StrategicRadiology
Better Medicine Together™

September 6, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

VIA www.regulations.gov
Re: File Code CMS-1807-P

Re: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule

Administrator Brooks-LaSure:

Strategic Radiology appreciates the opportunity to provide comments on the calendar year (CY) 2025 Medicare Physician Fee Schedule Proposed Rule. Strategic Radiology is a national coalition of physician-owned independent radiology practices representing 1,800+ radiologists who have come together to improve quality, gain operational efficiencies, and innovate the future of radiology's private practice model. Strategic Radiology represents the voice of independent, privately owned radiology practice on the national health-care landscape. As private practitioner radiologists, we are physicians, business owners, and employers that serve 23.2 million unique patients from all 50 U.S. states every year — and we share a unique perspective on the value of the private practice of medicine.

Conversion Factor Reduction

Strategic Radiology is concerned with the proposed 2025 conversion factor decline from $33.2851 to $32.3562. This reflects a 2.8% decrease from the factor set for 2024. This reduction primarily stems from the expiration of previous congressional measures designed to prevent conversion factor cuts. We wish to emphasize that the ongoing reduction is unsustainable for radiology practices, especially given the exclusion of the 2% sequestration from the initial analysis and the unresolved PAYGO threat for 2025. Additionally, the GPCI floor's expiration at the end of 2024 will further exacerbate these challenges.

Strategic Radiology acknowledges that CMS must adhere to budget neutrality guidelines and that congressional intervention is necessary. Strategic Radiology is committed to advocating for its members with Congress and maintains that the current trajectory poses a severe threat to the radiology specialty and the broader medical community.

Impact on Radiology Practices and Patient Care
The absence of an annual inflation adjustment for the MPFS has led to a 26% decline in inflation-adjusted payments from 2001 to 2023. Radiology practices face escalating costs for equipment, supplies, staff salaries, and facility leases — inflationary costs that are not currently reflected in

diminishing MPFS rates. This disparity prevents radiologists from investing in modern technologies and maintaining patient access to essential services, particularly in outpatient imaging offices and IDTFs.

Furthermore, reduced reimbursements are driving consolidation among radiology practices: Some groups are being absorbed by hospital systems that benefit from more predictable reimbursement policies, but others have been bought with private equity capital by corporate entities intent on achieving market power in specified geographic metropolitan statistical areas. While some consolidation within industries is a necessary and evolutionary response to the need for cost containment, research has shown that the trend raises overall health care costs by diminishing competition as well as limiting patient access to specialized radiology services, especially in rural and underserved areas.

According to the American College of Radiology job board, 1,904 radiology positions are currently unfulfilled. This indicates that the radiologist workforce is experiencing a significant shortage. The growing demand for imaging services, driven by an aging population, forces radiologists to work longer hours and increase reading speeds, raising concerns about reduced interpretive accuracy and heightened burnout. This situation is particularly dire in rural areas where hospital closures force patients to travel longer distances, exacerbating access issues and increasing the risk of negative health outcomes.

The proposed MPFS cuts directly affect Medicare beneficiaries, particularly those with chronic conditions requiring regular imaging. Delays or reduced frequency in imaging can lead to late diagnoses and suboptimal treatment, increasing long-term health-care costs and exacerbating pre-existing health conditions.

CT Colonography Coverage

Strategic Radiology commends CMS for proposing to expand coverage for colorectal cancer screening to include CT Colonography. This expansion will benefit Medicare beneficiaries and have a strong positive impact on patients in rural and underserved areas. However, we have concerns regarding the reimbursement implications under the Deficit Reduction Act of 2005 (DRA), which requires reimbursement for imaging services to be the lesser of MPFS or OPPS rates. The estimated reimbursement for CT Colonography under MPFS is significantly higher than under OPPS, and the disparity could limit access to this service. As a result, Strategic Radiology advocates for Congress to reconsider the DRA's provisions and exempt CT Colonography from the "lesser of" rule.

Physician Practice Information Survey

Strategic Radiology supports CMS's efforts to update practice expense costs but holds concerns about the current Physician Practice Information (PPI) survey process. Issues include inadequate physician education, difficulty in completing the survey, and outdated contact information. We encourage CMS to ensure that the final survey data is accurate, complete, and fully representative of the data. Additionally, Strategic Radiology would request that CMS publish the AMA's methodology and performance benchmarks.

Virtual Presence for Diagnostic Tests

As a result of the COVID-19 pandemic, CMS updated Title 42 of the Code of Federal Regulations Section 410.32(b)(3)(ii), permitting supervising physicians or non-physician practitioners to be "immediately available" through real-time audio/visual technology rather than requiring physical presence. This change allowed radiologists across the country to continue providing safe and dependable imaging services despite the escalating shortage of radiologists. Without this flexibility, imaging centers might face reduced operational hours or even closure, leading to delays or limitations in patient care. Consequently, Strategic Radiology strongly endorses CMS's proposal to extend virtual supervision through December 31, 2025, and advocates for making virtual presence via audio/video technology a permanent option for diagnostic tests that require direct supervision.

Outpatient hospital departments, physician offices, and independent diagnostic testing facilities have effectively implemented virtual direct supervision models over the last four years. These models have demonstrated their ability to enhance patient access and safety while maintaining program integrity and preventing overutilization. It is essential for imaging providers to have robust protocols for training both on-site personnel and supervising physicians to handle crash carts, assess patients, and manage adverse reactions to contrast materials.

Effective imaging relies on both proper supervision and the ability to quickly address contrast reactions. CMS regulations mandate that supervision be provided by a physician or, where permitted by state law, a non-physician practitioner in all settings, except for independent diagnostic testing facilities, which must have a physician skilled in Level 2 diagnostic tests, typically a radiologist. However, it is often more practical for immediate responses to contrast reactions to be managed by trained personnel such as radiologic technologists, nurses, or non-physician practitioners rather than the supervising physician or radiologist. Strategic Radiology also supports amending Section 410.32(b)(3)(ii) to require that virtual direct supervision be supported by a qualified individual, including a radiologic technologist, nurse, or non-physician practitioner with BLS certification and specific training in evaluating and addressing adverse reactions to contrast material.

MACRA/MIPS/MVPs

MIPS

We commend the decision to keep the MIPS scoring threshold at 75 points and to maintain the data submission requirement at 75 percent for the coming years. As MIPS evolves and becomes more administratively burdensome, these stable thresholds will help ensure accurate submissions without increasing the burden on practices. This consistency is especially crucial for radiology, which often faces challenges that other specialties may not.

We are encouraged by CMS's recognition of the limitations faced by radiology, particularly the scarcity of traditional MIPS measures that are not completely topped out. This places diagnostic and interventional radiologists at a disadvantage. We support the proposal to remove the 7-point cap on certain measures specific to diagnostic radiology, which will help prevent unfair penalties for high-

quality care. We urge CMS to continue developing new radiology measures and to consider the current gaps in available measures when evaluating QCDR options for radiology.

MIPS Value Pathways

The proposal to phase out traditional MIPS by CY 2029 is noted with caution. We advise against mandating MVPs until they are fully developed to reflect the diverse practice models within radiology. Radiologists may work in highly specialized roles, general practices with a mix of diagnostic and interventional work, or across various settings including offices, IDTFs, hospitals, and increasingly, remote locations. An MVP requirement that penalizes based on practice scope or location could adversely affect care access. We are concerned that creating MVPs that comprehensively cover all variations of radiology practice may be challenging and could fail to address the full spectrum of physician practices.

Cost Measures Beyond Radiology's Control

We have observed problematic consequences resulting from applying cost measures like Total Per Capita Cost (TPCC), Medicare Spending per Beneficiary (MSPB), and Episode Based Cost Measures (EBCMs) to radiology. Although radiologists are not directly included in TPCC, many practices employ (Advanced Practice Professionals) APPs whose costs contribute to TPCC penalties. Similarly, MSPB and EBCM metrics penalize radiology groups based on costs that are often unrelated to their direct actions or knowledge.

CMS's standards for cost measure construction include:

- Accurate assignment of services to the right clinicians
- Accountability for costs that clinicians can reasonably influence
- Clear guidance on how to improve performance based on cost measures

Although radiologists are not directly included in the Total Per Capita Cost (TPCC) calculation, many radiology groups find themselves affected by TPCC due to patient attribution to Advanced Practice Professionals (APPs) employed by the group, who are not registered under a radiology specialty. These APPs often deliver Evaluation and Management (E&M) services either before or after interventional radiology procedures, which are typically episodic and aimed at addressing acute issues, often among various problems a patient may have. Despite their role not being primary care, patients attributed to these APPs in sufficient numbers can trigger TPCC.

Similarly, for Medicare Spending per Beneficiary (MSPB) and Episode-Based Cost Measures (EBCMs), there is no transparency about who provided or ordered the services for which radiology groups are held accountable, or where these services were performed. Costs are assigned to radiologists for services they did not order and are often unaware of. For EBCMs, only standardized placeholders are reported rather than actual costs, rendering efforts to guide patients to lower-cost providers ineffective.

In summary, radiology groups are being held responsible for costs associated with services ordered by unknown clinicians, provided by unspecified providers, and at unidentified locations. Furthermore, EBCMs do not disclose actual costs, adding to the difficulty of making performance improvements. These conditions deviate significantly from the established standards.

The situation is exacerbated by the disproportionate impact of these cost measures on radiology groups compared to the actual cost of care. For instance, a radiology group serving approximately 130,000 Medicare beneficiaries annually faced penalties based on MSPB data for 118 patients and EBCM data for just 9 patients. This resulted in a reimbursement penalty approximately 60 times the total claim value for those patients. Similarly disproportionate effects have been observed with TPCC. The logical outcome for many radiology groups is to minimize or cease providing services that could lead to cost measure attribution, even if these services are cost-effective and beneficial for patients.

We urge CMS to reconsider the 35-case minimum threshold for MSPB assessments, which unfairly applies to both solo practitioners and large groups. A threshold of 35 cases per clinician would be more equitable.

Regarding the expansion of Episode-Based Measures, we recommend that CMS implement robust safeguards to prevent inappropriate or accidental attribution to radiologists and APPs in radiology groups, as many diagnostic and interventional radiology claims involve diagnosis codes for chronic conditions.

Additionally, with the proposed shift in cost scoring methodology from the decile approach to a median ± standard deviation method, we encourage CMS to thoroughly assess and disclose the impact of this change on scoring for each cost measure. There is a concern that the distribution may not be normal, potentially leading to unexpected and unfavorable results.

Ambulatory Specialty Care MVP

Regarding the Ambulatory Specialty Care MVP concept, many radiologists operate in a mix of settings, some of which might be classified as ambulatory. This variability makes it unlikely that an Ambulatory Specialty Care MVP would be suitable for many radiologists.

Mandatory Subgroup Reporting

We note concerns about the definition of multi-specialty groups and mandatory subgroup reporting. Many radiology groups include a variety of specialists, including diagnostic radiologists, interventional radiologists, and AAP's who enroll in specialties unrelated to radiology. This makes it unclear how such subgroup reporting would be applied. We worry that this requirement could add complexity without offering significant incentives for participation.

Population Health Measures

The application of population health measures within MVPs to radiologists requires careful consideration. Radiologists may not have a direct impact on patient populations compared to other clinicians, yet increasing imaging volumes might lead to higher case minimums for radiologists. This could lead to unintended negative consequences.

We urge CMS to weigh the cost and potential benefits of these proposals against the reduced incentives and ongoing conversion factor cuts. The projected increase in MIPS data submissions seems unrealistic given the minimal anticipated positive payment adjustments. Strategic Radiology requests that CMS consider that very few clinical conditions do not have radiologists in some way involved in care, and the radiology practice has a broad scope with a growing degree of hyper sub-specializations and limited patient interactions.

Payment for Radiopharmaceuticals

Strategic Radiology appreciates CMS's ongoing efforts to clarify radiopharmaceutical reimbursement; however, more emphasis must be given to the fact that radiology practices have reported inconsistencies in how Medicare Administrative Contractors (MAC) calculate and cover these reimbursements. While MACs are required to provide coverage for radiopharmaceuticals listed in National Coverage Determinations (NCD), they have the flexibility to set their own policies for other drugs. This flexibility results in significant coverage variations across jurisdictions, where patients might get a covered scan in one area but have to pay out of pocket in another for the same procedure.

Even where coverage is consistent, reimbursement practices can differ. A notable example is the Amyloid PET scan for dementia and Alzheimer's. Providers in outpatient settings have reported that Wisconsin Provider Services (WPS), which serves the CMS J5 & J8 jurisdictions, is not covering the tracer's cost and is reimbursing significantly below the expense. WPS appears to be disregarding Average Wholesale Price (AWP) guidelines, and repeated appeals have not resolved this issue.

As a result, some providers cannot offer this crucial diagnostic exam due to inadequate reimbursement, affecting Medicare beneficiaries in the affected regions. Strategic Radiology respectfully requests that CMS revise its directive to ensure uniform calculation and coverage of radiopharmaceutical reimbursements across all MACs, thereby guaranteeing that providers are appropriately reimbursed for their costs.

Discarded Drugs and Single-Dose Containers

Strategic Radiology supports efforts to clarify the identification of single-dose or single-use packaging. The current manual process for ensuring claims are submitted correctly based on the correct NDC code and modifier combination is challenging and often ambiguous. Presently, no single source exists that allows providers to validate the single use status of a drug based on its corresponding NDC code.

We recommend expanding the definitions for single-dose and single-use containers and regularly publishing NDC codes for these categories regularly to help providers verify and report accurately. Additionally, we recommend expanding the definition of single-dose and single-use packaging to include:

- Product furnished from an ampule for which product labeling does not have a discard statement or language indicating the package type term.
- Product furnished from a container with a total labeled volume of 2 ml or less for which product labeling does not have language indicating the package type term.

Medicare Overpayments and Refunds

Strategic Radiology supports CMS in establishing a formal policy that allows providers up to six months to investigate overpayments and issue refunds before the 60-day refund period. This will enable providers to conduct thorough investigations without fearing false claims violations.

MR Safety CPT Codes

We support the introduction of six new CPT codes to address the time, skill, and complexity involved in radiologists and radiology personnel conducting an assessment of patient records, implants, and medical devices in MRI procedures. These new codes will recognize the additional efforts required for customized protocols, programming, and patient safety, which are currently not accounted for in the existing CPT framework.

Conclusion

Strategic Radiology appreciates the opportunity to provide comment on the 2025 Medicare Physician Fee Schedule, Proposed Rule. We look forward to contributing to the national dialogue on the future of medicine by supporting a public policy agenda that promotes the ability of practices to remain independent.

Sincerely,

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Dr. Scott Bundy
Chief Executive Officer