March 1, 2021

Elizabeth Richter
Acting Administrator, Centers for Medicare and Medicaid Services
The U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Ms. Richter:

On behalf of the radiation oncology stakeholder community, including radiation oncologists, members of the radiation oncology cancer care team, group practices, hospitals, patient advocates, device manufacturers and more, we are writing to share our collective concerns about the Radiation Oncology (RO) Model, as it is currently designed, in the hopes of working with the new Administration to achieve our shared goals of value-based radiation oncology care. Ultimately, we believe that the RO Model is overly focused on achieving significant savings, at the risk of hurting access to care and quality. We understand that the Centers for Medicare and Medicaid Innovation (CMMI) is developing a proposed rule, and we want to ensure that our common concerns are fully understood and considered for incorporation into the RO Model proposed rule. We appreciate President Biden's longstanding leadership in the fight against cancer, and we believe the RO Model, with reforms, represents a real opportunity to advance radiation therapy care for cancer patients. The community remains committed to a RO Model that balances the needs and goals of Medicare and radiation oncology, while ensuring patient access to high value cancer care.

Transparency and an open dialogue with all members of the CMMI team involved in model development, including actuarial staff and policy staff, will be critical to the model's success. We urge the Agency to provide the radiation oncology community with the data used to formulate the various components of the payment methodology so that those required to participate under the RO Model have the opportunity to fully anticipate its impact and point to any flaws that may need to be addressed prior to implementation. We appreciate your consideration of the issues below and welcome the opportunity to meet with you to discuss these topics and address any questions.

Payment Methodology

<u>Discount Factor</u>

The application of a 3.75% discount off the Professional Component (PC) and 4.75% discount off the Technical Component (TC) fails to recognize that radiation oncology services rely heavily on the use of advanced technology and equipment and highly skilled staff that requires a significant financial investment, which is likely beyond that of anything else in medicine. The minimum total capital required to open a freestanding radiation oncology center is approximately $5.5 million. These facilities require an additional minimum $2 million in annual operating and personnel expenses. These significant fixed investments far outweigh the variable costs of operating a radiation oncology clinic and should be given far greater consideration as part of any

alternative payment model. While it is important to reduce the cost of care and drive value in healthcare, it is also important to ensure that efforts to generate savings do not cause access to care issues for patients by limiting practices ability to offer state-of-the-art radiation therapy delivered by expert clinical staff. This is particularly important for practices operating in rural areas.

Additionally, over the last ten years, radiation oncology total allowable charges have represented a declining portion of the total MPFS allowable charges. The overall $47 million or 3% decline in allowable radiation oncology charges between 2010 and 2020 pales in comparison to the overall $15.7 billion or 17% increase in total MPFS allowable charges over the same period. Radiation oncology has proven itself to be a high value form of cancer treatment. That value should not be eroded through the application of severe cuts that will reduce access to care.

We urge CMS to reduce the discount factors to 3% or less to ensure that practices can continue to operate successfully under the RO Model. This will ensure continued financially viability, while also meeting the MACRA nominal risk requirement, and would align RO Model discounts with those from other two-sided risk advanced APMs.

National Base Rates

CMS bases the National Base Rate calculation for the PC and TC on hospital outpatient prospective payment (HOPPS) data from 2016-2018. This data includes palliative care cases, which are frequently treated with ten or fewer fractions using 3-Dimensional therapy. By including palliative care cases, CMS has undervalued the cost of curative cases, particularly those that may require more expensive modalities of treatment. **We urge the Agency to revalue the National Base Rates based on cases with curative intent and establish a separate episode of care specific to palliative treatment.**

Additionally, because the National Base Rates payment rates are based on HOPPS, they do not adequately account for the cost of care involving services delivered in the freestanding setting, particularly for professional services. **We urge CMS to blend the historical MPFS and HOPPS rates for the PC of each cancer type to establish a more accurate payment rate. We believe that a blend more accurately accounts for the professional work taking place in both sites of service.**

Additionally, we urge the Agency to calculate the National Base Rates using data that rewards the delivery of guideline concordant care. As an example, the current methodology does not reflect the costs of guideline concordant care associated with cervical cancer, which involves both external beam therapy and brachytherapy for the treatment of cervical cancer. As a result, the National Base Rate for the cervical cancer episode is undervalued and will fail to incentivize guideline concordant care. Since cervical cancer is predominantly seen in women with poor access to health care, this decision further widens the health care disparities for socioeconomically disadvantaged populations. There are other clinical scenarios involving specialized multimodality treatment that are similarly disincentivized under the model that must also be addressed through the application of guidelines as a framework for appropriate payment.

Trend Factor

A stated purpose of the RO Model is to ensure rate stability throughout the demonstration period. The Trend factor methodology incorporates the Medicare Physician Fee Schedule (MPFS) and

Hospital Outpatient Prospective Payment System (HOPPS) rates as part of an annual update for the PC and TC of each disease site. If the MPFS and HOPPS experience significant payment shifts from year-to-year, that will create fluctuations in the payment rates within the RO Model. The goal of rate stability cannot be achieved unless there are guard rails established that prevent significant rate fluctuations in the existing MPFS and HOPPS from influencing the RO Model. **We urge the Agency to consider Trend Factor guard rails that will prevent significant shifts in payment rates under the RO Model.**

Case Mix Adjustment, Historical Experience, and Blend Factor

CMS introduced the Case Mix and Historical Experience adjustments in the proposed and final rules with only a cursory high-level explanation of how these methodologies were calculated. CMS also did not provide data tables to practices selected for the RO Model that were used to calculate these adjustments. **We urge CMS to provide information regarding the calculation of these methodologies, as well as the data used to determine the adjustments, so that practices compelled to participate in the RO Model can confirm their accuracy. Additionally, we urge the Agency to establish a COVID-19 adjustment to account for the growing evidence that patients will present with more advanced stage disease requiring more expensive treatment due to pandemic related treatment delays. This includes consideration for how significant reductions in revenue and patient volumes during 2020 could potentially impact the Case Mix Adjustment, once 2020 is included in the rolling three-year average.**

The Historical Experience Adjustment is used to determine the Blend, which determines the weighting between a practice's historical payment versus the National Base Rate over the duration of the RO Model. Practices cannot replicate their Historical Experience Adjustment to ensure that the methodology correctly reflects their historical payments. Furthermore, we remain concerned that the Blend has the potential to harm efficient practices. Efficient practices may recognize the 90% weighting for historical experience over the four-year demonstration; however, due to the lower overall episode-based payments they will receive, they are more likely to be put at financial risk for taking on more complex and expensive cases. This is particularly acute given concerns about growing rates of patients presenting with later stage disease requiring more expensive treatment, as described above. Additionally, the blend does not recognize the appropriate use of more expensive modalities of treatment. It is merely a means of bringing payments in alignment with the National Base Rates with little regard for guideline concordant care or more expensive treatment modalities, which may be necessary and appropriate due to each patient's unique needs. **We urge the Agency to reconsider the Blend and work with the stakeholder community to implement a methodology that addresses the flaws as outlined above.**

New Equipment and Service Lines

The RO Model does not recognize the continued evolution of technology that frequently provides clinical benefit and warrants the investment in new equipment and service lines; an investment that would not be captured in the 2016-2018 baseline data used to calculate a practice's episodic reimbursement. Failure to account for new equipment and service lines creates an unfair and uneven playing field between those markets required to participate in the RO Model and those outside the model. **We urge the Agency to consider the application of a rate review mechanism or some other formula for recognizing the need for upgrades, new**

equipment and new service lines, that provides equal support for all radiation oncology modalities, departments, and practices. Without such a mechanism, practices that are compelled to participate in the model will be unable to meet the evolving clinical needs of their patients and will be put at a clear competitive disadvantage in comparison to practices outside the model.

Exclusion of Brachytherapy Sources

Section 1833(t)(2)(H) of the Social Security Act requires that brachytherapy source payments be made separately from professional services. Currently, brachytherapy sources are paid at individual rates based on the type of radioactive source. Given the inherent differences in the types of sources needed for clinical care (including half-life, energy, dose rate, production in a medical reactor or cyclotron, and costs associated with manufacturing of the sources) the costs of each source can vary significantly and need to be ordered and made specifically for each patient. Billing for each patient would be based on the differences in isotopes, radioactive intensity, and the number of isotopes that are required for treatment of the individual patient. In the RO Model final rule, CMS excludes Yttrium-90 a "radiopharmaceutical" from the list of bundled HCPCS codes, so that it may be billed FFS. However, the Agency did not apply this exclusion to all brachytherapy sources, which jeopardizes the continued practice of this long-established, efficacious and decidedly value-based treatment option. **We urge CMS to exclude all brachytherapy sources from episode payments under the RO Model and allow them to be paid separately at the FFS rate per source.**

Quality Reporting Requirements

The RO Model establishes new burdens associated with quality and clinical data collection and reporting requirements. Practices will have to create separate billing systems, hire additional staff and devote significant staff time to learning the model and completing model functions, all while still reeling from staff layoffs and hiring freezes associated with the ongoing pandemic. Time spent on needless input of data that does not result in improved patient care is time poorly spent and a harmful distraction. **We urge the Agency to consider a stepped approach to the implementation of data collection and reporting requirements under the RO Model.**

Additionally, we remain concerned that small and rural practices will be required to use their already limited resources to adopt and implement certified EHR technology (CEHRT) in addition to other reporting requirements as required under the RO Model. The Merit Based Incentive Payment System (MIPS) exempts small and rural practices from these requirements. The RO Model 20-episode threshold opt-out option for low-volume entities is unlikely to address this issue, given that many small and rural communities have older populations, many of which are Medicare beneficiaries. The Agency has a long history of committing to the alignment of reporting systems, to ease the reporting burden of clinicians. **We urge CMS to apply that same approach to the RO Model and provide accommodations and exemptions for small and rural practices in multiple areas of performance. This is particularly important given that these practices continue to struggle during the COVID-19 PHE.**

Clinical Data Elements

CMS issued an RFI as part of the RO Model final rule seeking input on appropriate data elements. The deadline for comment submission was October 20, 2020. Several months have passed since that deadline; however, no additional information about the CDE requirements associated with the RO Model have been issued. **We urge the Agency to start with a small data set, based on stakeholder feedback, that allows at least 12-months for standards to be formalized, incorporated by vendors into upgrades, and allows physicians to change workflows to capture the required data.**

Monitoring Requirements

Similar to CDE collection, EHR vendors need time to develop discrete fields for the requested monitoring data elements, as they may be typically captured in clinical notes or external systems. We are concerned that the related financial costs associated with EHR upgrades will be borne by the radiation oncology clinics adding to the financial burden associated with participating in the RO Model. **Again, we urge the Agency to move forward with only those monitoring requirements that demonstrate improved patient care and apply a stepped approach to related data collection efforts.**

Advanced APM and MIPS APM Status

CMS intends for the RO Model to qualify as an Advanced APM and to also meet the criteria to be a MIPS APM. To be an Advanced APM, an alternative payment model must satisfy three specific criteria 1) Use of Certified Electronic Health Records Technology; 2) Payment Based on MIPS comparable quality measures; and 3) Meet the nominal financial risk standard. Another way of meeting the financial risk standard is through capitated arrangement:

> 42 C.F.R. § 414.1415(c)(6) - "a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed to reconcile or share losses included or savings earned by the APM entity."

We urge CMS to recognize the RO Model as a capitated payment arrangement in that it meets the definition set forth in 42 C.F.R. § 414.1415(c)(6) and insist that the Agency apply Advanced APM status to all RO Model participants.

Through greater transparency and meaningful collaboration, we can make the RO Model viable and meaningfully transition radiation oncology from FFS to value-based payment. We look forward to continued discussions and opportunities to engage with the Agency.

Sincerely,

Accuray
AdvaMed
American Association of Medical Dosimetrists (AAMD)
American Association of Physicists in Medicine (AAPM)
American Brachytherapy Society (ABS)
American College of Radiology (ACR)
American Medical Association (AMA)

American Society for Radiation Oncology (ASTRO)
Association of Community Cancer Centers (ACCC)
Association for Clinical Oncology (ASCO)
Boston Scientific Corporation
Community Oncology Alliance (COA)
Elekta
GenesisCare
IntraOp Medical Corporation
International Myeloma Foundation
IsoRay Medical, Inc
Medical Device Manufacturers Association (MDMA)
Medical Group Management Association (MGMA)
Medical Imaging & Technology Alliance (MITA)
Providence
RefleXion
Society for Radiation Oncology Administrators (SROA)
The US Oncology Network
Theragenics Corporation
Varian Medical Systems, Inc.
ViewRay

cc: Amy Bassano, Deputy Director, CMMI
Christina Ritter, Director, CMMI Patient Care Models
Lara Strawbridge, Director, CMMI Division of Ambulatory Models
Marcie O'Reilly, Health Insurance Specialist, CMMI