RADIATION THERAPY ALLIANCE

21st Century Oncology, Oncure Medical Corp., Vantage Oncology, Inc., The University of Pittsburgh Medical Center

1050 K Street | Suite 315 | Washington, DC 20001 | 202 442-3710

December 31, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 [CMS-1590-FC]

Dear Acting Administrator Tavenner:

The Radiation Therapy Alliance (RTA) appreciates the opportunity to submit comments regarding the 2013 Physician Fee Schedule (PFS) Final Rule. The RTA represents over 225 facilities in 21 states providing cancer care to over 80,000 patients annually. The RTA 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 quality cancer care. RTA members include 21st Century Oncology, Oncure Medical Corp., UPMC Cancer Centers, and Vantage Oncology.

We commend CMS for acknowledging updated radiation therapy equipment cost data from the RTA and lowering reimbursement cuts to radiation oncology from 15% in the Proposed Rule to 7% in the Final Rule.

While the cuts to our industry are lower than those proposed, they will not be without consequence to community-based radiation therapy providers. Quality cancer care in the freestanding radiation oncology sector requires acquisition and financing of expensive, long-lived equipment. Consequently, appropriate reimbursement levels and payment stability are essential for continued patient access to this vital form of treatment. The RTA will continue to offer its support to CMS in explaining the impact of funding cuts on the nation's community-based radiation therapy facilities and to pursue payment reform opportunities that better align patient, payor, and provider incentives.

While we are grateful to CMS for correcting reductions in important radiation oncology codes between the Proposed and Final Rules, we would like to take this opportunity to provide additional information regarding the categorization of the linear accelerator enclosure ("radiation treatment vault") as a direct input. In addition, we would like to highlight two outstanding concerns—interest rates for physician equipment and radiation oncology payment reform—that are of great importance to us and the patients we serve.

Updates to Treatment Codes

In our September 4, 2012, letter to CMS regarding the Proposed Rule, we provided data from 140 recent paid invoices to demonstrate the actual current equipment prices related to CPT code 77418 (IMRT delivery). These invoice data show that the costs for the linear accelerator and laser diode are greater than what was assumed in the CMS database. In addition, we noted that the median computer system cost has declined 9%, and the collimator is no longer a separate cost.

We appreciate CMS accepting these data. While we remain concerned about the fundamental methodologies involved in establishing the PFS, we believe that the assumptions now underlying the payment rate for CPT code 77418 are improved. Like other commenters, we also encouraged CMS to include two radiation therapists instead of one for CPT code 77418, and we commend CMS for doing so. Finally, we thank CMS for including seven direct equipment costs that were inadvertently dropped from 77418 in the CY 2012 PFS Final Rule, a matter that the RTA had commented on in our December 8, 2011, letter to CMS regarding that Final Rule.

We have observed, however, what appears to be a technical oversight with regard to the price of the laser diode. ***In the Final Rule, CMS notes with respect to CPT code 77418, "We are also updating the price of the 'laser, diode, for patient positioning (Probe)' (ER040) from $7,678 to $18,160." However, it appears from the Public Use File Table – Equipment file posted on the CMS website that this change did not occur. Instead, the original $7,678 price remains in this database. We request that CMS update this price as intended in the Final Rule as soon as possible.***

Linear Accelerator Shielded Enclosure ("Radiation Treatment Vault")

In radiation therapy, linear accelerators create primary and secondary radiation ("scatter radiation") of sufficient energy to be able to pass through the masonry, lathe, concrete, and even structural steel to expose both the health care professionals and caregivers within the freestanding office and non-radiation workers in adjacent sites in the general purpose medical office building. Therefore, radiation oncology offices are required to install special purpose enclosures for the linear accelerator to protect workers within the radiation office and in adjacent offices.

In clinical terms, the vault (better termed "vault system") is a complex system of materials and equipment that include not only specialized concrete and leaded shielding, but also specialized flooring, power conditioning equipment, and customized radioactive shielding materials that are calibrated to the size and type of linear accelerator that it contains. The radiation physicist needs to do a site survey with a specialized radiation source that mimics the output of the linear accelerator to determine how much hardening of existing walls is necessary and how thick additional walls must be to create an enclosure for the linear accelerator. This radiation "vault" also requires a special lead and plexiglass door in order to block any scattered radiation that might exit the room as a result of collisions of radiation particles against the hardened walls. Every vault is customized with regard to the specific characteristics of the linear accelerator it shields; when a facility upgrades its linear accelerator, the vault also generally requires modifications and upgrades.

In order to assess the state of the patient while he or she is being treated, specialized cameras, microphones, and speakers are built into the enclosure; specialized metal conduits are also built to allow for access of the wiring into adjacent areas without contamination by radiation. Finally, additional service ports need to be created so that ion chambers can be sited in the room but measurements made remotely during treatment or simulation of treatment for quality assurance of the treatment.

This thick enclosure, coupled with a variety of specialized and complex electronic components, is impossible to repurpose for other medical procedures or nonmedical office space. As such, the vault is medical equipment, and the RTA therefore asked CMS in our September 4, 2012, letter to include it as a direct input for CPT code 77418. This is appropriate not only because the linear accelerator enclosure is a real direct input, but also because it is consistent with the vault's inclusion in similar radiation treatment delivery codes. We commend CMS for acknowledging the inconsistency and including the vault as a direct input in CPT code 77418 in CY 2013. ***The RTA notes that CMS also included the vault and water chiller as direct inputs for CPT code 77373 (stereotactic body radiation therapy, or "SBRT") using the same logic, and we encourage CMS to include the vault and water chiller for 77372 (stereotactic radiosurgery, or "SRS") as well.***

We would also like to respond to CMS's concern in the Final Rule over the inclusion of the vault as a direct input:

> *We question whether it is fully consistent with the principles underlying the PFS PE methodology to continue to classify the radiation treatment vault as medical equipment (a direct cost) since it is difficult to distinguish the cost of the construction of the vault from the cost of the construction of the building. The submitted architectural invoices for vault construction illustrate the difficulty in making that distinction. Furthermore, the typical circumstances of the vault's use are unclear, especially regarding whether or not the vault may be servicing multiple patients at the same time.*

The RTA strongly urges CMS to treat the radiation treatment vault as a direct expense, and we offer the following three clarifications in response to CMS's concerns. First, it is of utmost importance to recognize that the radiation treatment vault is directly linked to the linear accelerator and is not merely an extension of the building, as certain architectural invoices may seem to indicate to those not familiar with the unique specifications of the vault system. Indeed, the IRS recognizes the vault as equipment, not structure, and permits taxpayers to depreciate it separate from the building. Facility practice managers and radiation oncologists alike have noted that the vault is necessary for the delivery of radiation therapy, and state regulations contain specific requirements relating to shielding and other aspects of the vault that must be approved by state agencies prior to installation or modification of facilities.[1] In layman's terms, the vault can be analogized to the hood of a vehicle, which shields and protects the engine, as opposed to the garage that houses the car.

[1] See, for example, state regulations in Florida (Fla Admin. Code R. 64E-5.502(2)(e)) and Massachusetts (105 CMR 120.420).

Second, the RTA believes that the vault's useful life is equivalent to that of the linear accelerator (i.e., seven years, rather than the fifteen years that CMS currently assumes). Because the vault is customized with regard to the specific linear accelerator it shields and generally must undergo extensive alterations when a new linear accelerator is installed, it is appropriate to assume the same useful life for both equipment items. CMS currently assigns a seven-year life to the linear accelerator. ***Therefore, we propose that CMS also treat the vault as a seven-year asset.***

An RTA member's review of its equipment financing documents found several instances where vaults were financed by the member's typical equipment financing lenders. These vault financings, provided by GE, CIT, Marcap, Varian, and other equipment finance providers, were on roughly similar terms and conditions as the financings for the linear accelerators, CTs, and other major equipment. In several instances, the vault financing was indistinguishable from the linear accelerator financing, with the equipment financing lender providing a single debt instrument to fund the vault, the linear accelerator, and the other major equipment needed to properly equip the cancer treatment center.

In addition, not only do the equipment finance providers treat the vault as major equipment, but landlords typically do as well. An RTA member's review of its facility leases found that the vault is often excluded from the tenant improvement allowance, as landlords may not treat the vault as medical office space, but rather as specialty medical equipment that is the tenant's responsibility to provide, install, and remove.

Third, regarding CMS's uncertainty about whether the vault can be used to service multiple patients simultaneously, we note that in radiation therapy the vault can only be used for one patient at a time. This is true not only due to space constraints, but also because treatment varies from patient to patient. In addition, state regulations often stipulate that no individual besides the patient receiving treatment may be present in the treatment room.[2]

Outstanding Concerns

1. Interest Rate Assumption for Physician Equipment

In our September 4 letter, the RTA urged CMS to reconsider the agency's proposal to use the Small Business Administration's (SBA) interest rate framework as the reference source for setting the CMS interest rate assumption. This proposal presumed that the SBA rate structure accurately represents financing costs for all physician equipment, but, as we detailed in that letter, the RTA believes that the SBA rates are not appropriate proxies for borrowing costs in radiation oncology. Loans to finance major radiation therapy equipment such as linear accelerators are fixed-rate loans that cannot be refinanced. Therefore, it is not appropriate to rely solely on any current interest rate metric. Instead, a historical average, related to the life of the equipment, is most appropriate.

[2] See, for example, state regulations in Florida (Fla Admin. Code R. 64-E.5.508(4)(d)(1)) and Massachusetts (105 CMR 102.436(R)(6)).

In addition, the SBA maximum rate for equipment costing more than $50,000 with a life of seven years or more is the prime rate + 2.75% (or 6%, given the current prime rate). However, as we noted in September, the actual interest rate spread between observed financing costs in radiation oncology and the historical average prime rate is significantly greater than 2.75%. During the two-year period for which the RTA collected actual financing cost data (January 2008–February 2010), the spread over the prime rate averaged 4.1%.

In our September letter, the RTA detailed several other reasons why the SBA interest rate framework was not applicable to radiation oncology equipment. Nevertheless, CMS did finalize the PFS as proposed with regard to this matter and reduced the assumed interest rate for all equipment from 11% to a "sliding scale" based on the SBA.

The RTA urges CMS to reconsider this decision and investigate actual equipment borrowing costs in radiation therapy. We urge CMS to work with all stakeholders to collect broader survey data on borrowing costs for expensive equipment. Any new data altering the interest rate assumption should be constructed using a rolling average over the life of typical loans, not solely a current-year rate.

At the very least, if CMS chooses to proceed with the sliding scale approach, the RTA recommends that the agency set a flat 8.75% interest rate for equipment valued above $1 million. Again, as noted above, the RTA recommends that CMS use a seven-year rolling average of the applicable interest rate for costly, long-lived equipment.

2. Fundamental Payment Reform for Radiation Oncology

The members of the RTA strongly believe that fair, stable, and predictable reimbursement policy is critical for the development and delivery of the community-based cancer care that we and other freestanding radiation oncology providers offer to patients. As the RTA has previously expressed, we do not find the PFS to be an appropriate framework for reimbursing freestanding radiation oncologists. As CMS is aware, the RTA has developed an episode-of-care bundle proposal for prostate cancer in the freestanding setting. We would like to thank CMS for meeting with us regularly over the last few years as we have refined this proposal, and we remain committed to working with the agency in pursuit of payment reform models that properly align incentives for quality care and cost containment while also creating the necessary payment stability required for the provision of radiation oncology services.

The RTA is continuing to investigate the feasibility of additional and broader bundles in radiation therapy. In conjunction with that effort, the RTA intends also to develop and research effective mechanisms to ensure high quality of care and monitor patient outcomes.

We note that CMS is required to submit to Congress by December 31, 2012, a report on payment bundling, and CMS has said that it will examine episode-based payments in this report. The agency has previously expressed interest in potentially engaging in a radiation therapy bundling project that would explore paying for episodes of treatment and related medical services. We urge the agency to consider including radiation therapy in its report to Congress as a well-suited specialty for this type of reform. We also believe that this report could serve as an opportunity to express to Congress any statutory changes

that would facilitate the establishment of a robust bundled payment reform for radiation therapy. The RTA remains eager to work with the agency, and, if appropriate, with Congress, on fundamental payment reform to achieve reimbursement stability and predictability and ensure patients' continued access to vital radiation therapy services in the community setting.

Conclusion

We thank CMS for the opportunity to comment on the CY 2013 PFS Final Rule, and we commend the agency for acknowledging and addressing many of our concerns regarding the Proposed Rule. We hope that the information we have provided here is of use in further rulemaking and ultimately pursuing payment reform for radiation oncology. We would be happy to discuss any of these matters further. 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