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September 2, 2014

Marilyn Tavenner  
Administrator  
Centers for Medicare and Medicaid Services  
Attention: CMS-1612-P  
7500 Security Blvd.  
Baltimore, MD 21244-1850

**RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015 (CMS-1612-P)**

Dear Administrator Tavenner:

The Radiation Therapy Alliance (RTA) appreciates the opportunity to submit comments regarding the CY 2015 Physician Fee Schedule (PFS) Proposed Rule (CMS-1612-P). The RTA represents 244 free-standing cancer care facilities in 22 states caring for over 100,000 patients annually. The RTA was established to provide policymakers and the public with a greater understanding of the value that community-based free-standing radiation therapy facilities bring to their patients and of the importance of logical, predictable payment reform to align incentives and ensure patient access to quality cancer care. RTA members include provider companies 21<sup>st</sup> Century Oncology, UPMC Cancer Centers, and Vantage Oncology, as well as equipment manufacturers Accuray and C&G Technologies.

#### **Summary**

The RTA is very concerned about the potential impact of the reimbursement cuts arising from the Proposed 2015 PFS and are equally concerned that additional, significant cuts may appear in the Final Rule that have not been proposed. Specifically, the American Medical Association (AMA) has just announced (August 28, 2014) that thirteen critical radiation therapy codes will be deleted and replaced by six new codes for which no PE RVU value has been proposed. This looming unknown makes it difficult if not impossible to accurately assess the impact of the Physician Fee Schedule for 2015 on radiation oncology. While the RTA is pleased that CMS is proposing to improve transparency in the rulemaking process by including future proposed RUC-related, new, revised and potentially misvalued codes in the Proposed Rule, we are extremely concerned that this new policy will only take effect beginning with CY 2016 and urge CMS to implement this new policy beginning with CY 2015.

The RTA also urges CMS not to finalize the proposal to reclassify the radiation therapy vault as an indirect expense. As discussed below, we firmly believe that the vault meets the definition of a direct expense because it is distinct from the general facility, is equipment necessary to provide patient care, and is inextricably tied to the treatment delivered by the linear accelerator.

Furthermore, CMS has solicited comment regarding the appropriate maintenance cost assumption used in determining the equipment cost per minute (pg. 40327). The RTA has carefully investigated this matter and in 2013 provided CMS nine, detailed linear accelerators maintenance contracts. Based on the median cost for those invoices and CMS's assumed cost of the linear accelerator, the RTA believes that the appropriate maintenance cost assumption for the linear accelerator is 8.4 percent, not 5 percent as is currently assumed. Finally, the RTA urges caution with regard to CMS's proposal to eliminate contractor pricing of two robotic radiosurgery codes G0339 and G0340.

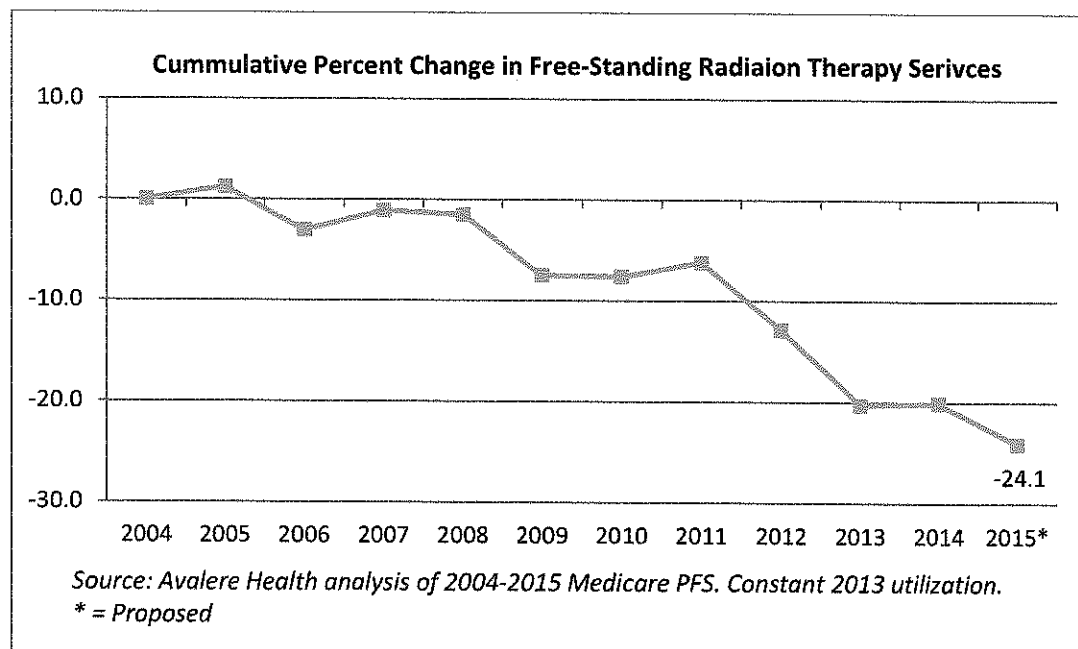
The remainder of this letter details the impact of the Proposed Rule—as best we can in light of the unknown factor noted above— on free-standing radiation oncology providers, explains why the radiation therapy vault should remain a direct PE, expresses our serious concern with CMS's proposal to delay implementation of a critical transparency policy, details evidence we have collected regarding the maintenance cost of the linear accelerator, provides comment on CMS's proposal related to Medicare reimbursement of robotic radiosurgery and describes the fundamental economics of a typical, new free-standing radiation oncology facility.

#### **1. Overall Impact of the Proposed Rule**

With regard to the overall impact of the Proposed Rule for free-standing radiation oncology, our analysis finds the following:

1. If finalized as proposed, reimbursement for free-standing radiation oncology would decline 5.1 percent relative to CY 2014. This impact is larger than the -4 percent cut reported in Table 60 (pg. 40523) of the Proposed Rule because that table combines payments to free-standing and hospital-based radiation oncology.
2. In addition to facing the largest proposed cut of any specialty in the CY 2015 Proposed PFS (pg. 40320), radiation oncology faces the fifth significant proposed payment reduction in six years. Repeated proposals by CMS to impose significant cuts, many of which have been finalized, have a highly disruptive impact on the radiation oncology industry as they impede providers' ability to secure financing to make necessary equipment upgrades, and this has obvious implications for patient care.
3. Certain frequently billed radiation therapy delivery codes (CPT 77403, 77404, 77407, 77408, 77409, 77413, 77414, 77416, 77417, and 77418) would face reimbursement cuts of greater than 10 percent in 2015 if the rule is finalized as proposed.
4. The Proposed Rule further exacerbates the payment disparity between free-standing and hospital-based radiation oncologists. Specifically, free-standing radiation oncology providers will experience a -5.1 percent reduction while hospital-based providers will receive a 1.5 percent increase in reimbursement. If finalized as proposed, CY 2015 payments to free-standing facilities for an average episode of care will be 84 percent of the amount paid in the hospital outpatient setting, compared to 90 percent of the amount paid in the hospital outpatient setting in CY 2014. The CY 2015 Proposed Rule will result in free-standing radiation facilities experiencing a reduction in reimbursement of over 24 percent since CY 2004 while hospital-based reimbursement will *increase* nearly 13 percent over the same period.

The following chart illustrates the decline in reimbursement for free-standing radiation therapy facilities from 2004 through the 2015 Proposed Rule.



## II. The Radiation Treatment Vault is a Direct Practice Expense

CMS has proposed removing the radiation treatment vault as a direct PE input for radiation treatment procedures based on the assertion that “the vault is not, itself, medical equipment, and therefore is accounted for in the indirect PE methodology,” (pg. 40331). This is the change with the largest reimbursement consequence across the entire Proposed Rule. The RTA strongly disagrees with this proposed change and urges CMS to keep the radiation treatment vault as a direct PE. CMS’s proposal significantly affects reimbursement for 14 CPT codes (77373 and 77402-77418). Below are a multitude of reasons why the radiation treatment vault should remain a direct PE expense:

1. The radiation treatment vault is directly and inextricably linked to the linear accelerator and, as such, should be considered medical equipment necessary for the treatment of the patient. The vault is not merely a roof and walls to protect the linear accelerator from the weather (as is the ordinary structure) but is a *regulated* and *mandated* necessary item, custom built to the precise specifications of the linear accelerator with which it is paired. Without the vault, which includes a myriad of equipment components, the accelerator cannot be operated and a patient cannot receive care.

As noted in our December 31, 2012 letter to CMS, “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.” The radiation therapy vault should not be considered simply an elementary structure of concrete walls but rather should be understood to be a complex design consisting of a multitude of components and equipment comprising a single system. It includes not only expensive and critical radiation shielding materials but also mechanical components, dedicated electrical feeds, dedicated plumbing (air compressor, chiller), and a specially made vault door.

2. By CMS’s own account, medical equipment, which is a component of the direct PE, is defined as an input typically used in the performance of a service. Specifically, the 2001 PFS Final Rule

notes, "The major criterion used for clinical staff time and supplies is that the suggested input must be typically used in the performance of a service to be included as a direct practice expense. We believe that the same criterion should be applied to equipment." Because a linear accelerator and the radiation treatment vault are so tightly related, a patient cannot be treated with radiation therapy without a proper radiation therapy vault. Similarly, a vault can serve no purpose other than for the provision of radiation therapy services.

3. The IRS recognizes the vault as equipment, not structure, and permits it to be depreciated as such. The AMA Physician Practice Information Survey, which collected data on equipment costs and other expenses utilized in the PE methodology, explicitly references IRS tax depreciation amounts in instructing respondents how to estimate medical equipment costs.
4. In addition to being treated as equipment by the IRS, the radiation therapy vault is generally treated by the property landlord as medical equipment, not medical office space. As such, many lease agreements require that the vault be removed at the end of the lease term much the same that the medical equipment must be removed.

For example, one RTA member company lease agreement for a facility states, "Upon the expiration or early termination of this Lease, Tenant shall, unless Landlord notifies Tenant to the contrary at least sixty (60) days prior to such Expiration Date or earlier termination, remove or cause to be removed, at its sole cost and expense, the Housing Structure and shall restore the interior and exterior of the Property (Building and surrounding land) to its condition prior to Tennant occupying the Premises, reasonable wear and tear and events of casualty excepted." For the purposes of this agreement, "Housing Structure" is to the radiation therapy vault.

5. RTA also believes that the consequence of removing the treatment vault as a direct PE is more significant than implied by CMS in the Agency's description in the proposed rule. All costs related to the treatment of patients, whether equipment, supplies, personnel, rent or other, should be accounted for in the PE methodology as either a direct or indirect expense. However, removing the vault as a direct cost expense not only eliminates reimbursement in the direct cost category, it lowers the indirect PE values for the affected codes as well. Due to the peculiarities of the CMS PE methodology, the value of the indirect PE actually declines as a result of removing the radiation therapy vault as a direct expense thereby further exacerbating the impact of this policy change. Simply put, rather than shifting the vault from direct to indirect the cost of the vault is dropped.

This atypical result is apparent from an analysis of the calculation of the PE RVUs for CPT 77418 (Radiation TX delivery, IMRT). This analysis, which is identical to the methodology and presentation in Table 4 of the Proposed Rule for other codes, indicates that the removal of the radiation therapy vault as a direct PE results in a decline in both the direct cost (lines 4, 8, 9, 13 and 14) and also a decline in the indirect cost (lines 19, 22 and 26). Below we have replicated the steps as presented in Table 4 of the Proposed Rule for CPT 77418. As described in line 18 of the table, the indirect PE allocation is determined by calculating the ratio of the adjusted direct cost (line 14) to the direct cost percentage (line 16) multiplied by the indirect cost percentage (line 17). As such, a reduction in the direct PE results in a reduction of the indirect PE as well. The change in the IPCI does not fully offset this effect.

### PE RVU Calculation for CPT 77418 with and without Radiation Therapy Vault

	Step	Formula	CPT 77418 (with vault)	CPT 77418 (without vault)
(1) Labor cost	Step 1		\$33.61	\$33.61
(2) Supply cost	Step 1		\$10.52	\$10.52
(3) Equipment cost	Step 1		\$326.41	\$326.41
(3a) Radiation Vault Cost	Step 1		\$58.34	
(4) Direct cost	Step 1	= (1)+(2)+ (3)	<b>\$428.88</b>	<b>\$370.54</b>
(5) Direct adjustment	Steps 2-4		0.5898	0.5898
(6) Adjusted Labor	Steps 2-4	= (1)*(5)	\$19.82	\$19.82
(7) Adjusted Supplies	Steps 2-4	= (2)*(5)	\$6.20	\$6.20
(8) Adjusted Equipment	Steps 2-4	= (3)*(5)	<b>\$226.93</b>	<b>\$192.52</b>
(9) Adjusted Direct	Steps 2-4	= (6)+(7)+ (8)	<b>\$252.95</b>	<b>\$218.54</b>
(10) Conversion Factor (CF)	Step 5		\$35.82	\$35.82
(11) Adj. labor cost converted	Step 5	= (6)/(10)	0.55	0.55
(12) Adj. supply cost converted	Step 5	= (7)/(10)	0.17	0.17
(13) Adj. equip. cost converted	Step 5	= (8)/(10)	<b>6.33</b>	<b>5.37</b>
(14) Adj. direct cost converted	Step 5	= (11)+(12) +(13)	<b>7.06</b>	<b>6.10</b>
(15) Work RVU	Setup File		0.00	0.00
(16) Dir_pct	Steps 6,7		0.43	0.43
(17) Ind_pct	Steps 6,7		0.57	0.57
(18) Ind. Alloc. Formula (1st part)	Step 8		$((14)/(16)) * (17)$	$((14)/(16)) * (17)$
(19) Ind. Alloc. (1st part)	Step 8	See 18	<b>9.49</b>	<b>8.20</b>
(20) Ind. Alloc. Formula (2nd part)	Step 8	See 11	-11	-11
(21) Ind. Alloc. (2nd part)	Step 8	See 20	0.55	0.55
(22) Indirect Allocator (1st + 2nd)	Step 8	= (19)+ (21)	<b>10.04</b>	<b>8.75</b>
(23) Indirect Adjustment	Steps 9-11		0.3813	0.3813
(24) Adjusted Indirect Allocator	Steps 9-11		3.84	3.34
(25) Ind. Practice Cost Index (IPCI)	Steps 12-16		1.04	1.11
(26) Adjusted Indirect	Step 17	= (24)*(25)	<b>3.98</b>	<b>3.70</b>
(27) PE RVU	Step 18	= ((14)+ (26)) * Other Adj	11.09	9.84

### III. Increased Transparency Proposal Should be Effective in CY 2015

In the Proposed Rule CMS details a significant policy shift intended to improve stakeholder engagement and policymaking transparency related to new, revised and potentially misvalued codes. As noted in the Proposed Rule (pg. 40360), "Some stakeholders who have experienced reductions in payments as the result of interim final valuations have objected to the process by which we revise or establish values for new, revised, and potentially misvalued codes. Some have stated that they did not receive notice of the possible reductions before they occurred." And as also noted in the Proposed Rule (pg. 40363), "[W]e are proposing to modify our process to make all changes in the work and MP RVUs and the direct PE inputs for new, revised and potentially misvalued services under the PFS by proposing the changes in the proposed rule, beginning with the PFS proposed rule for CY 2016."

The RTA supports the intent of the CMS proposed change and agrees with CMS that such a change would ensure that, "all RVUs for all services under the PFS would be established using a full notice and comment procedure, including consideration of the RUC recommendations, before they take effect. In addition to having the benefit of the RUC recommendations, this would provide the public the opportunity to comment on a specific proposal prior to it being implemented. This would be a far more transparent process, and would assure that we [CMS] have the full benefit of stakeholder comments before establishing values."

The RTA believes it is critical that CMS' transparency policy be put into effect beginning in CY 2015, and not delayed until CY 2016 or later. Agency transparency is a requirement under the Administrative Procedure Act (APA) and not an option. Transparency is required because it ensures that the regulated public has adequate notice of proposed agency action in a meaningful and timely manner so that the regulated public can provide similarly meaningful insight to the agency through comment. CMS violates that APA mandate here by delaying the implementation of transparent rulemaking. We are aware that the AMA has communicated to CMS a belief that this policy should be further delayed and we note CMS's concern regarding the CPT and RUC schedules and request for comment regarding the potential for delays beyond CY 2016. However, CMS should treat and consider the RUC as a complement to, not a substitute for, the public's input with regard to rulemaking and the PFS. The lack of a cogent explanation by CMS for not implementing this proposal in a timely manner, meaning for CY 2015, and thus imposing a delay in the implementation of this proposal violates the APA. As such, we consider the proposal in its current form arbitrary and capricious and otherwise contrary to the law. We urge CMS to implement this change beginning in CY 2015 and note this would be consistent with multiple letters submitted by Members of Congress expressing their concern about the lack of transparency in the establishment of RVUs.

We disagree with any suggestion that the RUC process may be an adequate substitute for a truly open and transparent process. The RUC is a private organization wielding significant public power due to its influence over Medicare spending, its exercise of which lacks any transparency or public accountability. While each specialty society may be represented in the RUC, CMS should not assume that each specialty society fully and accurately represents all views of physicians practicing within that specialty or is fully cognizant of all relevant information necessary for establishing appropriate RVUs. As acknowledged in the Proposed Rule, CMS is increasing its scrutiny of the RUC.

On August 28, 2014, the American Medical Association released the 2015 CPT code changes that will go into effect on January 1, 2015. As they relate to radiation oncology, thirteen treatment delivery codes will be deleted and six entirely new codes will be established. Most of the codes that will be deleted would be subject to the radiation therapy vault change discussed above. In other words, CMS is requesting comment on a significant policy change affecting radiation therapy delivery codes while the AMA announces their intention to delete these codes for 2015 and replace them with new codes for which the PE RVUs are entirely unknown to the public.

We believe that CMS has the means to address the fact that the 2015 CPT codes have already been published and we agree with the approach outlined in the Proposed Rule by CMS with regard to G-codes. Specifically, CMS noted, "One option would be to establish G-codes with identical descriptors to the predecessors of the new and revised codes and, to the fullest extent possible, carry over the existing values for those codes." Such an approach would permit the continuation of 2014 CPT values for 2015 and allow any new codes for radiation oncology to be subject to proper notice and comment

rulemaking. CMS and the provider community are well familiar with the use of G-codes and such a strategy could easily be utilized for radiation oncology, if not all affected specialties. Any additional administrative burden would pale when compared to the potential financial effects of revised values, especially where substantial payment reductions would result.

#### **IV. Equipment Maintenance Costs for a Linear Accelerator are Greater than CMS Assumes**

In the Proposed Rule CMS notes, "Several stakeholders have suggested that this maintenance factor assumption should be variable. We solicit comment regarding reliable data on maintenance costs that vary for particular equipment items," (pg. 40327). The current maintenance factor is fixed at 5 percent of the assumed equipment price as established by CMS for the CY 1998 PFS Final Rule. In 2013, the RTA carefully examined this issue and collected multiple maintenance contracts which were submitted to CMS in accordance with established CMS procedures.

In total, we collected nine invoices for the service contracts related to linear accelerators. These contracts are necessary to maintain the equipment in a safe and reliable working order after the first year of operation. The annual cost of these contracts range from \$170,000 to nearly \$250,000 with a median cost of \$228,723. However, Avalere Health has determined that the maintenance cost assumption used in CPT code 77418 and other similar codes is approximately \$132,089 annually. Thus, the actual service contracts (assuming the median cost) are approximately \$96,634 higher per year.

In a submission to CMS by Avalere Health on December 31, 2013 on behalf of the RTA, we proposed two strategies to rectify this improper assumption. First, we proposed that an adjustment to the equipment price could be made and would reflect the fact that the maintenance costs are significantly greater than 5 percent. Since the first year of service costs are included in the purchase price of the machine and because the accelerator has an expected life of 7 years, CMS could add an incremental \$579,804 to the price of the linear accelerator. Alternatively, CMS could create a separate input item related to the service contract for a linear accelerator. This could be either an item with a one-year depreciable life valued at \$96,634 (and no maintenance cost) or a one-year life item valued at \$228,723 with the maintenance costs removed from both this new item and from the linear accelerator itself.

In addition, we would propose that the maintenance cost assumption could be directly altered for the linear accelerator itself. In this case, the RTA would propose an equipment maintenance cost assumption of 8.4 percent for the linear accelerator (equipment code ER009, ER010 and ER089).

As a matter of process, the RTA would propose that any adjustment to the current maintenance factor assumption be based on provider submitted invoices in a manner consistent with the process established for updating equipment prices.

#### **V. Significant Reductions in Payment for Radiosurgery May Impact Patient Access**

CMS proposes to eliminate contractor pricing of two robotic radiosurgery codes (G0339 and G0340) that are used for fractionated treatment and have been in place since 2006. Under the CMS proposal, these services will be billed using CPT Codes 77372 and 77373 and payment will be made using the RVUs for these codes. If CMS moves forward with this proposal, centers in some states will see reductions in payment by as much as 66 percent for these services.

RTA is concerned that CMS's methodology for establishing RVUs for CPT 77372 and 77373 does not accurately account for the direct costs of these resource-intensive procedures that do not have work RVUs. For these reasons, we urge CMS to exercise caution and work with stakeholders to ensure that the costs of these procedures are fully accounted for in establishing appropriate RVUs.

#### **VI. Economics of Operating a Typical Free-standing Radiation Therapy Facility**

The RTA has shared data with CMS on the fundamental economics of operating a new free-standing radiation therapy facility. As RTA has pointed out, free-standing centers provide approximately 40 percent of all radiation treatments in the US and provide services that are accessible to over three-fourths of the US population. The RTA believes however, that CMS does not properly consider accurate and complete cost data when evaluating a free standing facility for purposes of determining the appropriate RVUs for critical radiation therapy services. To better assist CMS, RTA has worked cooperatively with CMS on a code-by-code basis to ensure accurate and appropriate reimbursement. For example, one RTA member company constructed an economic model illustrating the operating costs for a typical new free-standing facility along with the reimbursement for a facility treating a typical mix of Medicare and non-Medicare patients with an average disease case mix.

Based on this model, a breakeven analysis concludes that the necessary number of treatments to break even for a new facility would be 7,505 annually or approximately 30 patients a day, an unfeasibly high utilization rate for any normal facility. In fact, many RTA facilities are fully operational at a capacity of 20 -25 percent below this break-even point for a new facility.

While it is possible for an existing facility to remain operational at a utilization rate below the break-even point indicated in this analysis, such an outcome can only exist if a facility has previously fulfilled its financing obligation. Put differently, CMS reimbursement rates are completely inadequate for financing the construction and operation of any new facility in the U.S. Moreover, within the space of a few years, an older facility will be compelled to replace its equipment, requiring new financing which will be unavailable or financially unsustainable.

The consequences of the lower reimbursement rates for radiation oncology are severe. Specifically, they virtually prohibit a facility from being able to replace or upgrade any costly equipment such as the linear accelerator. Furthermore, the number of Americans aged 65 and older is projected to increase by about one-third over the next decade, yet current PFS reimbursement for free-standing radiation oncology services inhibits the construction of new facilities. As a result, patients will lack access to radiation therapy services in the free-standing setting. This problem will be exacerbated significantly due to the fact that existing facilities are unable to finance necessary equipment upgrades and replacements as a result of cash-flows that are unable to sustain any additional financing burdens.

#### **VII. Conclusion**

We thank CMS for the opportunity to comment on the CY 2015 PFS Proposed Rule. We are extremely concerned about both the proposal to remove the radiation treatment vault as a direct PE expense and CMS's proposal to delay implementation of a critical transparency policy beyond CY 2015. As explained above, current reimbursement rates for free-standing radiation therapy providers are insufficient to finance the development of new facilities or even to finance the necessary replacement of aged linear accelerators. Further cuts to reimbursement, either by removing the vault as a direct PE or through other changes implemented in the final rule, will yield two serious adverse results. First, it



will reduce access to the growing Medicare population to local, community-based radiation therapy services as existing facilities are unable to continue operation beyond the point at which costly equipment needs to be replaced. Second, the widening disparity in payment between free-standing and hospital-based radiation oncology (in conjunction with inadequate free-standing reimbursement) will lead some facilities to be acquired by hospitals. This trend, an acknowledged concern of CMS and MedPAC alike, will result in increased costs for Medicare given the higher reimbursement in this setting. Again, any further payment reductions, either those contained within the Proposed Rule or any forthcoming in the Final Rule but not yet proposed, will lead to this result.

We would be happy to discuss any of these matters further. If you have questions regarding these matters, please contact RTA Executive Director Andrew Woods at (202) 442-3710.

Sincerely,

A handwritten signature in black ink, reading "Christopher M. Rose". The signature is written in a cursive, flowing style.

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

# Change in Radiation Oncology Payments

	% change in payments <sup>1</sup>											Total
	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015P	
All radiation therapy	1.2%	-4.2%	2.4%	-0.4%	-5.1%	0.5%	0.7%	-6.5%	-7.5%	0.6%	-4.2%	-20.9%
Excluding conversion factor	-0.3%	-4.4%	2.4%	-0.9%	-6.1%	-0.8%	-0.2%	-6.5%	-7.5%	0.1%	-4.2%	-25.4%
Non-facility radiation therapy	1.2%	-4.2%	2.0%	-0.4%	-6.1%	-0.1%	1.5%	-7.1%	-8.5%	0.2%	-4.9%	-24.1%
Excluding conversion factor	-0.3%	-4.4%	2.0%	-0.9%	-7.2%	-1.4%	0.6%	-7.1%	-8.5%	-0.3%	-4.9%	-28.5%
Facility-based radiation therapy	1.6%	-4.5%	6.1%	-0.2%	5.7%	6.2%	-6.3%	-1.6%	0.6%	4.3%	1.1%	12.7%
Excluding conversion factor	0.1%	-4.7%	6.1%	-0.7%	4.5%	4.9%	-7.2%	-1.6%	0.6%	3.8%	1.1%	6.2%
Medicare conversion factor	1.5%	0.2%	0.0%	0.5%	1.1%	1.3%	0.9%	0.0%	0.0%	0.5%	0.0%	6.1%

<sup>1</sup> Uses 2013 utilization billed by physician specialty code 92 (radiation oncology) or code 74 (radiation treatment center) for every year  
 Annual change includes only services with valid RVUs in both years  
 Medicare conversion factor reflects inflationary updates only, and excludes any changes to the conversion factor due to budget neutrality adjustments  
 Source: Avalere Health analysis of 2004-20145P Medicare Physician Fee Schedules

% change in estimated Medicare payments						
Year	All radiation oncology		Hospital-based radiation oncology		Freestanding radiation oncology	
	Proposed	Final	Proposed	Final	Proposed	Final
2010	-18.3%	2.7%	3.0%	5.3%	-24.0%	2.0%
2011	2.6%	0.6%	0.4%	-3.2%	3.2%	1.5%
2012	-4.1%	-5.6%	-2.5%	-1.7%	-4.4%	-6.4%
2013	-14.4%	-6.6%	2.7%	0.5%	-18.5%	-8.4%
2014	-5.0%	1.2%	4.5%	4.6%	-7.7%	0.3%
2015	-3.5%		1.3%		-4.9%	

# Radiation Oncology Episodes Paid Higher in Hospital Outpatient Compared to Freestanding Clinics

Episode type	# of Episodes Included in Analysis	2014: Total Episode Payments			2015P: Total Episode Payments		
		Hospital Outpatient	Freestanding Clinic	Freestanding as Percent of Hospital Outpatient	Hospital Outpatient	Freestanding Clinic	Freestanding as Percent of Hospital Outpatient
All radiation therapy	8,134	\$11,372	\$10,260	90.2%	\$11,486	\$9,624	83.8%
All radiation therapy, > 25 fractions	3,520	\$17,860	\$16,132	90.3%	\$18,044	\$15,084	83.6%
IMRT, all episodes	2,663	\$19,296	\$16,903	87.6%	\$19,462	\$15,836	81.4%
IMRT, > 25 fractions	1,753	\$23,696	\$20,729	87.5%	\$23,902	\$19,382	81.1%
3D-CRT, all episodes	5,471	\$7,516	\$7,026	93.5%	\$7,604	\$6,601	86.8%
3D-CRT, >25 fractions	1,767	\$12,070	\$11,571	95.9%	\$12,233	\$10,819	88.4%
Episode type	# of Episodes Included in Analysis	2014: Total Episode Payments			2015P: Total Episode Payments		
		Hospital Outpatient	Freestanding Clinic	Freestanding as Percent of Hospital Outpatient	Hospital Outpatient	Freestanding Clinic	Freestanding as Percent of Hospital Outpatient
Prostate, IMRT, > 25 fractions	440	\$25,640	\$22,543	87.9%	\$25,903	\$21,036	81.2%
Breast, 3D-CRT, > 25 fractions	420	\$12,095	\$11,495	95.0%	\$12,292	\$10,715	87.2%
Lung, 3D-CRT, >25 fractions	193	\$13,207	\$12,777	96.7%	\$13,310	\$11,991	90.1%

Source: Avalere analysis of 2012 5% Medicare Outpatient Claims file. Any visit with a CPT code for radiation oncology was included. Analysis uses payments and packaging policies for 2014 and 2015P, and includes physician payments in both settings.



Avalere |

# Economics of a Typical Freestanding Radiation Oncology Center

June 2014



### **Freestanding Radiation Therapy Centers:**

- Deliver 40% of all radiation therapy treatments in the U.S.
- Operate in areas covering 77% of the population
- Provides accessible, community-based care to cancer patients
- Medicare payments for freestanding radiation therapy services are 90% of hospital outpatient rates in 2014

### **Radiation Therapy Alliance (RTA)**

- Vantage is a member of the RTA, which represents 233 community-based cancer care facilities in 20 states caring for approximately 98,000 patients annually and accounts for about 25% of all freestanding radiation therapy centers nationwide.
- The RTA and US Oncology represent approximately 1/3 of the freestanding sector
- RTA members also include 21st Century Oncology, UPMC, Vantage Oncology, Accuray, and C&G Technologies.

## Situation

- Current Medicare reimbursement for freestanding radiation oncology is challenging from an economic viability standpoint
- True and complete costs of operating a freestanding radiation treatment center are not properly considered
- Declining reimbursement rates at freestanding centers will result in more patients being treated at higher hospital pricing

## Model Overview

- Goal: Present a model to focus discussion on economic fundamentals of a freestanding center
- Model assumes volumes and costs of a typical radiation treatment center
- Inputs based on combination of CMS's own inputs and assumptions augmented by real-world costs

## Recommendation

- Model results indicate current reimbursement rates are not sustainable for a new facility and additional cuts would threaten viability of existing facilities

# Cost of Operating a Freestanding Center: Start-Up Capital



## Start-Up Requirements

- Total capital required to open a single freestanding center is approximately \$5.4 million
- Approximately \$1.1 million upfront cash is required
  - Assumes 80% of total capital requirements are financed
- Capital cost assumptions
  - Equipment costs and useful life assumptions per CMS CY2014 PFS Final Rule
  - Total depreciation (straight line, useful life) of ~\$820K per year

<u>Capital Costs</u>		
<i>(\$000s)</i>	<u>Total Cost</u> <sup>(1)</sup>	<u>Useful Life</u> <sup>(1)</sup>
Linear Accelerator	\$2,642	7
CT Room	1,284	5
Radiation Treatment Vault	773	15
Treatment Planning System	351	5
Computer System - Record & Verify	149	5
MLC Shaper	145	5
Water Chiller	26	7
<b>Total</b>	<b>\$5,369</b>	<b>7</b>
Total Capital Required	\$5,369	
% Financed	80.0%	
<b>Out of Pocket Cash</b>	<b>\$1,074</b>	
Financed Capital	\$4,295	
Rate	9.50%	
Term (months)	84	
Monthly Payment	\$70	

*(1) Source: CY2014 PFS Final Rule*



# Cost of Operating a Freestanding Center: Operating Expenses

## Operating Expenses

- **Occupancy and basic operating costs add nearly \$900K of annual expenses**
- Occupancy expenses based on U.S. average rent and associated costs
  - Average center size based on representative center
- 3% expense growth per year

<u>Occupancy Expense (Annual)</u>			
Total Sqft	6,500		
\$/Sqft (monthly)	\$1.95	Base Rent	\$152,100
Utilities/Sqft (monthly)	\$0.40	Utilities	31,200
CAM & Other/Sqft (monthly)	\$0.50	CAM & Other	39,000
Property Tax	1.5%	Property Tax	30,420
Cap Rate	7.5%	<b>Total Occup.</b>	<b>\$252,720</b>
<u>Other Operating (Annual)</u>			
Selling & Marketing			\$35,000
Professional & Legal Fees			25,000
Equipment Maintenance Contracts			275,000
Software license Costs			100,000
Office Supplies			15,000
Telephone and Data Network			35,000
Medical Supply Costs			20,000
Local Taxes and License			55,000
Insurance			30,000
IT Support			50,000
<b>Total Other Operating Expense</b>			<b>\$640,000</b>
<b>Total Operating Expenses</b>			<b>\$892,720</b>

# Cost of Operating a Freestanding Center: Personnel

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## Personnel Expenses

- **Salaries & wages plus benefits total ~\$1.1 million annually**
- 13 full-time employee equivalents
- Salary assumptions based on market rates across U.S.
- Assumes biller and accountant employed as full-time staff

<u>Staff</u>	<u>Avg. Salary</u>	<u>FTEs</u>	<u>Eff. Salary</u>
Front Desk	\$35,000	1.5	\$52,500
Radiation Therapist	65,000	3.0	195,000
Lead Radiation Therapist	82,500	1.0	82,500
Nurse	70,000	1.0	70,000
Medical Assistant	30,000	1.0	30,000
Center Manager	95,000	1.0	95,000
Biller	45,000	1.0	45,000
Accountant	45,000	1.0	45,000
<b>Non-Physics</b>		<b>10.5</b>	<b>\$615,000</b>
Dosimetrist	\$100,000	1.0	\$100,000
Senior Dosimetrist	120,000	0.5	60,000
Physicist	160,000	1.0	160,000
<b>Physics</b>		<b>2.5</b>	<b>\$320,000</b>
<b>Total Salaries &amp; Wages</b>		<b>13.0</b>	<b>\$935,000</b>
<b>Benefits % of Total Salaries &amp; Wages</b>			<b>22.5%</b>
<b>Total Salaries &amp; Wages and Benefits</b>			<b>\$1,145,375</b>

# Freestanding Center Economics: Breakeven Analysis

- Assuming \$1.1 million of cash required upfront is readily available, **total annual expenses exceed \$3.2 million**
- The revenue required to offset this expense structure equates to approximately **7,500 annual treatments<sup>1</sup>, or 30 average daily treatments (ADTs)**
  - 50% Medicare
  - Commercial pricing: 110% of Medicare
  - Technical / Professional Split: 80% / 20%
  - Rev/Tx based on representative cases by tumor site (see Appendix)
    - Total reimbursement per representative case / number of treatments per case
  - Tx mix per representative average for 2012–2013
  - Rev/Tx includes IGRT at 72% penetration

Annual Cost Structure	
Personnel	\$1,145,375
Occupancy	252,720
Other Operating	640,000
Depreciation & Amortization	818,300
<b>Total Operating Expenses</b>	<b>\$2,856,395</b>
Total Interest	388,625
<b>Total Operating Expenses &amp; Interest</b>	<b>\$3,245,020</b>

Annual Revenue		Total Annual				
Tumor Site	Tx Mix	Tx	Medicare Rev/Tx	Commercial Rev/Tx	Global Revenue	
Prostate	34%	2,568	\$597	\$657	\$1,611,160	
Breast	25%	1,877	408	449	803,814	
Chest (Lung)	8%	612	417	459	268,316	
H&N	8%	565	601	662	356,823	
CNS	4%	335	412	453	144,798	
GI-Abdomen	4%	295	624	686	193,215	
Lymphoma	3%	241	406	447	102,957	
GU (Bladder)	3%	188	611	672	120,765	
Anal, Rect, Gyn, Pelv	2%	152	641	705	101,971	
Other (Bone Metastasis)	8%	630	533	586	352,456	
<b>Total</b>	<b>100%</b>	<b>7,463</b>			<b>\$4,056,275</b>	
<b>Annual Technical Revenue (80% Technical / 20% Professional)</b>					<b>\$3,245,020</b>	

(1) Based on 255 business days per year

# Freestanding Radiation Centers Lack Long-Term Viability

Based on Current Reimbursement

*25 ADTs do not sufficiently support the economic viability of a typical freestanding center*

Tumor Site	Tx Mix	Tx	Total Annual		Global Revenue	% of Global Revenue
			Medicare Rev/Tx	Commercial Rev/Tx		
Prostate	34%	2,194	\$597	\$657	\$1,376,229	40%
Breast	25%	1,603	408	449	686,606	20%
Chest (Lung)	8%	523	417	459	229,192	7%
H&N	8%	483	601	662	304,793	9%
CNS	4%	286	412	453	123,684	4%
GI-Abdomen	4%	252	624	686	165,041	5%
Lymphoma	3%	206	406	447	87,944	3%
GU (Bladder)	3%	161	611	672	103,155	3%
Anal, Rect, Gyn, Pelv	2%	129	641	705	87,103	3%
Other (Bone Metastasis)	8%	538	533	586	301,062	9%
<b>Total</b>	<b>100%</b>	<b>6,375</b>			<b>\$3,464,810</b>	<b>100%</b>

Annual Global Revenue	\$3,464,810	\$	Gain/(Loss)
Annual Technical Revenue	2,771,848		
Personnel	\$1,145,375		
Occupancy	252,720		
Other Operating	640,000		Loss at 25
Depreciation & Amortization	818,300		ADTs
<b>Total Operating Expenses</b>	<b>\$2,856,395</b>		
Total Interest	388,625		
<b>Total Operating Expenses &amp; Interest</b>	<b>\$3,245,020</b>		
			<b>(\$473,171)</b>

# Revenue Buildup: Medicare Reimbursement by Tumor Site

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- Revenue/treatment based on Medicare 2014 PFS and typical CPT codes by disease site

Conventional Based Treatments												
Description	CPT Code	Reimbursement	Breast		CNS		Lymphoma		Chest (Lung)		Other (Bone Met)	
			Frequency	Revenue	Frequency	Revenue	Frequency	Revenue	Frequency	Revenue	Frequency	Revenue
New Patient Visit	99204	\$166	1	\$166	1	\$166	1	\$166	1	\$166	1	\$166
Simulation (simple)	77280	272	1	272	1	272	1	272	1	272	1	272
Treatment Planning (complex)	77263	167	1	167	1	167	1	167	1	167	1	167
Simulation (complex)	77290	507	1	507	1	507	-	-	1	507	1	507
3-D Simulation	77295	485	1	485	1	485	1	485	1	485	1	485
Basic Dosimetry	77300	67	4	269	4	269	2	135	4	269	2	135
Treatment Device (complex)	77334	150	4	602	4	602	2	301	4	602	2	301
Weekly Physics Check	77336	75	7	524	6	449	4	299	6	449	2	150
Daily Treatment (complex)	77413	224	33	7,400	30	6,728	20	4,485	30	6,728	10	2,243
Weekly Treatment Management	77427	186	7	1,304	6	1,118	4	745	6	1,118	2	373
Special Treatment Procedure	77470	155	-	-	-	-	-	-	1	155	-	-
Stereoscopic x-ray guidance (IGRT)	77421	74	24	1,762	22	1,602	14	1,068	22	1,602	7	534
<b>Total Reimbursement Per Case</b>				<b>\$13,458</b>		<b>\$12,364</b>		<b>\$8,122</b>		<b>\$12,519</b>		<b>\$5,331</b>
<b>Revenue Per Treatment</b>				<b>\$408</b>		<b>\$412</b>		<b>\$406</b>		<b>\$417</b>		<b>\$533</b>
IMRT Based Treatments												
Description	CPT Code	Reimbursement	Prostate		H&N		GI Abdomen		Anal / Rectal		GU (Bladder)	
			Frequency	Revenue	Frequency	Revenue	Frequency	Revenue	Frequency	Revenue	Frequency	Revenue
New Patient Visit	99204	\$166	1	\$166	1	\$166	1	\$166	1	\$166	1	\$166
Simulation (simple)	77280	272	1	272	1	272	1	272	1	272	1	272
Basic Dosimetry	77300	67	7	471	7	471	7	471	7	471	7	471
IMRT Treatment Planning	77301	1,960	1	1,960	1	1,960	1	1,960	1	1,960	1	1,960
MLC Device for IMRT	77338	502	1	502	1	502	1	502	1	502	1	502
Weekly Physics Check	77336	75	8	599	7	524	6	449	6	449	7	524
Special Physics	77370	115	1	115	-	-	-	-	-	-	-	-
Simulation (complex)	77290	507	1	507	-	-	-	-	1	507	1	507
IMRT Daily Treatment	77418	395	43	16,990	35	13,829	30	11,854	30	11,854	36	14,225
Weekly Treatment Management	77427	186	8	1,490	7	1,304	6	1,118	6	1,118	7	1,304
Special Treatment Procedure	77470	155	1	155	1	155	1	155	1	155	1	155
Stereoscopic x-ray guidance (IGRT)	77263	167	1	167	-	-	1	167	1	167	-	-
<b>Total Reimbursement Per Case</b>	77421	74	31	2,296	25	1,869	22	1,602	22	1,602	26	1,922
<b>Revenue Per Treatment</b>				<b>\$25,690</b>		<b>\$21,052</b>		<b>\$18,715</b>		<b>\$19,222</b>		<b>\$22,008</b>
				<b>\$597</b>		<b>\$601</b>		<b>\$624</b>		<b>\$641</b>		<b>\$611</b>

- According to Avalere Health, Medicare payments for freestanding radiation therapy services are 90% of hospital outpatient rates in 2014
  - Site-of-service payment disparity is likely to grow in 2015 even if CMS does nothing to radiation therapy in the 2015 PFS rule because the OPPS marketbasket updates are typically larger than PFS updates year-to-year.
  - MedPAC, in May 2014 testimony to Congress, expressed concern regarding shifts in billing practices from freestanding setting to other, more highly reimbursement settings.
- Payments for radiation therapy in the freestanding setting have been reduced by almost 19% over the last decade.
  - On June 17, 2013, OnCure, a leading radiation oncology provider, declared bankruptcy, “blaming cuts in federal health-insurance payments”
  - OnCure employed 370 people and provided services to 32 radiation-treatment centers in Florida, California, and Indiana.

**Additional cuts to freestanding centers will mean access problems for cancer patients and shifts in billing practices that raise costs for CMS.**

- **Utilize new authority under Section 220 of the Protecting Access to Medicare Act of 2014** to establish practice expense values that accurately reflect the cost of providing radiation therapy in the freestanding setting.
- **Update treatment codes with December 2013 RTA submission to CMS:**
  - Add line item to the PERVU methodology to reflect the amount by which maintenance costs are underestimated (\$96,634)
  - Update 2005 vault cost to \$894,806
  - Depreciate the vault with over a 7-year life
- **Work with CMMI to establish episode-of-care payment alternative to 2015 PFS** based on RTA's response to CMMI's RFI on "Procedural Episode-Based Payment Opportunities," which described radiation therapy as an example of a treatment where "significant opportunities exist for specialty practitioner engagement in care redesign."