RADIATION THERAPY ALLIANCE

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

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November 17, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3321–NC
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models

Dear Acting Administrator Slavitt:

The Radiation Therapy Alliance (RTA) appreciates the opportunity to submit comments in response to your recent Request for Information (RFI).[1] The RTA represents 296 freestanding facilities in 35 states and was established to provide policymakers and the public with a greater understanding of the value of community-based radiation therapy facilities and the importance of logical, predictable payment reform to align incentives and ensure patient access to high-quality cancer care. RTA members include 21st Century Oncology, Association of Freestanding Radiation Oncology Centers (AFROC), Large Urology Group Practice Association (LUGPA), and Vantage Oncology.

We appreciate the opportunity comment on the implementation of Medicare payment reforms in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The RTA strongly supports the MACRA legislation as it both mitigates the risk of large reductions in reimbursement through the repeal of the SGR and aligns physician reimbursement with value and quality of care for patients as opposed to the current fee-for-service reimbursement structure. While the RTA has serious concerns regarding the adequacy of reimbursement for freestanding radiation oncology providers under the physician fee schedule (PFS), we remain hopeful that those issues will be favorably resolved and that radiation oncologists can participate in an effective and well-tailored alternative payment model (APM).

Below are detailed responses to questions raised in the RFI. These questions fall broadly within the categories of (1) eligible APM entities and (2) physician-focused payment models (PFPMs). CMS notes that it published an RFI on specialty practitioner payment model opportunities on February 11, 2014, and that comments received in response to that RFI also will be considered in developing the proposed rule for the criteria for PFPMs. The RTA responded to that RFI, and

[1] 80 FR 59102

encourages CMS to continue to rely on that March 25, 2014 RTA submission as well as this response. As we noted, the previous RFI described radiation therapy as an example of a therapeutic intervention where "significant opportunities exist for specialty practitioner engagement in care redesign" and one that was "conducive to an episode-based payment model." We continue to agree with that assessment.

We envision a modular method of constructing episode-based payments for specific conditions in which 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 as well as payments to the providers of that care. We believe such a system should encompass different modalities as clinically appropriate for common conditions while facilitating patient access to multiple physicians in multiple specialties across multiple sites. Radiation therapy offers a ready modality to begin the effort since detailed protocols and published clinical guidance are available to serve as a foundation for building episodic payments in oncology.

I. ELIGIBLE APM (EAPM) ENTITIES

What entities should be considered EAPM entities?

As noted in the RFI, an EAPM entity is defined as an entity that (1) participates in an APM that requires participants to use certified electronic health record (EHR) technology and provides payment for covered professional services based on quality measures comparable to measures under the performance category in the Merit-Based Incentive Payment System (MIPS) and (2) bears financial risk for monetary losses under the APM that are in excess of a "nominal amount" (or is a medical home). Providers must meet a minimum percentage Medicare payment threshold beginning in 2019 that will increase each year. Beginning in 2021, the formula allows payments from all payers to meet the threshold. Success of the EAPM will depend on adequate volume of data to drive practice transformation. In terms of governance and leadership/management, we believe that the following criteria should be considered when defining EAPM entities:

Governance

Entities participating in APMs will likely come in many shapes and sizes. In establishing more detailed guidance in the future, we recommend the following principles/criteria:

- Authority to execute the functions of the APM, including defining processes to promote evidence-based medicine and patient engagement, reporting on quality and cost measures and coordination of care, and the appointment and removal of an executive officer;
- Authority for final decision-making;
- A conflict of interest policy that applies to members of the governing body, requires disclosure of all relevant financial interests and other conflicts of interest, identifies processes for resolution of conflicts of interest, and sets forth remedial processes for noncompliance;
- A transparent governing process to ensure that CMS has the ability to monitor and audit as appropriate;
- A provider-driven decision-making process, since providers will be at risk as owners and non-owner participants, and, accordingly, a minimum floor such as 75% control;

- Prioritization by members of their fiduciary duty to the entity before the interests of any participant or provider/supplier or other individual or entity; and
- Inclusion of an independent Medicare beneficiary representative or a trained and/or experienced nonaffiliated, independent consumer advocate in the governance structure to ensure representation of patient interests.

Leadership and Management
An EAPM entity should have a leadership and management structure that includes clinical and administrative systems that align with and support the goals of the EAPM entity and the aims of better care for individuals, better health for populations, and lower growth in expenditures. The EAPM will accomplish these goals by clinical integration of the members of the EAPM using common infrastructure and processes.

The EAPM entity's operations should be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the EAPM entity's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes. Clinical management and oversight should be managed by a senior-level medical director who should be (1) a board-certified physician; (2) licensed in a state in which the EAPM operates; and (3) physically present on a regular basis at any clinic, office, or other location of the EAPM, an EAPM participant, or an EAPM provider/supplier.

Other Considerations
While we recognize that there may be administrative challenges to avoid "double billing," we suggest that beneficiaries and clinicians have the ability to participate in more than one APM each year to provide access to all necessary care and to enable clinicians to participate in APMs, thereby satisfying APM participation thresholds.

For example, many oncology patients will have multiple comorbidities that may be treated by more than one group of specialists. Indeed, because cancer is more episodic, one could expect that many patients would already be receiving care from another APM for chronic conditions. If a majority of a patient's care is, for instance, for heart disease, but he or she develops a malignant disease that requires radiation, involvement in the internal medicine APM would tend to prevent the patient from having radiation care rationalized. By allowing beneficiaries to participate in more than one APM each year, they can receive the coordinated care they need from each specialized APM.

For clinicians, it is important to allow them to share in savings from multiple models being developed in the marketplace. EAPMs should be tied to both identified physicians and specified practice venues. Since, not unlike other specialties, physicians who practice in the radiation oncology sector may see patients in more than one practice venue (and under more than one TIN), the limitation of one APM per year may prevent these physicians from participating in a lower-cost venue for at least part of the time.

Also, participation in one Medicare APM should not preclude participation in parallel APM development by commercial payers. In fact, we recommend including language to encourage

these parallel APM efforts by commercial payers. APM success will substantially increase with commercial payer participation .

To this end, we recommend the identifiers for the EAPM be based on NPIs tied to TINs rather than TINs exclusively, and accommodate specified practice sites. The union of these physicians (identified by their NPIs) practicing at all of the specified sites should be limited to a single radiation oncology APM.

In addition, we do not believe an EAPM should be at risk for total Medicare spending (Part A and Part B). Under a radiation therapy episodic-payment model, we believe an EAPM entity should only be at risk for the spending related to the case rate for the episode itself. This would include not only the radiotherapy care, but also management of toxicity directly or indirectly attributable to the radiotherapy care. However, an oncology-focused EAPM entity should not be at risk for other spending outside of the bundle due to the multiple chronic comorbidities often present among Medicare beneficiaries.

Under section 1833(z)(2)(D) of the Act, the Secretary can use percentages of patient counts in lieu of percentages of payments to determine whether an EP is a QP or partial QP. Should this option be used in all or only some circumstances? If only in some circumstances, which ones and why?

We believe that the statute clearly gives the Secretary broad authority on the approach to determine an EP's eligibility and, as such, should be applied. Individual providers and practices may differ depending on specialty, payer mix, and services provided that may achieve this threshold. EPs that want to participate in an EAPM ought to be given as many options as possible to meet the thresholds of the program. As it is the goal of the APMs to increase participation and services, EPs with various case specialties and case mixes should be enabled to meet the criteria. EPs should have the option to elect to use percentages of patient counts in any given year. At least initially, the criteria should not be limited to certain circumstances.

What criteria could be considered when determining "comparability" to MIPS of quality measures used to identify an EAPM entity? Please provide specific examples for measures, measure types (for example, structure, process, outcome, and other types), data source for measures (for example, patients/caregivers, medical records, billing claims, etc.), measure domains, standards, and comparable methodology.

In addition to radiation oncology quality measures currently utilized under Medicare's Physician Quality Reporting System (PQRS) program, the EHR Incentive Program might be used to demonstrate "comparability" to measures under the performance category in the MIPS. Our March 25, 2014 comment to the RFI on specialty practitioner payment model opportunities envisioned that a new radiation therapy APM also would involve (1) physician adherence to evidence-based guidelines (e.g., such as those developed by, or consistent with those of, the American Society for Radiation Oncology, American College of Radiation Oncology, and American College of Radiology); (2) reporting to a qualified clinical data registry; and (3) the collection of meaningful outcomes data. That comment letter provides details for a number of specific outcomes data we believe could be used for the development of real-time, evidence-based guidelines and quality measures that continuously evolve alongside advancements in cancer care. We believe such guidelines could be even more impactful than current quality

measures used in Medicare's PQRS program and EHR Incentive Program and other related quality initiatives. By allowing reporting through qualified clinical data registries, specifically of outcomes, data can be collected specific to disease or condition, which could foster further care coordination and improvement in an APM.

What components of certified EHR technology as defined in section 1848(o)(4) of the Act should APM participants be required to use? Should APM participants be required to use the same certified EHR technology currently required for the Medicare and Medicaid EHR Incentive Programs or should CMS consider other requirements around certified health IT capabilities?

For the rollout of the EAPM, the participants should be required to conform to **any** Certification Commission for Healthcare Information Technology (CCHIT)-approved radiation oncology EHR that will meet the requirements of Stage 3 Meaningful Use, though for smaller practices there may need to be a transition period. Since the data gathering necessary to validate the model will require ICD-10 diagnostic information (and comorbidities), American Joint Committee on Cancer TNM stage, tumor grade, radiation dose and fractionation data, patient-reported morbidity and quality of life information, local control and survival information, and financial outcomes, the use of any CCHIT-approved EHR should allow for data extraction.

What is the appropriate type or types of "financial risk" under section 1833(z)(3)(D)(ii)(I) of the Act to be considered an APM entity?

In April 2014, CMS stated that even though Medicare Shared Savings Program participants have the option to accept either one-sided or two-sided risk, they must operate under a two-sided risk agreement after the first agreement period.[2] We agree that EAPM entities should share financial risk but only after being given sufficient time to allow entities to operate under the APM. An implementation period and sufficient time post practice transformation must be considered when deciding on the first agreement period duration. We suggest that the time period be similar to that used within the various ACO models and the Oncology Care Model (OCM).

A new benchmark is to be established at the beginning of each agreement period, but rebasing should not occur on a yearly basis. Twelve months is too short and will not allow predictability and stability for practice transformation. During the initial agreement period, CMS must allow for practice transformation to occur and reach equilibrium. Both financial and clinical positive outcomes must be in alignment to be considered a sustainable transformation.

Because the entity will be driving cost out of the system before the time of the next agreement, CMS should consider adjusting the discount percentage down. This will help incent providers to become more efficient year after year. There should be a reasonable interception between benchmark recalibration that includes savings already achieved and the discount rate that CMS applies each agreement period. Otherwise, entities and participants will be penalized for success.

[2] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Methodology_Factsheet_ICN907405.pdf

Most importantly, reimbursement cannot be less than the cost of care, as oncology centers operate with high fixed costs owing to the cost of the linear accelerator and the radiation therapy vault as well as related expenses. Decreasing reimbursement by hypofractionation, referral of patients from higher-cost to lower-cost environments, elimination of duplicative and unnecessary services, and operational efficiencies will eventually reach a point where the fixed costs can no longer be amortized. In a two-sided risk scenario, there should be consideration for risk corridors for outlier patient cases that can protect smaller provider groups that may not be able to absorb outlier risks with smaller patient pools. If there is no protection against outlier cases, it may preclude providers from opting into the two-sided risk model. A goal of APM compensation should be to reimburse for the total cost of maintaining an optimized oncology center able to deliver the entire range of medically appropriate radiation care with a mutually agreed upon patient census, normalized for venue (e.g., rural vs. urban), and a mutually agreed upon margin. The cost of care calculation will be flawed if it is calculated based on the current fee-for-service reimbursement structure.

What is the appropriate level of financial risk "in excess of a nominal amount" under section 1833(z)(3)(D)(ii)(I) of the Act to be considered an APM entity?

Please see our above comments. We suggest that the initial agreement period incorporate a one-sided risk model in which the EAPM is targeted to produce savings in order to share in them but is not at risk if the desired level of savings is not achieved. After the first reimbursement period, we suggest that levels of financial risk for the two-sided risk model be similar to those utilized in the OCM, subject to the above comment that the two-sided reimbursement target should not subject the entity to a degree of savings greater than the total cost of delivering the care. Also, total cost of care must be recalibrated as necessary if there are market changes. For example, at the time of APM maturation, operating costs and margins may differ from what they are today.

II. PHYSICIAN-FOCUSED PAYMENT MODELS

How should "physician-focused payment model" be defined?

Our previous comment to the RFI on specialty practitioner payment model opportunities provided details relating to a procedural episode-based payment model constructed around outpatient radiation oncology treatment episodes. This model contemplated reimbursement for technical and professional services (e.g., treatment delivery, planning, and other related services such as treatment-related imaging) in a single, bundled payment (or case rate) rather than the current fee-for-service approach of billing codes for individual treatments. ***We urge CMS to make this radiation oncology APM option available for radiation oncology providers as soon as possible, but no later than 2019.***

What criteria should be used by the Physician-focused Payment Model Technical Advisory Committee for assessing PFPM proposals submitted by stakeholders?

We believe that the Committee should, among other criteria, look to what is already being utilized effectively in the private sector. Our previous comment to the RFI on specialty practitioner payment model opportunities noted that an episode-based alternative payment model for radiation therapy already exists in the private sector. This agreement between a leading radiation therapy provider and a leading private payer has been in routine and successful

operation for almost four years. By establishing a bundled, episode-based payment in conjunction with a patient satisfaction survey and collection of outcomes data, this agreement encourages efficienct and high-quality care.

Under the agreement, each bundled payment calculates reimbursement based on technical and professional radiation therapy services that would be appropriate for a patient with a particular diagnosis over the entire episode of care, depending on cancer diagnosis, stage, treatment, and comorbidity. Under a fee-for-service methodology, each technical and professional service is otherwise billed separately, typically creating 50–100 unique charges and significant administrative burden for both the insurer and provider. The services included within each cancer-specific bundled payment were codeveloped by insurer and provider medical advisors and are founded on current evidence-based best medical practices. The ongoing agreement is national in scope and includes nearly 150 facilities in 17 states and all commercial as well as Medicare plan beneficiaries treated by the provider. Greater ease in adjudicating claims under this agreement has resulted in meaningful savings in direct and indirect costs for both the provider and the health insurance plan.

Patient satisfaction surveys also are collected and scored quarterly. Domains of patient satisfaction, including the patient's insurance experience – inclusive of satisfaction with pre-authorization procedures and explanation of copayments – are among those studied and have improved significantly during the agreement period. Short- and long-term toxicities and complication rates are also tracked by the provider's longitudinal patient registry, have remained low, and support the position that high-quality care and more efficient payment systems in health care can and should coexist.

It is critical that CMS develop an efficient and accelerated process to ensure that those models accepted and recommended for implementation based on the Committee's criteria be considered APMs. Without an efficient and timely process, those with worthwhile models will languish or look for legislative relief.

Conclusion

Thank you for the opportunity to respond to this RFI. The RTA believes that radiation therapy is a well-suited modality for the payment reforms intended by MACRA, and we look forward to working collaboratively with CMS as these models are developed. 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,

Christopher M. Rose, M.D., FASTRO

Chair, Radiation Therapy Alliance Policy Committee