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September 10, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically via http://www.regulations.gov

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

The Radiology Business Management Association (RBMA) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Calendar Year (CY) 2019 Medicare Physician Fee Schedule Proposed Rule.

ABOUT RBMA

Founded in 1968, the RBMA represents over 2,300 radiology practice managers and other radiology business professionals. In the aggregate, RBMA's influence extends to over 24,000 radiologic technologists and 26,000 administrative staff. RBMA is the leading professional organization for radiology business management, offering quality education, resources and solutions for its members and the health care community, and helping shape the profession's future.

APPROPRIATE USE CRITERIA FOR ADVANCE DIAGNOSTIC IMAGING SERVICES

Implementation Timeline

RBMA has been a strong supporter of Section 218(b) of the Protecting Access to Medicare Act (PAMA) and the promotion of the use of Appropriate Use Criteria (AUC) for advanced diagnostic imaging services. As there continues to be several important steps in this process leading to implementation beginning January 1, 2020, RBMA remains committed to working with CMS and industry stakeholders in developing a process that will provide patients and physicians the most advanced and appropriate imaging.

As codified in the CY 2018 final rule, the AUC program will begin on January 1, 2020, with a year-long educational and operations testing period during which time claims will not be denied for failure to include proper AUC consultation information. RBMA supports the proposed implementation date of January 1, 2020, as an educational and operations testing period. While 2020 will be a "testing" year for AUC, there continues to be challenges with building a process for

information flow in order for the consultation to be noted correctly by all systems that flow through to billing and reimbursement. **RBMA appreciates that CMS remains committed to engaging with stakeholders to facilitate this process.**

Claims-Based Reporting

CMS explains that in the CY 2018 MPFS proposed rule, the agency discussed using a combination of G-codes and modifiers to report the AUC consultation information on the Medicare claim, but as RBMA and many other commenters reported, a unique consultation identifier (UCI) would be a less burdensome and preferred approach. Nonetheless, due to concerns that the UCI seems limited to claims-level reporting, CMS proposes to use G-codes and modifiers to report the required AUC information on Medicare claims. Meanwhile, the agency explains they will consider future opportunities to use a UCI and will engage with stakeholders to this end.

RBMA remains committed to engaging with CMS in discussions about creating a uniform taxonomy, identifying a location on the claim form, obtaining support and permission to use a field, and solving the challenge of a UCI being a claim level reporting tool. This is a very complicated process that will need time to be developed in order to ensure the referring physician consultation regarding AUC did take place and is reportable. While we understand the decision to implement the program by using G-codes and modifiers, **RBMA recommends that the AUC system move expeditiously to requiring qualified Clinical Decision Support Mechanisms (CDSM) to generate a unique identifier for each consult. Further, RBMA encourages CMS to clarify that CDSMs report the actual G-code and modifier as part of the information transmission obligation.**

Application of AUC to the Professional Component

Under the Medicare Physician Fee Schedule , payment for many diagnostic tests including the advanced diagnostic imaging services to which the AUC program applies can be made either "globally" when the entire service is furnished and billed by the same entity, or payment can be made separately for the technical component (TC) of the service and the professional component (PC) when those portions of the service are furnished and billed by different entities. The TC for an advanced diagnostic imaging service is the portion of the test during which the patient is present, and the image is captured; the PC is the portion of the test that involves a physician's interpretation and report on the captured image.

With the exception of those imaging procedures for which claims to CMS are submitted globally, imaging activity will result in CMS receiving information from both facilities and radiologists for the same exam. While this may ultimately provide future opportunity for reconciliation, managing two different sources of information as this process is implemented and refined will result in unnecessary additional resources invested by CMS and awarded imaging providers while offering little to no additional value.

Radiologists generally receive the supporting medical record information from the facilities that provide the TC of the imaging service to allow them to submit claims to CMS for the radiologists professional services . In this instance, the AUC used in the qualifying CDSM will be submitted by the referring/physician to the facility providing the TC. The process of transferring the CDSM data to the PC provider from the TC provider needs to be refined and implemented.

RBMA believes that it will be a challenge for facilities providing the TC to ensure that their policies, procedures, and information transfer protocols are adequately refined to be implemented by radiology physician providers. To that end, we look forward to continuing to work with CMS to ensure that this process is implemented effectively and with a recognition of this potential barrier.

Auxiliary Personnel

In the proposed rule, CMS would allow the use of "auxiliary personnel" to perform the AUC consultation assuming the individual is "incident to" the ordering physician or non-physician practitioner's professional service. Traditionally, the term "incident to" under Medicare pertains to identifying conditions under which certain services that are incident to a physician's service can be billed. As detailed by CMS in the proposal, "this approach is appropriate under this program and still accomplishes the goal of promoting the use of AUC. This policy would allow the ordering professional to exercise their discretion to delegate the performance of this consultation."

Consistent with 42 CFR 410.26**, RBMA would suggest that the definition of "auxiliary personnel" be further refined as it relates to "incident to" service. We recommend that in order to follow the intent of PAMA as it relates to consultation and education the auxiliary personnel should be a licensed or certified professional. We would also recommend that the auxiliary personnel should be employed by and/or under the direct supervision of the referring physician.**

Finally, because only the treating physician can order a diagnostic test, **we suggest that CMS consider what steps should be taken and documented if the physician's auxiliary personnel learns after consulting the CDSM that the test ordered does not adhere to the AUC.**

Independent Diagnostic Testing Facilities

CMS proposes to expand the definition of applicable settings for which AUC consultation and reporting requirements apply to include independent diagnostic testing facilities (IDTFs). Given that IDTFs furnish services for a large number of Medicare beneficiaries, the addition of IDTFs to the definition of applicable setting will ensure that the AUC program is in place across settings in which outpatient advanced diagnostic imaging service s are furnished. To achieve the goal of AUC in developing a process that will provide patients with the most appropriate imaging across outpatient settings, **RBMA supports the expansion of AUC into IDTFs.**

Hardship Exemptions

For CY 2019, CMS proposes to revise the significant hardship criteria in the AUC program to include: (1) insufficient internet access; (2) electronic health record (EHR) or CDSM vendor issues; or (3) extreme and uncontrollable circumstances. To minimize the burden involved in seeking significant hardship exceptions, CMS is proposing that ordering professionals self-attest if they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order. Ordering professionals attesting to a significant hardship would communicate that information to the furnishing professional with the order and it would be reflected on the furnishing professional's and furnishing facility's claim by appending an HCPCS modifier. The modifier would indicate that the ordering professional has self-attested to experiencing a significant hardship and communicated this to the furnishing professional with the order.

While RBMA understands that hardships may exist within a physician practice, we expect that the hardship exceptions would be extremely rare in today's physician practice electronic environment. As the agency estimates in the proposal, less than 1 percent of ordering professionals are expected to submit such a request. **We agree with the areas of hardship exception noted but recommend that CMS further define the "self-attest" process that a practice would use to note a hardship exception. Further, RBMA would encourage CMS to ensure that furnishing providers would be held harmless in instances of self-attestation, even if the agency ultimately determines that the ordering physician was not eligible for a hardship exemption.**

RADIOLOGIST ASSISTANTS AND RADIOLOGY PRACTITIONER ASSISTANTS

In response to the Request for Information (RFI) on CMS Flexibilities and Efficiencies that was issued in the CY 2018 MPFS proposed rule, the agency proposes to revise the supervision requirements for radiologist assistants (RAs) to

specify that all diagnostic imaging tests may be furnished under the "direct supervision" of a physician — rather than "personal supervision" — when performed in accordance with state law and state scope of practice rules. The agency notes that for diagnostic imaging tests requiring the general level of supervision, this proposal would not change the level of physician supervision to direct supervision.

Specifically, CMS proposes adding a new paragraph to state that diagnostic tests performed by a registered radiologist assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants, require only a direct level of physician supervision, as permitted by state law and state scope of practice regulations. **RBMA supports this expanded use of RRAs and RPAs and agrees that those tests that are currently subject to general supervision should not require an increase to the direct level of supervision. We also concur with CMS that the revised level of supervision of diagnostic tests will occur only if such level of supervision is permitted by state law and state scope of practice regulations.**

Additionally, **RBMA would encourage CMS to further investigate and implement revisions to Medicare's rules to permit RAs to perform additional radiology services consistent with their training, certification and state licensure. Specifically, RAs should be able to personally perform various radiology procedures that are described in the 20000 and 30000 series of CPT codes for various radiological physician/surgical services, when performed under the direct supervision of a radiologist.** RAs are qualified to personally perform the "radiology" components of radiology supervision and interpretation (RS&I) services. On the other hand, we maintain that only radiologists or other qualified physicians should perform the interpretation services.

PRACTICE EXPENSE RVUS

RBMA has begun a preliminary review of the work the CMS contractor StrategyGen Company has performed in developing the market research and review of supply costs, equipment pricing and labor costs that make up the components of the practice expense (PE) RVUs. Our initial review shows several serious flaws in the results of this study, which could lead to extreme reduction in reimbursements if implemented. For example, based on recent analysis of the StrategyGen report by the Ultrasound Access Coalition (UAC), the cost of an ultrasound room would decrease from approximately $370,000 to $130,000. Additionally, there is concern that the values associated with breast magnetic resonance (MR) — both equipment and time — are significantly undervalued. We look forward to the opportunity to engage further with the agency on these concerns.

A myriad of external factors that could impact PE RVUs have the potential to introduce significant variability on both a practice-by-practice and quarter-by-quarter basis. For example, recently imposed tariffs that could increase equipment costs by 20 to 30 percent could have an unpredictable impact on practice expenses. Moreover, the impacts of these tariffs will not be known or felt until 2019 or 2020. Additionally, labor costs have proven to be variable, equipment pricing is often contingent on practice size and purchasing power, and additional regulatory burden (such as new FDA requirements) exist, and all have the potential to increase costs. Lastly, the radiology community has been impacted by shortages in the contrast agent used to perform procedures, also affecting price.

Overall, we strongly oppose and urge CMS not to finalize its proposal due to the potentially devastating impact it could have on beneficiary access to critical, lifesaving imaging services. While we recognize CMS' statutory authority to collect information on PE inputs to improve the valuation of services, we have significant concerns with the process and lack of transparency regarding the market research contract with StrategyGen as well as StrategyGen's subsequent market research study on direct PE inputs (DPEI). With that in mind, **RBMA encourages CMS to delay the implementation of the practice expense RVUs pending further review of the study and the impact of these various externalities.**

EVALUATION AND MANAGEMENT CODES

CMS is proposing a number of coding and payment changes for evaluation and management (E/M) visits, which we hope will serve to reduce administrative burden and improve payment accuracy. Among the policy changes proposed in the regulation: (1) to allow practitioners to choose to document office/outpatient E/M visits using medical decision-making or time instead of applying the current 1995 or 1997 E/M documentation guidelines; (2) to allow practitioners to use time as the governing factor in selecting visit level and documenting the E/M visit, regardless of whether counseling or care coordination dominates the visit; (3) to allow practitioners to focus their documentation on what has changed since the last visit or on pertinent items that have not changed, rather than re-documenting information, provided they review and update the previous information; and (4) to allow practitioners to simply review and verify certain information in the medical record that is entered by ancillary staff or the beneficiary, rather than re-entering it. RBMA broadly supports the effort by CMS to reduce administrative burden and believes that the initiative to transform the reporting of E/M codes is a step in the right direction to further streamline physician coding and reimbursement methodology.

Regarding the proposal to collapse payment rates for eight office visit services for new and established patients down to two each, **RBMA is concerned that there are a number of unanswered questions and potential unintended consequences that would result from the coding policies in the proposed rule. We oppose the implementation of this proposal because it could hurt certain physicians and other health care professionals, ultimately jeopardizing patients' access to care. Additionally, we urge that the new multiple service payment reduction policy in the proposed rule not be adopted, as the issue of multiple services on the same day of service was factored into prior valuations of the affected codes.**

QUALITY PAYMENT PROGRAM

Meaningful Measures

CMS is considering the implementation of the Meaningful Measures Initiatives (composite measures) as a way of simplifying and reducing burden for participating clinicians. RBMA respectfully requests more information to understand how the meaningful measure framework will specifically apply to radiology quality measures. Similarly, RBMA is concerned that the proposed rule discusses removing "topped out measures" and considers a tiered structure (gold, silver, bronze) where points are awarded based upon the value of measure. **RBMA would like to encourage CMS to consult with the various physician subspecialties before removing measures, implementing tiered structures, and/or creating a new framework.** We need to ensure that sufficient measures remain available for clinicians to report, especially for those clinicians who have categories re-weighted to the quality component in the composite score.

Assessment Periods

In order to align eligibility determination periods for the different components of MIPS, CMS has requested comments on their proposal that beginning with the year 2021, the MIPS determination period would be a 24-month assessment period including a two-segment analysis of claims data consisting of: (1) an initial 12-month segment beginning on October 1 of the calendar year two years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, and (2) a second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs. **RBMA supports this proposal; however, we request that in publishing participation status and/or eligibility on the QPP website, CMS also indicate which segment was used in determining their status/eligibility in order that providers will know what their MIPS participation status is and what factors may cause change.**

Data Collection and Submission Terminology

CMS has expressed concern that the way in which they have described data collection and submission lacks proper identification and specificity. To ensure clarity, CMS is proposing to revise existing terminology and define additional terminology to precisely reflect the user's experience when submitting data. RBMA understands the new terminology as follows:

- ***Collection Type*** — Referring to a certain type of quality measures such as MIPS Clinical Quality Measures, QCDR measures, CMS Web Interface Measures, CAHPS, etc. Additionally, going forward CMS will replace what was formerly referred to as registry measures with the term MIPS CQMs (clinical quality measures).
- ***Submitter Type*** — Referring to who is submitting the data (e.g., MIPS eligible clinician, third party intermediary etc.)
- ***Submission Type*** — Mechanism used to submit the data (e.g., direct, log in and upload, log in and attest, Medicare Part B claims and CMS Web Interface). CMS proposes to provide clarity as to how each component of the composite MIPS score can be submitted.

RBMA supports providing this level of clarity to providers, but also emphasizes the importance of ensuring that submitting and attesting to measures is flexible and easy for clinicians to do. Further, RBMA supports CMS' consideration to expand Web Interface submission types and asks for considerations that are more applicable to specialties such as radiology.

MIPS Performance Categories

RBMA appreciates CMS holding the cost component of the MIPS composite score at 15 percent for reporting year 2019, payment year 2021. We commend CMS for acknowledging that the "cost measures are still relatively early in the process of development and that clinicians do not have the level of familiarity or understanding of cost measures." Moreover, **RBMA would encourage CMS to publicly release the cost data for physicians and groups. As cost data is currently unavailable, it is extremely difficult for clinicians to understand the metric and how a physician's or group's activities could impact the measure.**

Additionally, under the PQRS program, clinicians were given a QRUR report accompanied by data that showed what patients were attributed to their TIN, and this attribution played a role in the value modifier process. Clinicians were surprised that a similar reporting mechanism did not exist for QPP year 1 reporting. **RBMA respectfully requests that clinicians be provided a reporting mechanism on how well they performed on the cost measure, the attribution methodology used for the cost calculation, and patients attributed to their TIN.**

RBMA continues to be very concerned that the planned attribution methodology for MSPB will result in inpatient hospitalizations being inappropriately attributed to diagnostic radiologists who have had little or no face-to-face patient contact and only provided professional services pursuant to the orders of other treating clinicians. We understand that a minimum threshold of 35 cases per TIN is planned for the MSPB measure. Measurement at the TIN level will unfairly hold clinicians to different standards based on group size. Based on past QRUR reporting, we have seen significant numbers of cases attributed to diagnostic radiologists under MSPB, frequently well over 35 per TIN, but rarely 35 per NPI. We ask that CMS reconsider, and clarify that the MSPB minimum threshold is 35 cases per NPI in order to ensure that all clinicians are held to the same standard regardless of group size and minimize the impact of inappropriate attribution to diagnostic radiologists and other similarly situated clinicians. Alternatively, professional component imaging services could be excluded from the claims plurality used for MSPB attribution.

Finally, **RBMA supports and encourages CMS to finalize the proposal presented in Table 52 for alternative redistribution policies in which the Promoting Interoperability and Cost performance categories are reweighted.**

CONCLUSION

RBMA appreciates the opportunity to provide comments on the CY 2019 MPFS proposed rule. We encourage CMS to continue to work with physicians and subspecialists through the rulemaking process in order to create a stable and equitable payment system. RBMA looks forward to continuing discussion with the agency about these and other issues that impact the practice of radiology. If you have any questions or comments about our letter, please contact Robert Still at Bob.Still@rbma.org.

Sincerely,

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President

Robert T. Still, FRBMA
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