills resulting from out-of-network care, particularly in emergencies or when they unknowingly receive care from out-of-network providers at in-network facilities. When drafting this law, Congress worked to ensure fairness between providers and insurers in payment disputes. Congress carefully specified the factors that would be considered during the independent dispute resolution (IDR) arbitration process, and the development of the IDR process was robust and extensive.[6] By establishing a framework for resolving payment disputes between insurers and providers, the NSA ensured that patients are not financially penalized for circumstances beyond their control.

[6] U.S. Representative Richard Neal, Press Release: Neal Opening Statement at Hearing on Implementation of the No Surprises Act, September 19, 2023, https://neal.house.gov/news/documentsingle.aspx?DocumentID=3797.

The ACR strongly supports the NSA "hold harmless" provisions, removing patients from reimbursement disputes between insurers and providers. In addition, the ACR appreciates the NSA's intended balanced approach with respect to insurance companies and medical practices. The law was designed to end the problem of surprise medical billing while preserving access to care by protecting good-faith negotiations between insurance companies and provider groups, giving neither side unbalanced leverage in network contract negotiations.

Unfortunately, the previous administration did not implement the law as intended, resulting in legal action to correct problematic regulations and much higher usage of the IDR process than anticipated. The previous administration was delayed in releasing new regulations which include policies that would greatly improve efficiency and decrease unnecessary utilization of the Federal IDR process. **The ACR requests the administration consider swift release of the IDR Operations final rule (CMS-9897)[7].** This action would remedy the delays in improvements that would be easily implementable as stakeholders have already provided public comment. We believe there are vital reforms included in this regulation that will help improve some of the current deficiencies in the Federal IDR process.

The IDR Operations proposed rule was published in the *Federal Register* on November 3, 2023, with public comments initially due on February 5, 2024. There was an expectation such that the final rule would be released in early-to-mid summer 2024. Unfortunately, the final rule has still not been released. **While the rule is currently listed on the Administration's Unified Agenda for potential August 2025 action, the ACR urges the Administration to issue a final rule as soon as possible, given the already lengthy delay and ongoing concerns of physicians who are seeking fair reimbursement from health insurer underpayments under the process laid out by the statute signed into law by President Trump.**

Conclusion

The ACR greatly appreciates the Administration's efforts to collect feedback on burdensome regulations and improperly implemented laws. The ACR is available to provide clarification and guidance regarding areas identified for simplification. If you have any questions and/or would like to schedule a meeting, please contact Kathryn Keysor, ACR Senior Director, Economics and Health Policy at kkeysor@acr.org.

Sincerely,

D Smetherman

Dana Smetherman, MD, MPH, MBA, FACR, FSBI
Chief Executive Officer

[7] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202404&RIN=0938-AV15