RADIATION THERAPY ALLIANCE

21st Century Oncology, Accuray, Association of Freestanding Radiation Oncology Centers & Large Urology Group Practice Association

1425 K Street, NW | Suite 650 | Washington, DC 20005 | 202 442-3710

June 27, 2016

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

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS–5517–P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-P)

Dear Administrator Slavitt:

The Radiation Therapy Alliance (RTA) is pleased to offer its comments to the Centers for Medicare and Medicaid Services (CMS) on the Proposed Rule: *Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models* (CMS-5517-P)[1]. The RTA represents 235 freestanding cancer care facilities in 25 states caring for approximately 100,000 patients annually. The RTA was established to provide policymakers and the public with a greater understanding of the value that community-based radiation therapy facilities bring to their patients and of the importance of logical, predictable payment reform to align incentives and ensure patient access to quality cancer care. RTA members include provider organizations such as 21st Century Oncology, the Association of Freestanding Radiation Oncology Centers, the Large Urology Group Practice Association, as well as the equipment manufacturer, Accuray.

The RTA appreciates this opportunity to comment on the proposed regulations. This letter will comment on the following issues:

- Overview of the MACRA Proposed Rule
- Proposed Advanced APM for Radiation Oncology
- Performance Year for Advanced APMs
- Timely Feedback and Transparency of Submitted APMs
- Conclusion

[1] Federal Register, 81 FR 28162 (May 9, 2016)

OVERVIEW OF THE MACRA PROPOSED RULE

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) streamlined various quality payment programs affecting clinicians into a single framework and advanced a pathway for providers to be paid through alternative payment systems. Specifically, the proposed rule would implement two paths for physicians:

- The Merit-based Incentive Payment System (MIPS), essentially an updated version of the current "fee-for-service" system; and
- Advanced Alternative Payment Models (AAPMs), which are new payment systems outside of the "fee-for-service" system.

It is important to note that while under the MACRA statute physicians will be paid according to these systems staring in 2019, under the proposed rule, **the performance year for these programs begins on January 1, 2017.**

PROPOSED ADVANCED APM FOR RADIATION ONCOLOGY

Due to payment instability and unpredictability in the Medicare Physician Fee Schedule, the RTA has supported episode-based case rates as a better payment model for radiation therapy reimbursement and began presenting RTA commissioned research to CMS on such models as early as 2011.[2] Although early models focused on prostate external-beam radiation therapy, the RTA believes a procedural episode-based AAPM now could be constructed around outpatient radiation oncology treatment episodes for most cancers. Patients who receive radiation therapy treatment routinely receive a distinct set of outpatient procedures that could be bundled into a single payment to encourage greater efficiency for care delivery. These episodes are predominantly defined by the presence of distinct CPT codes that are used by providers to denote the actual delivery of radiation treatment.

Opportunities to improve the quality of care and reduce expenditures

We believe every common and most uncommon oncology disease states that require radiotherapeutic intervention are amenable to an episode of care based payment model. Pathways have been developed to treat these diseases in a coordinated manner (e.g. ASTRO Treatment Guidelines, ACR Appropriateness Guidelines, NCCN Guidelines) using literature evidence and expert consensus panels. However, the billing methodology explicit in the CPT/HCPCS

[2] See, for example, the Avalere White Paper, *An Analysis of a Proposed Medicare Bundled Payment System for Freestanding Radiation Centers*, May 2011

descriptors for radiation oncology and developed in the late 1970s to early 1980s to describe procedures, and their professional oversight incents an atomized approach to treatment rather than holistic disease management. As such, the current system always rewards complexity, fee-for-service and volume rather than optimum cancer outcomes and improved patient experience.

As cancer treatment improves and local control rates (i.e. the arrest of cancer growth at the site of origin) in the 70-100% range are being achieved, physicians (through prospective clinical studies and well-designed registries) are examining when shorter courses of therapy and even less intensive therapy is appropriate. While increased treatment complexity is sometimes necessary in order to avoid side effects, lower doses, and decreased numbers of treatments may be optimal. Shifting from a "high volume, high dose, low tech" approach to a "lower volume, lower dose, higher-tech" approach presents a higher standard of care in radiation oncology but that change is inhibited when the reimbursement methodology is both radiation modality specific and the payment remains per treatment or procedure.

Important Considerations in Defining the Episode

The RTA believes there are five key factors that must be considered when designing a radiation oncology episode. These factors include: episode duration; episode services; episode participants; the intent of treatment; and disease state.

- *Episode Duration:* Most patient who receive radiation therapy treatment for cancer require between 3-5 weeks of care. However, some patients may require shorter therapy, especially if the treatment intent is palliative. Likewise, some patients may require more than 5 weeks of care. The episode-based bundled payment may need to allow for both shorter and longer than average episodes. Of course, guardrails would be appropriate to ensure that patients are receiving the standard of care as defined in the consensus guidelines from peer-reviewed literature that would protect against potential under-treatment.
- *Episode Services:* Patients who receive radiation therapy treatment will largely receive a limited set of services that are directly related to the actual provision of radiation therapy. However, these patients may also receive care that is unrelated to radiation therapy, and should therefore be excluded from any radiation payment bundle.
- *Episode Participants:* Radiation therapy can be provided in either a freestanding radiation therapy center or in a hospital outpatient department, where the costs of capital equipment, vault construction and shielding, and highly qualified clinical staff are equivalent. The RTA believes CMS should work with stakeholders to develop consistent payment policies across both sites of services to reduce the risk that one site of service is disadvantaged, which may lead to large shifts in care settings, consolidation and closures

in communities, and limits patient access to innovative technologies that may only be available in a particular community in one setting.

- *Intent of Treatment:* Patients may receive radiation therapy for curative treatment or palliative relief of symptoms. Often, the intent of the treatment determines the number of sessions a patient will receive, which in turn determines the overall resources necessary for the episode. The episode should account for this intent as an upfront adjustment.
- *Disease state:* Clearly, episode-based payment would differ based on the type of cancer (e.g. breast cancer vs. prostate cancer) and may need to be appropriately risk-adjusted to reflect the patient's complexity.

Continuing the Effort to Build Oncology Case Rates

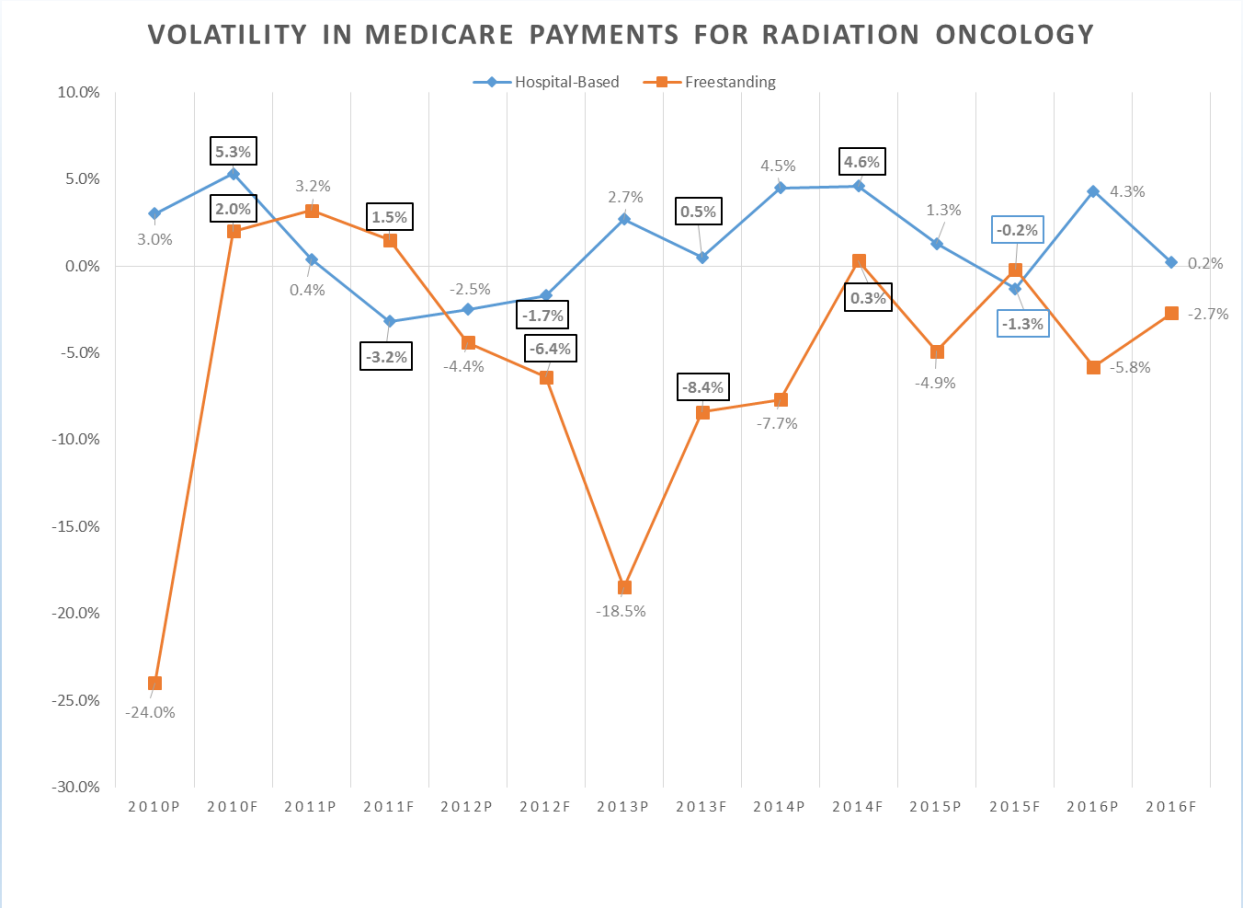
For most cancer conditions, multiple therapeutic modalities – namely, surgery, radiation therapy and chemotherapy – are available for the care of the patient. In some cases, one modality may be used in order to augment effectiveness of another. An example is the use of post-operative radiation therapy following lung cancer surgery to sterilize any residual microscopic disease and therefore improve the opportunity for cure. In other cases, one modality may be used as a replacement for a more traditional treatment when the patient may be judged to be a poor candidate for the traditional therapy. An example is the use of radiation therapy in place of surgery to treat a lung cancer patient who may otherwise be too ill for an operation. One result of this variable utilization of different cancer treatments for a common disease is the challenge of accounting for all therapeutic possibilities within the structure of an episodic payment system.

To address this challenge, we have developed a 'bottoms-up' approach of seeking to complete a system of disease-specific, episodic payments for radiation therapy services first and later integrating surgical and medical oncology as alternative payments systems around those disciplines. We envision a modular method of constructing episode-based payments for specific conditions where the costs of appropriate services and supplies are determined for each discipline and then integrated and managed by a set of clinical and business rules that govern the care of the patient and ultimately the distribution of payments to the providers participating in that care. We believe such a system allows for the flexibility of different modalities to be used for common conditions as clinically appropriate while facilitating patient access to the multiple physicians who may have a component of the overall care to provide.

Considerations in Implementing a Radiation Therapy APM

The challenge to implementing payment reform within radiation therapy was the same challenge faced by Congress when addressing the untenable sustainable growth rate (SGR). That is, in

order to encourage providers to move to more integrated, coordinated care possible under APMs, the SGR had to be repealed and replaced with predictable conversion factor updates over the long-term. Similarly, it would be imperative that underlying volatility in Medicare Physician Fee Schedule relative value units (RVUs) for radiation therapy also be removed as a barrier to payment reform. As indicated in the chart below,[3] this volatility has been such that Congress felt compelled to enact legislation providing a freeze for key radiation therapy services until the 2019 start date for APMs contemplated in MACRA.[4]



Although a bundled, episode-of-care payment system will incent salutary cost efficiencies in the program, a way to guarantee savings would be to establish case rates for the new system at some lesser percentage of prior year spending for radiation therapy services, such as was achieved in the ESRD setting. We believe this could be structured in way that is both consistent with the risk parameters provided in the MACRA proposed rule and which maintains payment stability until the new radiation therapy APM is substantially adopted. Without such a structure, the payment

[3] Source: Physician Fee Schedule Regulation Impact Tables, Chart Shows Percent Change in Estimated Medicare Payments from Prior Year (P = Proposed Rule; F = Final Rule)

[4] S.2425, the Patient Access and Medicare Protection Act

volatility inherent in the underlying Physician Fee Schedule will preclude stakeholders from establishing appropriate payment case rates for two key reasons. First, payment volatility will force stakeholders to focus on addressing payment concerns in a given year, rather than focusing on the development of the new payment system. Second, it would make it impossible for stakeholders to reach agreement on case rates as the total pool of resources for such a system would continually change from year to year.

PERFORMANCE YEAR FOR ADVANCED APMS

As noted earlier in this letter, CMS has set a 2017 performance period for the 2019 payment year for AAPM participation. This is a serious problem. The January 1, 2017 start date of the AAPM performance year will prevent the vast majority of physicians from having any possibility of being qualified for these payments. **We strongly urge CMS to adopt a radiation oncology AAPM this year (i.e. in calendar year 2016) as described above or, if that is not possible, to adjust the performance period for the 2019 AAPM payment year to give physicians additional time in 2017 to become Qualifying APM participants in 2019.**

TIMELY FEEDBACK AND TRANSPARENCY OF SUBMITTED APMS

Under MACRA, providers are strongly incentivized to move to APMs. However, the Agency's proposed processes for evaluating and approving such models in an efficient manner, are inadequate and lack transparency. CMS provides no guidance on timeframes to review and approve/disapprove a submitted APM proposal even for the statutorily-created Physician Focused Payment Model Technical Advisory Committee. Indeed, under the proposed rule, CMS may only issue its own APMs at sporadic times, leaving most specialists with no viable model. For example, in Table 32 of the proposed rule, only certain nephrologists and oncologists could participate in an Advanced APM.

The final rule should require CMS to review and issue a decision on a submitted APM within 90 days. If the APM is not approved, CMS should enumerate the specific deficiencies in the application so that the applicant can address and potentially rectify the problems. Without this transparency, stakeholders will not know why their APM applications were denied or if it was even reviewed.

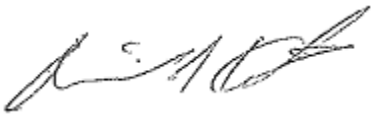
The need for improvements in the evaluation and approval process is urgent, given that MACRA establishes increasingly stringent standards, such as the percentage of payments required, for QPs every year.

CONCLUSION

The uncertainty and volatility that the annual PFS process creates are a significant burden on the ability of the freestanding radiation oncology industry to provide quality care to patients. We urge CMS to continue to pursue a radiation therapy AAPM to incent quality outcomes instead of the current fee-for-service structure, which incentives volume. The RTA remains committed to the pursuit of payment reform in the form of an episode-based, bundled payment combined with appropriate quality metrics. Fundamental to the establishment of this new, episode-of-care system is a stable payment structure to allow stakeholders to focus on long-term payment reform instead of near-term payment volatility. As we have maintained since the establishment of the RTA in 2010, only fundamental payment reform can create the proper incentives and the predictability necessary to improve outcomes and control costs.

If you have additional questions regarding these matters and the views of the RTA, please contact RTA Executive Director Andrew Woods at (202) 442-3710.

Sincerely,



Michael Katin

Chair, Radiation Therapy Alliance Policy Committee