RADIATION THERAPY ALLIANCE

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

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

September 4, 2012

Marilyn Tavenner
Acting Administrator
Center for Medicare and Medicaid Services
Attn: CMS-1590-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1590-P; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2013; Proposed Rule; (July 30, 2012)

Dear Acting Administrator Tavenner:

The Radiation Therapy Alliance (RTA) appreciates the opportunity to submit comments regarding the 2013 Proposed Physician Fee Schedule (PFS) 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., Radiation Oncology Services of America, UPMC Cancer Centers, and Vantage Oncology.

The RTA is extremely concerned by the potential impact of the Proposed PFS Rule. The rule's 15% reduction in allowable charges to radiation oncology and 19% reduction for radiation therapy centers would be highly disruptive to our practice of medicine and could result in reduced access to care for a significant number of cancer patients, particularly those in rural settings. As detailed in this comment letter, we believe that CMS is relying on incorrect assumptions and incomplete analysis to reach the conclusions underlying the proposed changes. In addition, we believe that the rule, if finalized, may result in harmful consolidations in the marketplace that would reduce competition and lead to additional services in the hospital outpatient setting. This, in turn, will result in increased costs for the U.S. health care system, including higher out-of-pocket costs for Medicare recipients.

Following a summary of our comments, Section 1 of this letter discusses concerns regarding specific proposals contained within the Proposed Rule. Section 2 discusses the potential market impact of the net effect of these changes on the provision of cancer care in the community setting. Section 3 summarizes the RTA's views regarding the importance of payment reform for freestanding radiation therapy and reviews a proposal we have developed, and previously presented to CMS, to establish a bundled payment for an episode of care.

Summary

The RTA's views regarding the Proposed PFS Rule may be summarized as follows:

1. Dramatic reductions to CPT 77418 (IMRT) and 77373 (SBRT) are inappropriately constructed and should not be finalized. The data source for reducing the number of minutes for these services lacks any statistical validity and is inconsistent with other time-based RVU setting processes. A failure to consider changes in other key components, particularly equipment cost, yields an unbalanced revision to the assumptions underlying these codes' payment rates. For example, based on a review of actual paid invoices performed by Avalere Health, the RTA believes that the actual equipment cost is up to 85% greater than CMS currently assumes. The RTA has collected paid invoices from manufacturers in support of this claim. The RTA requests that CMS defer changes to CPT 77418 and CPT 77373 until the agency conducts a comprehensive review of all relevant assumptions and allows for stakeholder input.

2. CMS's proposed change in the assumed interest rate from 11% to the Small Business Administration's (SBA) subsidized loan program interest rate cap presumes that the SBA rate structure accurately represents financing costs for physician equipment. We believe that the SBA rates to which CMS refers are not appropriate proxies for borrowing costs in radiation oncology. In addition, 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. The RTA requests that this aspect of the rule not be finalized as proposed and that CMS use a seven-year rolling average of the applicable rate for long-lived equipment (and a shorter duration rolling average for equipment with a useful life of less than seven years). Alternatively, CMS should consider deferring this proposal until the agency is able to conduct a survey on borrowing costs for expensive equipment.

3. With regard to CMS's expressed concern regarding the potential for overutilization of IMRT, the RTA finds no evidence of this trend and instead observes a corresponding decline in traditional EBRT treatment vis-à-vis the rise in utilization of IMRT. However, the RTA understands and shares the concern about potential overutilization. To analytically investigate the possibility of any overutilization of IMRT, CMS should consider imposing a modifier code or F code to collect data on the use of appropriate guidelines when treating

patients with IMRT. Together with patient characteristics, such data could be used to compare practice patterns to objective, peer-reviewed guidelines such as those put forth by the National Comprehensive Care Network (NCCN). Such an effort would yield fact-based insights to guide future policymaking instead of relying on journalistic accusations.

4. The RTA remains concerned about the PPI Survey adopted in 2010 and in its final transitionary year of implementation. We continue to believe that the results from that survey do not accurately reflect the actual practice expense (PE) costs incurred by freestanding radiation oncologists. The RTA recently completed an internal survey of PE costs in 2011 and determined that PE/HR in the freestanding setting averaged approximately $964. This result is similar to the $939 PE/HR rate reported for freestanding radiation oncology by CMS from the AMA/Lewin survey. The RTA recognizes CMS's intentions to implement the final year of the PPIS but urges CMS to explore alternatives to the current methodology to more appropriately reflect actual costs.

5. If the PFS Rule were to be finalized as proposed, Medicare reimbursement to physicians practicing in the freestanding setting would no longer be comparable to that in the hospital-based setting. The Proposed Rule creates a payment disparity of up to 40% in favor of services provided in the hospital outpatient setting, whereas 2012 payment rates for freestanding and hospital-based IMRT are in near parity. There is no reason for CMS to pursue such a non-neutral reimbursement strategy, as both the cost structure and the services rendered in freestanding and hospital outpatient settings are the same. Furthermore, the RTA believes that such a divergence from site-neutral payment objectives would be harmful to beneficiaries over time.

6. The net impact of the Proposed Rule, whether it is implemented entirely in 2013 or phased in over time, would be highly disruptive to the practice of medicine. If finalized as proposed, this rule could severely restrict access to radiation therapy services in certain communities and could dramatically restrict competition in the marketplace, leading to higher costs over time. Specifically, an analysis of CMS and Medstat data predicts that two out of every five freestanding radiation oncology facilities would be at risk for closure or consolidation if the PFS Rule were to be finalized as proposed.

Section 1. Comments Regarding Specific Elements of the Proposed PFS Rule

We offer the following four comments on provisions of the Proposed Rule for your consideration.

1. Major revisions to procedure time assumptions for CPT Code 77418 and CPT Code 77373 should not be finalized without accompanying reevaluation of all direct cost inputs, particularly equipment costs.

CMS has proposed reducing the number of minutes for two important radiation oncology codes, IMRT delivery (CPT Code 77418) and SBRT delivery (CPT Code 77373), from 60 minutes to 37 minutes and from 114 minutes to 84 minutes, respectively. We are extremely concerned by CMS's fragmented approach to the reevaluation of these codes and urge CMS to instead pursue a holistic evaluation of all key assumptions about a given code's direct costs. In particular, a revision of the procedure time without a re-estimation of the equipment costs for these codes leads to an inappropriate reduction in payment, as newer, more efficient, but costlier equipment is, in part, responsible for improvements in procedure time.

The RTA has undertaken, through a contract with Avalere Health and in consultation with two leading equipment manufacturers, an extensive analysis, described in the appendix to this letter, to determine the actual current equipment prices related to CPT 77418. This analysis examines the net total average price, based on 140 recent paid invoices, for the equipment assumed in calculating payment for IMRT. Looking at updated prices for the current assumed equipment, the analysis concludes that costs are at least $449,728 greater than CMS assumes. When also considering required items not included in 77418, such as the treatment vault, water chiller, and certain service contract expenses, costs are at least $2.08 million greater. For example, Avalere Health has collected invoice data on the linear accelerator that shows, based on 73 paid invoices, that the cost is 44% greater than what is currently assumed in the CMS database. Avalere Health has also collected invoice data on other equipment costs and determined that the collimator is no longer a separate cost (even though CMS continues to pay for it as such), the median computer system cost has declined 9%, and the laser diode cost has increased $10,482. (See Table 1.)

Furthermore, the RTA believes that there are important missing items (equipment and related costs) that should be considered for inclusion in CPT 77418. Those items, namely the treatment vault, the water chiller, and the mandatory service contracts required to maintain and operate the linear accelerators and their complex operating systems (electronic record and verify system), would raise the total cost significantly. Specifically, the RTA believes that the water chiller and the treatment vault are appropriate direct costs for inclusion in CPT 77418, and we note that both of these items are currently considered a direct cost for CPT 77402, 77403, 77404, 77406, 77407, 77408, 77409, 77411, 77412, 77413, 77414, and 77416. In discussions with facility practice managers and radiation oncologists, all noted that the vault and the water chiller are necessary for the delivery of radiation therapy. (For example, the chiller prevents the linac from overheating, while the vault is essential to shield the radioactive nature of the accelerator.)

Specifically with respect to the radiation treatment vault, we note that CMS currently includes the costs of specific treatment rooms as direct costs in hundreds of codes, including, for example, mammography (room, mammography: $168,214); fluoroscopy (room, radiographic-fluoroscopic: $367,664); ultrasound (room, ultrasound: $369,945); CT (room, CT: $1,284,000);

PET (room, PET: $1,328,996); angiography (room, angiography: $1,386,816); MRI (room, MRI: $1,605,000); and PET-CT (room, PET-CT: $2,136,283). Furthermore, we note that the IRS recognizes the vault as equipment, not structure, and permits taxpayers to depreciate it over a five-year period, separate from the building.

Based on nine recent paid invoices RTA members provided Avalere Health, we believe that the median price of a water chiller is $26,100. CMS assumes the cost for a vault to be $773,104 in other codes (it is not recognized at all in 77418.) However, an analysis based on eight paid invoices indicates that the treatment vault construction cost is $1,600,917, more than double the cost CMS assumes for this item when it is included in other CPT codes.

Finally, the RTA believes that CMS is significantly undervaluing hardware and software maintenance costs relating to the linear accelerator and related equipment. Avalere's review of RTA service contracts indicates that such costs are in excess of $200,000 annually. This is far higher than the uniform maintenance cost assumption that CMS applies to all equipment, $0.05 per minute.

As Table 1 summarizes and the appendix to this letter details, the current CMS assumptions regarding equipment prices for CPT 77418 are significantly misvalued.

Table 1. Evidence of Mispriced and Missing Equipment Related to IMRT (CPT 77418)

	CMS Price	Avalere Research (Median Price)	Percent Difference
Equipment Currently Assumed in IMRT CPT 77418			
Linear accelerator	$1,832,941	$2,641,783	44%
Collimator	$355,030	$0	-100%
Computer system	$163,593	$149,027	-9%
Laser diode	$7,678	$18,160	137%
Other equipment in 77418	$85,466	$85,466	0%
Subtotal, updated prices	$2,444,708	$2,894,436	19%
Missing Equipment for 77418			
Water chiller	$0	$26,100	n/a
Vault	$0	$1,600,917	n/a
Subtotal, missing equipment	$0	$1,627,017	n/a
Total Equipment Costs	$2,444,708	$4,521,453	85%
Service Contract Costs			
Linac service contract (annual expense)	$0	$200,000	n/a

Furthermore, we are concerned about the appropriateness of using patient brochures from the internet for the purpose of determining procedure times. Sec. 1848 of the Social Security Act calls upon the Secretary to use surveys, data collection, studies, and analytic contractors in setting values, in addition to "existing processes" (i.e., the AMA RUC). CMS notes in the Proposed Rule, "While we generally have not used publicly available resources to establish procedure time assumptions, we believe that the procedure time assumptions used in setting payment rates for the Medicare PFS should be derived from the most accurate information available." We are very concerned that the source CMS relied on is nonscientific and falls short of the methods cited in the statute. For example, as CMS acknowledges in the Proposed Rule, one of the sources, a patient brochure, relates only to the treatment time for prostate cancer, whereas a head and neck cancer or a tumor with respiratory motion requires a much longer treatment time. However, IMRT is frequently used to treat a variety of cancers. Based on an analysis of Medicare 5% sample claims, almost 50% of IMRT treatments were for cancers other than prostate cancer.

Because of concerns regarding the data source for the reduction in duration of delivery and the lack of consideration for other relevant changes to equipment prices, we urge CMS not to finalize the proposed changes to IMRT (CPT 77418) and SBRT (CPT 77373). As we note above, there have been efficiencies in the delivery of IMRT in part due to the introduction of improved equipment. If CMS believes that the minutes are no longer 60 and 114, respectively, then it should collect valid data to set the correct duration. To the extent that CMS is not satisfied with the traditional means by which it gets recommendations on PFS values, the RTA notes that in the CY 2011 PFS Final Rule, CMS finalized a proposal to establish a regular and more transparent process for considering public requests for changes to PE database price inputs for supplies and equipment used in existing codes. Under this process, CMS accepts requests for updating the price inputs for equipment and supplies. Data submitted prior to December 31 of a given calendar may be considered for inclusion in the next Proposed Rule. Moreover, the Affordable Care Act (ACA)—and, prior to that, the BBRA—provides the Secretary with authority to receive data from other stakeholders. Rather than adopt piecemeal and flawed changes to IMRT and SBRT, the RTA urges CMS to request updated equipment and supply data and update IMRT and SBRT holistically and according to the procedure that CMS adopted in the CY 2011 PFS Final Rule.

If CMS decides to change the minutes for these codes, we would urge the agency to also incorporate all the results from the updated equipment price analysis as provided here.

<u>2. We believe that the CMS proposal to rely on the interest rates for SBA loans is not an appropriate proxy for the financing costs associated with equipment used in radiation oncology</u>.

CMS has proposed to "use a 'sliding scale' approach based on the current SBA maximum interest rates for different categories of loan size (price of the equipment) and maturity (useful life of the equipment)." Currently, 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. CMS

proposes to update this assumption through annual rulemaking to account for fluctuations in the prime rate. We believe this proposal is inappropriate for the following reasons.

A. The existing capital stock of linear accelerators was generally purchased over the last seven years and was financed at the prevailing interest rate at the time of the loans, not the current rate today. Loans to finance major radiation therapy equipment 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. According to data available from the Federal Reserve Board, the average prime rate for the last seven years is 5.1%, significantly higher than the current 3.25% rate. If one were to consider the rolling seven-year average for the prime rate, the relevant interest rate would rise from 6% to 8.1%.

B. Furthermore, SBA 7(a) loans may contain an additional cost to the borrower referred to as the guaranty fee. This charge from SBA to the lender is permitted to be passed on to the borrower. The fee is a one-time cost ranging from 2% to 3.75% of the loan value. On an annualized basis, this cost raises the effective borrowing rate by approximately 0.5% for a $3 million seven-year loan.[1] Therefore, the true, net effective interest rate incurred for an SBA loan could be 0.5 percentage points higher than proposed.

C. Based on a survey of recent loans obtained by one large member of the RTA, the weighted average interest rate for financing radiation therapy equipment between January 2008 and February 2010 (all most recent available financing) was 8.22%. We note that stand-alone facilities and sole proprietorships would likely face higher financing costs.

D. Based on financing cost data provided by a large equipment manufacturer that regularly facilitates financing for its customers, the weighted average effective interest rate cost for thirteen recent transactions for linear accelerators and related equipment was 8.23%. Interest rates for these loans ranged from 7.1% to 9.1%.

E. The RTA also notes that the actual interest rate spread between observed financing costs in radiation oncology and the historical average prime rate is significantly greater than the 2.75% proposed by CMS. 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%. As noted above, given that the current average prime rate for the last seven years is 5.1%, the net interest rate assumption by this framework would be 9.2%.

[1] According to SBA, guaranty fees are 2% of 85% of the first $150,000 borrowed plus 3% of 75% of the next $550,000 plus 3.5% of 75% of the next $300,000 plus 3.75% of any additional amount borrowed. For a $3 million loan, the fee would be $97,300, or 3.26%. This one-time cost equates to approximately 0.5% annually for a seven-year loan.

F. With regard to the borrowing cost data described above in C and D, there exist additional financing costs that significantly impact the true, net effective cost of funds. Appraisal costs, landlord waiver costs, financial advisory fees, and legal and documentation costs are all examples of one-time transaction costs associated with financing equipment. These costs, like the guaranty fee for SBA loans, raise the net effective interest rate by approximately 0.5 percentage points per year on average, depending on the particular loan. As such, the net effective interest rate, inclusive of all origination costs, likely averages approximately 8.75%.

G. Finally, we note that the borrowing cost to finance expensive radiation therapy equipment is never a fixed increment above any standard, published rate. While the historical interest rate data we obtained are similar to our adjusted, historical estimate of the SBA loan maximum, that relationship may not hold true in the future.

The RTA believes that if CMS chooses to finalize a change in the interest rate assumption—whether using SBA or other "benchmarks"—it is critical that the agency rely on a rolling average of historical rates commensurate with equipment life. We propose that for equipment with a life of seven years or more, CMS average seven years of historical interest rate data. For equipment with a life of less than seven years, CMS should average five years of data.

Moreover, we urge CMS to reconsider the SBA maximum interest rate framework as the reference source for setting the CMS interest rate assumption, and we urge CMS to work with stakeholders in the coming year to collect broader survey data. If CMS does decide to alter the interest rate despite the objections cited above, we would propose that for equipment valued above $1 million, CMS phase down from the current 11% assumption to 8.75%.

3. The RTA questions the assumed number of staff (i.e., radiation therapists) for CPT 77418 based on provider experience and published guidelines and urges CMS to assume two or three radiation therapists along with the requisite minutes.

The American College of Radiology (ACR), in guidelines published in June 2012, outlined the appropriate number of radiation therapists present for providing radiation oncology services. That report, *Radiation Oncology Accreditation Program Requirements*, indicates that the number of FTE radiation therapists in ACR-accredited facilities averages between 2.7 and 3.3 per linear accelerator, depending on the number of patients treated annually.

Furthermore, certain states mandate a minimum of two radiation therapists per linear accelerator in order to grant an operating license.

Furthermore, the American Society of Radiologic Technologists House of Delegates adopted the following resolution in June 2008: "It is the position of the American Society of Radiologic

Technologists that two registered radiation therapists per patient per treatment unit is the minimum standard for safe and efficient delivery of radiation therapy."

The American College of Radiation Oncology's (ACRO) July 2012 *Manual for ACRO Accreditation* states, "Two credentialed radiation therapists must be available per treatment unit for treatment delivery to ensure optimal quality of care, and to allow for vacations, meetings and absences. Additional RT(T)s per treatment unit may be required if there are longer than standard work hours or larger than average patient load for the treatment unit."

Furthermore, data provided by a member company of the RTA that operates 42 freestanding radiation oncology facilities indicate that the median number of FTE radiation therapists per linear accelerator is 3.0.

4. To properly investigate the concerns CMS raised regarding potential overutilization of IMRT, the RTA urges CMS to consider imposing a requirement for providers of radiation oncology services to include a HCPCS Modifier Code (F Code) along with claims for patients diagnosed with prostate cancer (ICD-9 code 185, 233.4, or 236.5).

The RTA does not observe in the Medicare 5% Sample evidence of overutilization of IMRT, but we share the concern that CMS expressed in the Proposed Rule. The RTA believes that a policy requiring an F Code would yield informative data for policymakers concerned with potential overutilization of IMRT or other services for low-risk patients. Furthermore, the request for such information may discourage any potential for excessive utilization.

Just as private insurers in Massachusetts imposed on January 1, 2011, CMS could require providers to indicate one of the following Category II F-Codes: 3271F: Low risk of recurrence, prostate cancer; 3272F: Intermediate risk of recurrence, prostate cancer; or 3273F: High risk of recurrence, prostate cancer. Such data would permit CMS to gauge the extent to which providers are adhering to established guidelines for the treatment of prostate cancer. Guidelines, such as those promulgated by NCCN, could, in conjunction with patient demographics, be used to understand utilization patterns. This approach is consistent with PQRS measure #102, which requires reporting of 3271F, as bone scans are not generally appropriate for staging prostate cancer for low-risk patients.

Section 2. Estimated Impact of Proposed Cuts to Radiation Oncology

In order to assess the impact of the proposed rate cuts on radiation therapy centers' viability, the RTA retained a data analytics contractor to estimate the number of facilities at risk for closure based on a simple break-even analysis. This model forecasts the number of patients treated per day based on local demographic data for the 1,047 freestanding facilities operating in the United States. The break-even analysis relies on average center costs and a mix of Medicare and non-

Medicare reimbursement rates for a weighted blend of CPT codes representing 95% of freestanding radiation oncology billed charges.

While we recognize that the break-even number of patients varies significantly with current utilization of IMRT, we believe a utilization rate of IMRT approximating 50% is representative of the largest percentage of freestanding centers. We further assume 50% of a practice's business is derived from Medicare patients. Based on these assumptions, the model found that an average center so situated would break even (meaning that it would have zero profit or loss as an enterprise, including all lines of business) when treating sixteen patients per day. Below sixteen patients per day, centers would be at greater risk of closure.

To estimate the number of treatments per center, we estimated the number of EBRT treatments per capita by age and gender using data from CMS and Medstat and applied these factors to the U.S. population by zip code. These zip code allocated treatments were further allocated to freestanding radiation oncology facilities based on the proximity of a facility to a patient zip code. If there were only one center within a twenty-mile radius, then that center would receive all of the projected treatments for patients residing in that zip code. If there were more than one center, treatments were allocated pro rata.

Based on this framework, 425 freestanding centers (out of a total of 1,047) would be at risk for closure or consolidation if the PFS Rule were finalized as proposed. According to this analysis, in eight states, all freestanding facilities would be at risk for closure. Those states are Connecticut, Delaware, Idaho, Maine, Massachusetts, New Hampshire, Utah, and Virginia. In three additional states—Illinois, Louisiana, and North Carolina—more than two-thirds of the freestanding facilities would be at risk of closing.

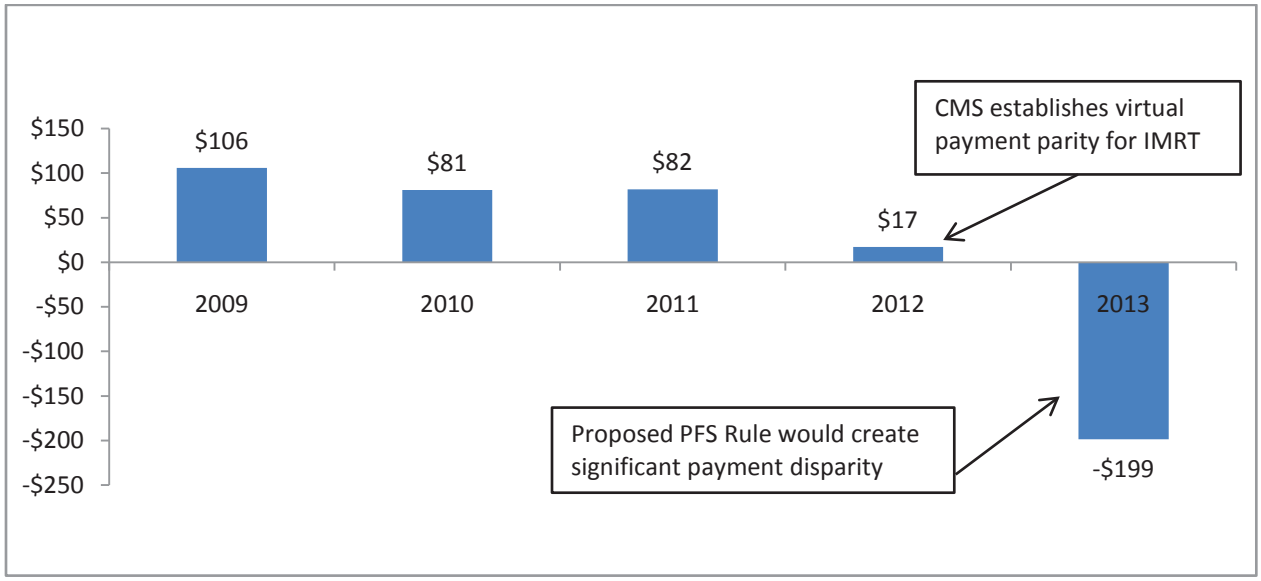
The clinical consequences of the projected facility closures are potentially significant. Numerous peer-reviewed studies have documented the effect of facility proximity on patient access. As described in Onega et al. (2008), "Greater travel-time, travel-distance, and rural residence each have been associated with decreased geographic access to health care. Recent evidence suggests that utilization of specific treatments is related to travel distance." In their own empirical research quantifying the impact of travel time on access to NCI Cancer Centers, Onega et al. find that a ten-minute increase in travel time decreases the probability of a patient's going to a facility by 10%.

Important recent research published in the *Medical Journal of Australia* by Peter Baade et al. (2011) concludes that, after controlling for other factors, there is a 6% increase in mortality risk for each additional 100 kilometers (62 miles) between a rectal cancer patient and the nearest radiation therapy facility.

In addition to fearing potential facility closures if the Proposed Rule is finalized without change, we are concerned that this policy will lead to greater hospital-physician practice consolidation, in which costs now paid under the PFS will migrate over to the higher payment of the OPPS, as many facilities would convert from freestanding to hospital-based. The incentive to convert would be strong, given the large disparity in reimbursement that would be established in favor of hospitals if the Proposed Rule were finalized. Such a move would limit the savings to CMS from the proposed change to reimbursement for radiation oncology and could result in highly concentrated market power for some hospitals. Furthermore, there is no policy rationale for promulgating such a disparity in reimbursement, as the cost structures in both settings are nearly identical. In fact, it is common that the same physician will render identical services in both settings. In fact, according to further analysis, five of six freestanding radiation oncology facilities are within 35 miles of a hospital-based facility that already operates a radiation oncology department.

Chart 1 illustrates the difference between Medicare payment for IMRT in the hospital-based and freestanding settings. At present, the reimbursement rates are nearly equivalent between these two settings. If CMS were to finalize the PFS Rule as proposed, a large disparity would be recreated, this time in favor of treatment in the hospital setting.

Chart 1. IMRT Payment Disparity between Freestanding Facilities and Hospitals (2009–2013)



Section 3. Need for Fundamental Payment Reform for Radiation Oncology

In addition to the concerns expressed here with regard to the specific proposals contained within the CY 2013 Proposed PFS Rule, RTA wishes to express a broader concern with regard to the appropriateness of reimbursing freestanding radiation oncologists through this fee schedule. As CMS is aware, the RTA has developed an episode-of-care bundle proposal in the freestanding

setting that we believe could start with treatment of prostate cancer, with other cancers added in succeeding years. 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 create the necessary payment stability required for the provision of radiation oncology services. In particular, we believe that a patient registry will ensure continued progress toward improved patient outcomes. In fact, we note that on August 1, 2012, one RTA member company entered into a contract with a private insurer, Humana, to receive bundled payments for radiation therapy provided for thirteen distinct types of cancer. The three-year contract will establish bundled payments between Humana and this provider in sixteen states.

We also note that CMS is required to submit to Congress by December 31, 2012, a report on payment bundling, and we urge CMS to consider radiation oncology as a well-suited specialty for this type of reform.

Notwithstanding the Congressionally mandated study, we note that CMS has the authority to implement bundled payments under Sec. 3134 of the ACA. Indeed, in this Proposed Rule, as part of the discussion of the proposed reduction in IMRT and SBRT, CMS points to its authority under Sec. 1848(c) of the Social Security Act (as amended by Sec. 3134 of the ACA) to make coding revisions that "may include consolidation of individual services into bundled codes for payment under the PFS." Therefore, CMS need not await action on the aforementioned study on payment bundling, nor on a more limited demonstration, should it choose to act through the PFS. Indeed, CMS has some experience in the PFS around certain surgical bundles. We encourage CMS to consider exercising its authority to create one or more bundled payment codes, along the lines of the episode-of-care bundle, referenced above, that we have previously shared with the agency. Particularly if used in conjunction with F codes, such an approach would ensure that CMS could observe additional details regarding utilization of IMRT.

Conclusion

The RTA has engaged in a multiyear effort to work with CMS, Congress, and other stakeholders to encourage the development of bundled payments. We believe that a payment reform comprising bundled payment for an episode of care along with a comprehensive commitment to quality metrics can yield improved outcomes and cost savings. We have proposed starting with EBRT for prostate cancer and, over time, adding additional bundled payments. We continue to refine our proposal and seek collaborative opportunities with CMS.

With regard to the Proposed PFS Rule for 2013, the RTA is extremely concerned that the proposed cuts would have a significant negative impact on patient care. Freestanding radiation oncology endured a 15% reduction in Medicare reimbursement between 2008 and 2012, and the proposed cuts would increase the cumulative reduction to 32%. Facilities treating lower-than-

average volumes of patients or higher-than-average proportions of Medicare patients may not be sustainable if these cuts are finalized. In some states, all facilities may be at risk for closure; in other states, facilities in more rural communities will face this risk.

Facilities located near hospitals will likely choose to convert to hospital-owned facilities and enjoy the higher reimbursement allowed by the OPPS Payment Rule. Such a consolidation would significantly reduce competition in many health care markets and, over time, lead to higher costs and lower quality of care.

The RTA urges CMS to refrain from finalizing the proposed cuts specific to radiation oncology and instead to carefully consider all direct cost assumptions comprehensively next year, including the data summarized in this letter. With regard to the interest rate assumption, we urge CMS to reconsider the proposal outlined above. Based on the evidence presented here, we believe that an 8.75% interest rate is more appropriate for high-cost equipment.

We are confident that a holistic review of critical CPT codes for radiation oncology with a combination of F Codes to designate diagnosis and group codes to ensure properly aligned incentives will yield greater savings and superior access to quality care.

We thank CMS for the opportunity to comment on the CY 2013 Proposed PFS Rule. We would be happy to discuss any of these matters further. If you have questions regarding these matters or the RTA's views, please contact RTA Executive Director Andrew Woods at (202) 442-3710.

Sincerely,

Christopher M. Rose, M.D., FASTRO
Chair, Radiation Therapy Alliance Policy Committee

Appendix: Updated Equipment Prices

The Radiation Therapy Alliance (RTA), working in conjunction with equipment manufacturers and through our own internal surveys, has gathered data, including verifiable invoice data, for major equipment inputs for IMRT (CPT 77418). The analysis presented below was performed by Avalere Health.

Equipment Costs for IMRT, CPT 77418

Data:

Avalere Health collected equipment cost data from multiple sources for this analysis.

RTA member companies provided a total of forty-five confidential paid invoices for equipment used in the delivery of IMRT therapy. In addition, two equipment manufacturers provided a total of ninety-five paid invoices for similar equipment. All invoices are from January 2010–June 2012 and reflect the cost of the equipment after any rebates or discounts.

The majority (seventy-three) of the invoices were for the linear accelerator used for IMRT therapy. Other invoices identified the net cost of the computer system (thirty-five invoices), water chiller (nine invoices), treatment vault (eight invoices), service contracts (five invoices), and laser diode (four invoices).The remaining invoices were each for separate items; Avalere was unable to identify an "average" cost using only a single invoice.

Since many invoices could contain multiple items, some of which were bundled together, Avalere reviewed the invoices and spoke directly with the RTA member companies and equipment manufacturers to determine how to categorize each of the invoices. The findings below present Avalere's assessment of the costs of the equipment based on this categorization.

Findings:

In the CY 2013 Proposed PFS Rule, CMS includes equipment input costs for CPT 77418 of $2.44 million. The invoices that Avalere Health collected and reviewed suggest that the actual equipment input costs for 77418 are between $2.89 million, which represents only the current list of IMRT input equipment, and $4.72 million, which includes the cost of additional equipment identified by RTA member companies and manufacturers as routinely required for IMRT therapy.

Table A1 indicates the current input price used by CMS in the PERVU methodology for CPT 77418, the Avalere-reviewed survey price for those same items, and the median price for items that RTA member companies and manufacturers indicated are required for IMRT therapy.

Table A1. Summary of Equipment Price Data Collected by Avalere Health

Equipment	CMS input price	Median price based on invoices	Number of invoices reviewed by Avalere	Currently included in CPT 77418?	Currently included in other radiation therapy codes?
Linear accelerator	$1,832,941	$2,641,783	73	Yes	Yes
Collimator	$355,030	$0	n/a	Yes	Yes
Computer system	$163,593	$149,027	35	Yes	Yes
Laser diode	$7,678	$18,160	4	Yes	Yes
Water chiller	$0	$26,100	9	No	Yes
Treatment vault	$0	$1,600,917	8	No	Yes
Service contract	$0	$200,000	5	No	No
Other inputs not reviewed	$85,466	$85,466	n/a	Yes	Yes
Total	**$2,444,708**	**$4,721,453**			