Radiology Business Management Association

11166 Fairfax Blvd., Suite 500 ● Fairfax, VA 22030
888.224.7262 ● 703.621.3355 ● 703.621.3356
www.rbma.org

September 11, 2023

Ms. Chiquita Brooks-Lasure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted via www.regulations.gov
File Code CMS-1784-P

Dear Administrator Brooks-Lasure:

RE: Medicare Program; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-Lasure:

The Radiology Business Management Association (RBMA) appreciates the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding the CY 2023 Medicare Physician Fee Schedule (MPFS) Proposed Rule. Established in 1968, RBMA is a professional association that consists of over 2200 radiology practice business leaders who represent over 800 radiology practices in all 50 states. This includes diagnostic radiology, interventional radiology, nuclear medicine, IDTFs and radiation oncology.

Once again, CMS has issued an MPFS Proposed Rule that includes cuts to radiology services in the fee schedule. After 16 straight years of cuts to radiology this is an unsustainable environment in medicine. There continue to be factors within medicine and radiology that point to a system that may be at a tipping point regarding access to care by Medicare beneficiaries.

- Radiology volume continues to increase due to an aging population.
- There are increasingly fewer radiologists to accommodate this growth. There are currently over 1,700 position listings in the American College of Radiology's Career Center.
- Radiologists are working longer hours and increasing their reading speed, but the consequences have been an alarming increase in concerns over diminished interpretive accuracy and widespread accounts of radiologist burnout.

- An increasing volume of radiology procedures which will be generated by growing CMS funded therapeutics requiring imaging before ordered and follow up for complications, new indication advanced imaging studies with research driven literature guidelines and minimally invasive procedure opportunities are increasing.

Examples of new treatments which now will require pre-treatment imaging include:

- Lecanemab and aducanumab for Alzheimer's Disease which are expected to enormously increase MRI volume.
- Imaging studies include Breast MRI for cancer screening of women with dense breasts, CT lung cancer screening (both also health equity issues) and cardiac CTA as first-line imaging for patients with stable angina.
- The latter will help avoid cardiac catheterization lab procedures for those with non-significant stenosis and the two formers should aid earlier diagnosis when less expensive treatments are possible and patient outcome enhanced.

Minimally invasive procedures which are better and reduce costs in comparison to more invasive interventions with examples including transcatheter aortic valve replacements (TAVR), transcatheter mitral value replacements and repairs and left atrial appendage occlusion.

Proposed 2024 MPFS Conversion Factor:

Under the newly released Calendar Year (CY) 2024 Medicare Physician Fee Schedule (MPFS) Proposed Rule, the proposed calendar year (CY) 2024 physician conversion factor (CF) is $32.7476. This represents a decrease of 3.36% from the final CY 2023 physician CF of $33.8872.

The proposed CF update is primarily based on three factors: a statutory 0% update scheduled for the MPFS in CY 2024; a negative 2.17% budget neutrality adjustment, and a funding patch passed by Congress at the end of CY 2022 through the Consolidated Appropriations Act, 2023. This bipartisan legislation partially mitigated the CF cut by providing a 2.5% increase for the CY 2023 CF but only a 1.25% increase to offset part of the reduction to the CY 2024 CF.

We should also note that these figures do not incorporate the government wide budget sequestration of 2% which was reimplemented in the third quarter of 2022.

Figure 1 below illustrates the decline of Radiology Medicare reimbursement as compared to Primary Care specialties from 2013-2022. During the same time period the cumulative inflation rate was 31.22% according to the Bureau of Labor Statistics.

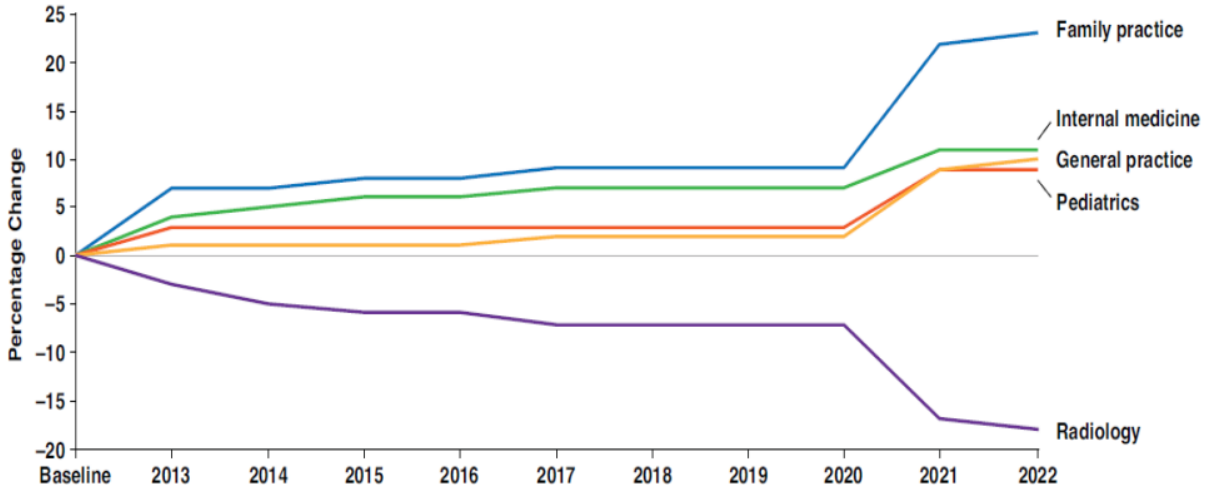

Fig. 1—Comparison of primary care specialties and radiology with respect to Medicare reimbursement policy changes over 10 years. Graph shows cumulative year- over-year percentage change from 2013 to 2022, with 2012 as baseline, in expected impact resulting from policies in Medicare Physician Fe PFS) Final Rule. Data obtained from Department of Health and Human Services MPFS Final Rule, Impact Tables, for calendar years 2013 through 2022 [

Again, radiology and other specialties are faced with declining MPFS reimbursement as well as steep inflationary headwinds. This combination of factors points to an urgent need to include an inflationary update within the MPFS. As we noted in our 2023 MPFS Proposed Rule comment letter it is worth repeating again this year: "Ultimately, this unsustainable trend will be an insurmountable obstacle in our efforts to address the radiology manpower crisis. As radiology volumes increase — which will happen inevitably with an aging society — the sheer volume of services within the Medicare program results in our services bearing an increasingly large brunt of rebasing relative value units (RVU) and budget neutrality. RBMA and other thought leaders in the industry are openly working on alternative payment solutions, and we invite CMS to engage with us in these discussions".

In our ongoing efforts to ensure optimal patient access to high-quality healthcare services, we wish to underscore the significance of adopting an inflationary update to the MPFS. This is not just a recommendation from our organization but is also backed by the endorsement of the Medicare Payment Advisory Commission (MedPAC) which is often reluctant to support increased physician payments. MedPAC's endorsement speaks to the understanding that keeping payments in line with inflation is imperative to safeguard the financial sustainability of healthcare providers. Without such an update, there is a genuine risk of providers becoming increasingly financially strained, which could lead to a further reduction in services or diminished willingness to treat Medicare beneficiaries. This would be detrimental to the Medicare program's goal of ensuring beneficiary access to care.

HCPCS Add-On Code: G2211:

RBMA notes that CMS plans to implement HCPCS code G2211, which is described as *Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*

It is well established that reimbursement of this code will be quite costly and have exceptionally large impacts on the conversion factor. We note that CMS has significantly reduced its estimated utilization rate for this code, but we have seen no reason for such optimism. The description of the code is exceedingly vague. The terms "serious condition" and "complex condition" are not defined, and therefore subject to financially driven interpretation. RBMA is very concerned that utilization of G2211 in 2024 will drive very significant future reductions in the conversion factor, which will make radiology services to Medicare beneficiaries increasingly unsustainable.

We urge CMS not to proceed with implementation of G2211. We believe there is no longer a need for an add on code, since normal E&M coding now offers the flexibility to code based on time. There are also numerous other codes available to report work and time related to continuing care. Implementation of G2211 is likely to result in duplicative payment in many cases.

In the event CMS proceeds with implementation of G2211, **we urge CMS to issue clear and well-defined guidance on its use, including detailed documentation requirements, correct coding guidance with respect to other codes describing the same services, and clinical examples of appropriate and inappropriate use. We also urge CMS to immediately announce and implement a robust focused auditing program to discourage misuse of the code.**

Physician Practice Information Survey

RBMA appreciates the opportunity to comment regarding the need to update the data collected through a process called the Physician Practice Information Survey (PPI). As CMS is aware, the last time this survey was conducted (2006/2007) radiology was significantly underrepresented in the survey process. To recap:

•No current data exists to accurately represent the indirect costs of radiology.
•The 2007/2008 PPI survey did not have sufficient responses to provide accurate information, the instrument was extremely difficult to complete, nor was it conducive to capturing accurate information.
•The practice of radiology has changed dramatically since that original survey as radiology entities/structures are much more complex.
RBMA is aware of the American Medical Association's (AMA) initiative currently in process to refresh and capture current data relative to the PPI survey. Through the American College of Radiology, RBMA has been engaged and active with this process for the past two years.
RBMA expresses concern with AMA's current initiative:
•The last time the AMA took the lead with this survey, several subspecialties, including Radiology, were severely underrepresented and there were gaps in the data.
•RBMA is concerned that the education to physicians and group leadership about this survey has been inadequate and physician groups are not prepared for this data request. We know that AMA has relied on the various subspecialty associations to assist with this education but despite these efforts we do not think there has been adequate outreach.
•RBMA is concerned that the survey tool will be difficult to complete creating barriers to participation and conducting the survey in a two-part process will lead to confusion and drop in participation.
•RBMA is concerned that information being requested in the survey is not relevant to revisiting the indirect cost structure of practice groups and the additional information requested will be a barrier to groups completing the survey.
•RBMA is concerned that the process of using 3rd party databases for contact information for physician groups will be old and outdated and the request to participate will not be sent to the correct individual within the physician group organizations.
•**We respectfully request CMS carefully consider the accuracy, completeness, and representation of the final survey data before moving forward with incorporating the survey data into future compensation formulas. RBMA recommends that CMS include the publishing of the AMA methodology and stipulate publicly that CMS publish performance benchmarks in order for this PPI data to receive consideration.**

Soliciting Public Comment on Strategies for Updates to Practice Expense Data Collection and Methodology:

In the proposed rule, CMS is asking follow-up questions on how best to update practice expense data collection and best methodology. They seek comments on strategies and incorporation of information that could address known challenges CMS has experienced in implementing the initial AMA PPIS data. CMS seeks to understand whether the updated PPIS data collection effort by the AMA, contingencies or alternatives may be necessary and available to address the lack of data available or response rates for a given specialty or related specialties who are paid under the PFS.

In light of the considerations discussed above, RBMA provides feedback on the following:

(1) If CMS should consider aggregating data for certain physician specialties to generate indirect allocators so that PE/HR calculations based on PPIS data would be less likely to over allocate (or under-allocate) indirect PE to a given set of services, specialties, or practice types. Further, what thresholds or methodological approaches could be employed to establish such aggregations?

The specialty of radiology includes diagnostic radiology, interventional radiology, nuclear medicine, radiation oncology and IDTFs. Any radiology responses collected in the AMA PPI survey will include these services if they are provided by that practice. Therefore, we do believe in aggregating data for these known CMS radiology-related specialties. In the previous PPI survey response rates were very low for these separate radiology specialties and no data was collected for IDTFs. Therefore, it would be appropriate to aggregate the data in order to allocate indirect PE to these services in order to have a larger overall response rate and to reflect that most radiology practices provide all of these services.

(2) Whether aggregations of services, for purposes of assigning PE inputs, represent a fair, stable, and accurate means to account for indirect PEs across various specialties or practice types?

As noted above, RBMA supports aggregating the data for specialties contained within the field of radiology in order to allocate indirect PE costs.

(3) If and how CMS should balance factors that influence indirect PE inputs when these factors are likely driven by a difference in geographic location or setting of care, specific to individual practitioners (or practitioner types) versus other specialty/practice-specific characteristics (for example, practice size, patient population served)?

RBMA believes the geographic practice cost index in its current fashion provides the necessary differential for geographic cost disparities but would consider alternative methodologies if CMS believes the current formula is not accurately reflecting these cost differences when it comes to PE inputs.

(4) What possible unintended consequences may result if CMS were to act upon the respondents' recommendations for any of highlighted considerations above?

The unintended consequences of inaccurate valuation of services of which, if not accurate or underpaid, reduce the likelihood that radiology practices will be able to afford to provide these services in the office setting.

(5) Whether specific types of outliers or non-response bias may require different analytical approaches?

All physicians have indirect practice expenses (e.g., administrative costs, cost of billing, Information Technology, Electronic Health Records etc.) It is typical for the AMA to accept responses from academic and hospital-based physicians that say they have no expenses and therefore the answer is zero. This is inaccurate. A PPI survey response from a physician group that is filled with zeros is not a valid survey response and skews the aggregated data.

Extension of Virtual Supervision through CY 2024 and beyond

RBMA applauds CMS' proposed amendment of 42 CFR 410.32(b)(3) to extend the current flexibility allowing direct supervision to be provided virtually through real-time audio and visual interactive telecommunications. The current flexibility was set to expire on December 31, 2023, and CMS has proposed extending it through December 31, 2024, noting that patient safety and access would only be hurt by reverting to the pre-Public Health Emergency definition of direct supervision on January 1, 2024.

RBMA continues to urge CMS to make this flexibility permanent either in the final version of the CY2024 final rule or ultimately for CY2025. During the past three years, radiology and imaging providers have demonstrated that virtual direct supervision of imaging services is safe and effective and is not a threat to program integrity or overutilization. Outpatient hospital departments, physician offices and free-standing independent diagnostic testing facilities have safely and effectively implemented direct supervision models that included some aspect of virtual supervision and have shown that deploying virtual supervision is an excellent innovation that drives patient access while at the same time not harming patient safety or program integrity. It should also be noted that without this flexibility in place, the continuing national radiologist labor shortage described earlier will require imaging providers to reduce imaging center hours of operation, or even close centers, restricting or delaying patient care.

Patient Safety and Program Integrity:

Safe and effective imaging is accomplished both through the supervision requirements and through the ability to immediately respond to contrast reactions in patients. Supervision is required by CMS regulation to be provided by a physician or non-physician practitioner, to the extent permitted by state law, in all settings but an independent diagnostic testing facility where a physician proficient in the performance and interpretation of the Level 2 diagnostic test (typically, a radiologist) is required. Notwithstanding CMS's supervision requirements, it is often best that emergency contrast reactions, when they occur, be attended to through intervention by clinical staff with requisite contrast reaction training—often emergency medical personnel and not the supervising physician or radiologist. If CMS is concerned about patient safety in making the policy permanent due to contrast reactions, RBMA supports additionally amending Section 410.32(b)(3)(ii) to require that virtual direct supervision be augmented with on-site clinical staff with requisite contrast reaction training for Level 2 diagnostic tests that require contrast in case of adverse reaction.

Additionally, RBMA would like to note that program integrity and utilization is not going to be negatively impacted by making the virtual direct supervision for imaging services permanent. That is guarded by the requirements at 42 CFR 410.32(a) that limit the test ordering authority only to the patient's treating physician or practitioner.

Application of the policy to "incident to" services:

RBMA would also like to highlight an issue we identified in the federal regulations for direct supervision in the spirit of identifying possible unintended consequences from the proposed rule.
We recommend that the direct supervision requirements for "incident to" services reference the direct supervision requirements for diagnostic tests – meaning, as written, changes to 42 CFR 410.32(b)(3)(ii) would also apply to "incident to" services described at 42 CFR 410.26(a)(2).

Generally, we are agnostic to direct supervision requirements for incident to services and seek only to make the policy permanent regarding diagnostic tests. To that point, we recommend CMS consider adding a narrative definition of direct supervision at 42 CFR 410.26(2) that de-links the two requirements and gives "incident to" services their own direct supervision requirement.

Merit-Based Incentive Payment System (MIPS)

Over the past several years changes to the MIPS program have had a significant negative impact on radiology practices, which we don't believe have been shared by many other specialties. **We urge CMS to consider the significant impacts of the MIPS programs on radiology, especially considering the significant expected reduction to the conversion factor and make adjustments so that payment penalties are not unavoidable.**

Cost Measures

The RBMA is extremely concerned about the impact of re-implementation of cost measures for the 2022 Performance Period on radiology practices, the lack of any meaningful opportunity for clinicians to impact future performance, and the impact re-implementation of cost measures will have on 2024 reimbursement in light of going from zero to 30% weighting.

CMS has not provided cost data since 2019, and there is no interim reporting during the performance period, so there has been no opportunity for clinicians to understand how they are performing on cost measures. Additionally, the post-performance period reporting that has been provided is extremely difficult to use and seems to contain almost no actionable information. Some radiology groups have also noted apparent errors in the data, such as double counting costs and inclusion of 2021 trigger services.

The only identifying information concerning patients in the reporting provided is the MBI and DOS. Most practice management systems don't offer the ability to look up patients using this data, and even for those who do, it would be a manual process. It is impossible to tell where the service was rendered, who ordered it and why, who rendered it, or in many cases any meaningful information about the nature of the service being counted against the clinician. Since the point of the exercise is to reduce costs, it is curious that the actual costs are not reported.

It defies logic to expect clinicians to impact costs for patients who cannot be readily identified, for unknown services with unknown costs, ordered and rendered by unknown providers and suppliers for unknown reasons. Given the fact that the meager data is not provided until after the end of the reporting period, no one can expect it to impact program costs.

Many radiology practices have reported being scored on the Medicare Spending per Beneficiary (MSPB) measure. They express frustration with this, since radiologists rarely admit patients to the hospital, and even more rarely manage post-

discharge care. Radiologists most commonly act as consultants or perform a specific procedure, and then return the patient to the care of their primary or treating physician. Holding radiologists accountable for the cost of care that they neither initiated nor managed (SNF or rehab, for example) is unfair. Such care is frequently indirectly or completely unrelated to the care rendered by a radiologist. Finally, we continue to believe that the 35 case MSPB threshold is unfair. All such thresholds should be per clinician so that they apply fairly to all groups, especially in view of the fact that payment adjustments are largely budget neutral.

Some radiology practices are also being measured on Episode Based Cost Measures (EBCM). Here again, radiologists are being held accountable for care initiated and managed by others, often unrelated to the trigger procedure rendered by the radiologist. EBCM minimum case minimums should also be adjusted per clinician so that they don't disadvantage larger groups.

Most troubling, and illustrative of the overall unfairness and ineffectiveness of the MIPS Cost Measure structure, is the fact that radiology groups are receiving large payment penalties across all the services they will render to Medicare patients in 2024 based on a tiny fraction of the services they rendered in 2024. Further, that tiny fraction is largely unrelated to the types of services being penalized.

For example, one hospital-based radiology group achieved a Quality score of 54.5/55, and a Practice Improvement Score of 15/15. Interoperability was reweighted. Without application of the cost score, they estimate that their overall score would have been 99.2, which would result in a positive payment adjustment on the order of 8%. This group served more than 65,000 traditional Medicare patients in 2022. The group had 118 patients assessed in the MSPB measure, and 9 patients assessed in an Episode Based Cost Measure, with a resulting score of 87.35 and a +1.1% payment adjustment. Based on 0.2% of the care provided in 2022, their 2024 reimbursement will be reduced by about 7% on 100% of the services they render to Medicare patients in 2024. In view of the extremely difficult radiologist labor market, inflation, ongoing reductions in the conversion factor, and the absence of any meaningful opportunity to prospectively understand or change cost measure performance, they believe the only logical option is to discontinue providing services to Medicare beneficiaries that are likely to trigger cost measures. Surely reduced access to care that triggers cost measures is not an objective of the program, but it is clearly a consequence of the application of cost measures.

We have also heard of numerous cases of apparently incorrect cost data. For example, inclusion of trigger cases from 2021, potential double counting of attributed costs where EBCM trigger codes are repeated within 90 days, and improper application of TPCC measures to groups of diagnostic and interventional radiologists, which are excluded specialties.

RBMA urges CMS to reconsider the application of cost measures for the 2022 performance period. In view of the lack of cost measure reporting since 2019, we believe it would make sense to reweight cost for the 2022 performance period, and treat 2022 as an informational and educational period, allowing an opportunity to clean up the data and improve reporting.

Before cost measures can be reasonably used for payment adjustments, we believe there is a need for more robust reporting to include actionable data and interim reporting on a quarterly basis. Costs should be attributed only to clinicians who ordered or initiated the related service.

RBMA urges CMS to pause the use of cost measures until they can be restructured so that the impact of any payment adjustment stemming from cost measures is proportionate to the scope of services being measured. One way to achieve this would be to apply payment adjustments stemming from cost measures only to the trigger services.

Quality Measures

The limited number of applicable quality measures proposed for 2024 will make it impossible for many radiologists reporting via claims or traditional registry to avoid a penalty. Since 2020, CMS has removed four widely used radiology MIPS measures:

- Measure #146 for screening mammography BIRADS codes removed in 2021.
- Measure #225 for screening mammography reminder systems removed in 2022.
- Measure #195 for carotid imaging removed in 2022.
- Measure #76 for PICC lines removed in 2023.

These measures applied to a substantial number of radiology studies and no measures were added for high-frequency radiology studies. With the proposed removal of Measures #147 (bone nuclear medicine), #324 (cardiac nuclear medicine/calcium scoring), and #436 (CT dosage reduction), this eliminates three additional high frequency MIPS measures without replacement.

The combined impact of these measure removals from traditional MIPS reporting leaves most diagnostic radiology groups with only 6 MIPS measures to report by traditional registry or claims-based reporting. Unfortunately, many of the remaining measures cannot be documented adequately because hospital-based radiologists often don't see patients and do not control the information systems.

For example, Measure #360 requires radiologists to report the number of previous CTs or cardiac nuclear medicine exams the patient received over the past 12 months. In a hospital setting, most radiologists simply have no way to obtain this information.

Measure #145 requires radiologists to report on the radiation exposure indices for all studies involving fluoroscopy. Prior to 2023, there was an option to report the exposure indices OR the number of images and fluoro time. Unfortunately, many fluoroscopy machines installed in hospitals do not have the capability or functionality to provide the exposure indices. Hospital-based radiologists do not have any control of this equipment. RBMA urges CMS to restore the 2022 definition, or an exclusion for studies performed using equipment that is not capable of reporting exposure indices, so that this measure can be used more widely.

RBMA urges CMS to delay the removal of Measures #147, #436, and #324 until such a time as sufficient replacement measures can be developed and tested.

Measure 418 includes a denominator restriction for age that may keep some radiology practices from achieving the required minimum number of cases. **RBMA asks that the age restriction be removed from this measure.**

Supporting Radiology Residency Programs:

RMBA requests that CMS support Congressional expansion of radiology residency training slots that would greatly benefit the availability and quality of future radiology care. It is in the best interest of both cost and care quality to have the critical diagnostic contributions which drive the selection of appropriate treatment made by those with the most radiology training and experience. While higher cost initially than utilizing less extensively trained diagnosticians reading exams, the benefit to patient care and the overall cost of care is positively impacted by having the most accurate diagnosis to directing care appropriately initially.

The current level of residents in training is insufficient in our teaching institutions to have radiologists taking advantage of even current volumes to be training the next generation of radiologists. They often 'read' alone, losing a teaching training pipeline enhancing opportunity. The current level of graduating radiology residents is not sufficient to meet the demand for retiring radiologists and the coupled with the increasing demand for radiology services. This drives up healthcare costs as radiology practices are experiencing a current shortage and compete with one another for available radiologists. The demographics of the radiologist workforce is skewed toward those nearing retirement with 53% at age 55 and over which leads to the concern that this radiologist supply problem will only grow.

Radiology would experience an even more significant decrease, due to a range of proposed policy changes related to physician work, physician expense (PE) and malpractice RVUs. The proposed 2024 MPFS reduction follows years of declining reimbursement and further increases the gap between physician practice expenses and Medicare reimbursement rates. These proposed cuts could increase healthcare costs overall and further limit access to quality care.

Appropriate Use Criteria/Clinical Decision Support:

CMS has proposed a suspension of the Medicare program which arose from the U.S. Congress's enactment in 2014 of the Protecting Access to Medicare Act (PAMA). The implementation of the requirement that ordering physicians consult appropriate use criteria (AUC) via a clinical decision support mechanism (CCDS) when outpatient advanced diagnostic imaging services are ordered has long faced a problematic implementation. RBMA believes the pause in the AUC program is justified given the resistance of ordering physicians to consulting AUC as well as the reliance on enforcement tools that have been misdirected at diagnostic imaging suppliers, and not to those physicians who fail to properly consult the appropriate use criteria.

Nevertheless, we support implementation of an AUC program that would properly align incentives and penalties that physicians can access to enable them through interoperable EMR/EHR the ability to select the best test for patients based on those patients' individual signs, symptoms, and conditions, guided by peer-developed, scientific based appropriateness criteria. We agree with comments made my CMS In the proposed rule that highlights the potential positive benefits and substantial program expenditure savings that would result from a well redesigned program. But much work is needed to improve the program.

We pledge to work with CMS and the Congress to find a path to a more effective and efficient design and implementation of this program.

Drugs and Biological Products Paid Under Medicare Part B; Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amounts (§§ 414.902 and 414.940)

In the CY 2023 MPFS final rule, CMS finalized that for all claims for drugs from single-use vials or single-use packages payable separately under Part B, either the JW modifier would be used to identify any discarded amounts or the JZ modifier would be present to attest that there were no discarded amounts. This includes drugs excluded from the definition of "refundable single-dose container or single-use package," such as radiopharmaceuticals and contrast agents used in medical imaging. Drugs drawn from multi-dose containers are exempt from the modifier JW/JZ requirement. Starting July 1, 2023, providers are required to report the JZ modifier on all claims for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts. Such claims that do not report the modifiers as appropriate on or after October 1, 2023, may be returned as un-processable.

Therefore, we do not view reporting the amounts of unused imaging contrast agents and radiopharmaceuticals, if any, as providing a benefit to CMS when the agency is prohibited from collecting the corresponding refunds from their manufacturers by statute.

The RBMA along with the American College of Radiology (ACR), RadNet and Rayus Radiology spelled out several objections to this policy in a July 18, 2023, letter to CMS Division of Ambulatory Services (Attachment 1).

RBMA, et al, note that "the reporting of the JW and JZ modifiers for imaging contrast agents and radiopharmaceuticals by outpatient radiology practices and imaging center is burdensome and serves no meaningful purpose. We respectfully request that this requirement be waived for these drugs. Additionally, while our request is being considered, the July effective date and the October 1st claims denial date should be paused."

In summary:

RBMA continues to be concerned about the detrimental effects that the 16-year trend of cuts to radiology fees will have on our industry. As noted, it is unsustainable in its current form. The RBMA Board of Directors continues to advocate for a new physician payment model. To that end, the Board of Directors approved a resolution in April 2023 to research and advance an alternative payment model for radiology and to collaborate with CMS and Congressional officials in the development and application of this model.

We appreciate the opportunity to provide these comments and are available as a resource as you move towards a 2024 MPFS Final Rule. If you have any questions or need additional information, please contact me directly at bob.still@rbma.org.

Sincerely,

Robert T. Still
Executive Director

Attachment: 1

July 18, 2023

Submitted Electronically via laura.kennedy@cms.hhs.gov

Laura Kennedy, PharmD, BCPS
Division of Ambulatory Services
Hospital & Ambulatory Policy Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Kennedy:

The undersigned organizations which represent outpatient radiology practices and imaging centers respectfully request waiving the JW and JZ modifier reporting requirement for Medicare Part B separately payable imaging contrast agents and radiopharmaceuticals in light of the fact that the manufacturers of these products are excluded by law from the mandate to refund CMS for the amount that is unused or discarded. These requirements add a significant amount of additional time, resource, and administrative costs to providers, with no additional benefit to CMS.

Background

Section 90004 of Infrastructure Investment and Jobs Act requires manufacturers to provide a refund to CMS for unused portions of refundable drugs in single-use dose containers or packages.[1] A refundable single-dose container or single-use package drug **does not include a radiopharmaceutical or imaging agent** [emphasis added], certain drugs requiring filtration, and certain new drugs.[2]

In the CY 2023 Medicare physician fee schedule (MPFS) final rule, CMS finalized that for all claims for drugs from single-use vials or single-use packages payable separately under Part B, either the JW modifier would be used to identify any discarded amounts or the JZ modifier would be present to attest that there were no discarded amounts.[3] **This includes drugs excluded from the definition of "refundable single-dose container or single-use package," such as radiopharmaceuticals and contrast agents used in medical imaging**.[4] Drugs drawn from multi-dose containers are exempt from the modifier JW/JZ requirement.[5] Starting July 1, 2023, providers are required to report the JZ modifier on all claims for drugs from single-dose containers that are separately payable under Medicare Part B when there are

[1] Pub. L. 117-9
[2] https://www.govinfo.gov/content/pkg/BILLS-117hr3684enr/pdf/BILLS-117hr3684enr.pdf
[3] https://www.federalregister.gov/d/2022-23873/p-2566
[4] FAQ #7, https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf
[5] Ibid

no discarded amounts. Such claims that do not report the modifiers as appropriate on or after October 1, 2023 may be returned as un-processable.[6]

Therefore, we do not view reporting the amounts of unused imaging contrast agents and radiopharmaceuticals, if any, as providing a benefit to CMS when the agency is prohibited from collecting the corresponding refunds from their manufacturers by statute.

Confusion

The language used in the CY 2023 MPFS final rule and subsequent Frequently Asked Questions (FAQ) is a source of confusion. Many in our industry concluded that the exclusion for radiopharmaceuticals and imaging contrast agents meant that complying with the JW and JZ modifiers was unnecessary. Others were unaware of the requirement because it was not included in the CY 2023 MPFS proposed rule and not explicitly discussed pertaining to outpatient practices or imaging centers in CMS' FAQ, transmittal, or MLN Matters article.[7,8,9]

Unnecessary Administrative Burden

Collecting and documenting imaging contrast agent and radiopharmaceutical use is burdensome. First, there is the shear magnitude of the requirement. We estimate over 3 million imaging studies with contrast agents and over 1.5 million diagnostic nuclear medicine exams involving radiopharmaceuticals are performed annually for Medicare beneficiaries in the office setting.[10]

Second, compliance with the requirement will require updated workflows, revised forms, changes to the radiology information system (RIS). Radiological technologists or other clinical staff will have to record the beginning and ending doses to estimate the amount unused and discarded, if any. This information then will be documented in the radiologist's report; further contributing to "note bloat" of adding administrative information with little to no clinical usefulness to the ordering clinician or the patient. Similarly, radiologist clinical workflows will have to be modified, report templates revised, and RIS updated with the necessary fields. All of this distracts from providing patient care and without any benefit in return. Our experience is not unique, CMS received multiple public comments on the proposed rule regarding the burden associated with implementing this policy. (*We acknowledge and appreciate that CMS did postpone the start-date and claims denial date from January 1, 2023 originally*.)

Finally, radiopharmaceuticals are custom-ordered for the patient and the exam. This is done because they have short radioactive half-lives and to minimize the radiation dose to the patient and risk of prolonged exposure. The specified amount of radiopharmaceutical arrives pre-measured from the manufacturer and ready to be administered to the patient. There is no wastage. Meaning that, each claim for a radiopharmaceutical will be accompanied by the JZ modifier. Thus, applying the JZ modifier to Medicare claims for radiopharmaceuticals is redundant and unnecessary.

Billing and Coordination of Care Challenges

We are concerned that the JZ modifier may result in billing errors, inadvertent claim denials, and slow claims processing, not only for providers but also for CMS. In particular, coordination of care with Medicare supplement plans and Medicare as a secondary payor could be problematic as these payors

[6] Ibid
[7] FAQ
[8] https://www.cms.gov/files/document/r12067cp.pdf
[9] https://www.cms.gov/files/document/mm13056-new-jz-claims-modifier-certain-medicare-part-b-drugs.pdf
[10] Analysis of CMS' 2021 "Medicare Physician & Other Practitioners – by Geography and Service" datafile. https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners/medicare-physician-other-practitioners-by-geography-and-service

are slower to adopt new modifiers. Clearinghouses used in claims processing will need to update their systems otherwise claims containing the JZ modifier risk being rejected which further delays processing and timely payment to outpatient radiology practices and imaging centers.

Another potential claims issue is the appearance of duplicate billing of the imaging contrast agent or radiopharmaceutical since the same HCPCS code will be reported twice albeit with different modifiers. Importantly, for CMS' claims processing edits, this introduces the potential for error and accidental claims rejection.

Finally, imaging contrast agents come in single-dose and multi-dose containers. As previously stated, drugs in multi-dose containers are exempt from the JW/JZ requirement. Consequently, CMS' claims processing edits will have to distinguish between imaging contrast agents coming from single-use vials versus those from multi-dose containers to ensure correct claims adjudication.

****

In summary, the reporting of the JW and JZ modifiers for imaging contrast agents and radiopharmaceuticals by outpatient radiology practices and imaging centers is burdensome and serves no meaningful purpose. We respectively request that this requirement be waived for these drugs. Additionally, while our request is being considered, the July 1st effective date and October 1st claims denial date should be paused.

Thank you in advance for the opportunity to bring this issue to your attention and for considering our request. If you have questions or would like to discuss this further, please contact Michael Mabry, RadNet's Senior Director for Public Policy & Economic Analysis at 443.810.4798 or Michael.Mabry@RadNet.com.

Sincerely,

American College of Radiology
Radiology Business Management Association
RadNet
RAYUS Radiology

cc: Adam Brooks, CMS
Rachel Radzyner, CMS
Christina Berry, ACR
Robert T. Still, RBMA
Christopher "Kit" Crancer, RAYUS Radiology