RADIATION THERAPY ALLIANCE

21st Century Oncology, Oncure Medical Corp., Vantage Oncology, Inc., The University of Pittsburgh Medical Center, Accuray, C&G Technologies

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September 6, 2013

Marilyn Tavenner
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, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014 (CMS-1600-P)

Dear Administrator Tavenner:

The Radiation Therapy Alliance (RTA) appreciates the opportunity to submit comments regarding the 2014 Physician Fee Schedule (PFS) Proposed Rule (CMS-1600-P). The RTA represents over 227 freestanding radiation therapy facilities in 21 states providing cancer care to over 98,000 patients annually. The RTA was established to provide policymakers and the public with a greater understanding of the value community-based radiation therapy facilities bring to their patients and the importance of logical, predictable payment reform to align incentives and ensure patient access to quality cancer care. RTA members include provider companies 21st Century Oncology, Oncure Medical Corp., UPMC Cancer Centers, and Vantage Oncology, as well as equipment manufacturers Accuray and C&G Technologies.

Summary

The RTA, while appreciative of certain aspects of the Proposed Rule, is concerned that the 7.7% proposed cut to freestanding radiation oncology services—a cut significantly larger than the aggregate cut to all radiation oncology providers—would be disruptive to our practice of community-based medicine. In particular, the Proposed Rule would reduce payment for the standard treatment of breast and lung cancer by 16%. These impacts are driven by cuts of 23–34% in reimbursement for conventional external beam radiation (3D CRT) treatment codes and other key treatment codes.

While the reductions in the CY 2014 PFS Proposed Rule accumulate from a variety of policy changes, the OPD/ASC cap policy is our primary concern. As this letter details, we urge CMS not to finalize this policy because we strongly believe that it is inappropriate to link reimbursement rates across fee schedules. Should CMS decide to pursue the OPD/ASC cap policy, the RTA recommends that the agency use 2014 OPPS CPT values, rather than 2013 values, to set the cap.

Our comment letter also addresses the proposed price adjustment for the laser diode probe and the inclusion of the vault as a direct expense for radiation treatment codes in the CY 2013 PFS Final Rule.

Financial Impact of 2014 Proposed Rule on Freestanding Radiation Oncology

The Proposed Rule would result in a 7.7% reduction in reimbursement for freestanding radiation oncology. This cut is larger than reported in Table 72 of the Proposed Rule because that table combines payments to freestanding and hospital-based radiation oncology. Under the Proposed Rule, hospital-based radiation oncologists actually would receive a 4.5% increase in reimbursement. Table 1 disaggregates the impact of the Proposed Rule on radiation oncology by setting.

Table 1. Impact of CY 2014 PFS Proposed Rule on Radiation Oncology by Setting				
	2013 Payments*	2014 Payments*	Change	% Difference
Hospital-based	*$386,577,792*	*$403,842,256*	+$17,264,464	*+4.5%*
Freestanding	***$1,393,994,432***	***$1,286,886,204***	**–$107,108,228**	***–7.7%***
Total	*$1,780,552,224*	*$1,690,728,460*	–$89,823,764	*–5.0%*

*Analysis of 2013 and 2014 payments assumes 2012 Medicare utilization patterns.

These cuts primarily result from two policies: 1) the implementation of Medicare Economic Index Technical Advisory Panel recommendations and 2) a proposal to cap reimbursement in the freestanding setting at the lesser of the OPPS or ASC payment rate. Hospital-based radiation oncologists are not only immune from these policy cuts, but actually would receive an increase in reimbursement. As discussed in greater detail below, the RTA strenuously objects to the OPD/ASC cap policy.

The overall proposed reduction in reimbursement to freestanding radiation oncology is concentrated in certain key conventional radiation therapy (3D CRT) delivery codes.[1] These cuts range from 22% to 34%. Table 2 summarizes the conventional radiation therapy codes most impacted along with the reduction in PE RVUs and the aggregate payment reduction for each service.

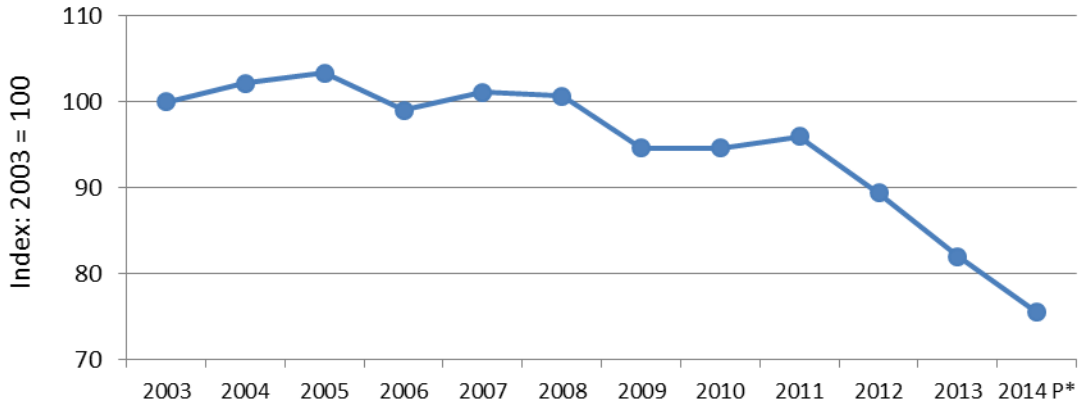
Table 2. Conventional Radiation Treatment Delivery Codes Affected by OPD/ASC Cap Proposal			
CPT	Descriptor	Proposed Reduction in PE RVUs	Aggregate Proposed Payment Reduction
77403	Radiation Treatment Delivery	–25%	–$378,181
77404	Radiation Treatment Delivery	–33%	–$250,730
77406	Radiation Treatment Delivery	–33%	–$41,740
77412	Radiation Treatment Delivery	–25%	–$159,442
77413	Radiation Treatment Delivery	–22%	–$23,886,694
77414	Radiation Treatment Delivery	–31%	–$30,980,071
77416	Radiation Treatment Delivery	–31%	–$4,290,862
77280	Set Radiation Therapy Field	–23%	–$3,240,194
77290	Set Radiation Therapy Field	–34%	–$17,256,968

[1] 3D CRT is distinct from other radiation therapy, such as intensity-modulated radiation therapy (IMRT).

We also believe that the cuts in the CY 2014 PFS Proposed Rule should not be considered in isolation, but rather in a historical context. Based on an analysis performed by Avalere Health, holding utilization at 2012 levels and excluding legislative changes to the conversion factor, freestanding radiation oncology reimbursement has been reduced 21.2% from 2008 to 2013. Including the CY 2014 PFS Proposed Rule, the cumulative reduction since 2008 will be 27.4%. Even after removing legislative changes to the conversion factor, the net reduction is 18.6% from 2003 to 2013, and 25% including the CY 2014 PFS Proposed Rule. The cumulative cut to freestanding radiation oncology since 2003 is plotted in Figure 1.

Figure 1. Freestanding Radiation Reimbursement

Change in reimbursement for freestanding radiation oncology, assuming constant 2012 Medicare utilization rates.

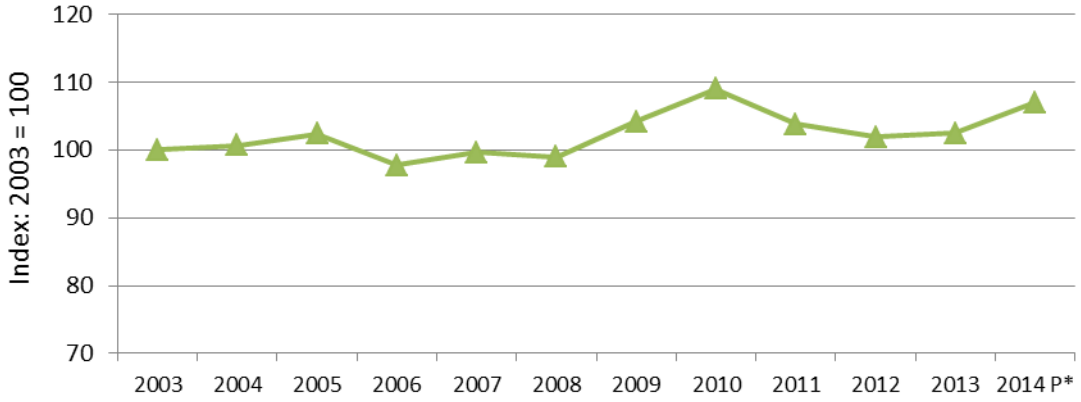


2014 P* = Proposed CY 2014 PFS Reimbursement

We note also that the historical impact of changes to the PFS for hospital-based radiation oncology is markedly different than that experienced by freestanding radiation therapy. Figure 2 illustrates the cumulative change in reimbursement to hospital-based radiation oncology in the PFS since 2003.

Figure 2. Hospital-based Radiation Reimbursement

Change in reimbursement for hospital-based radiation oncology, assuming constant 2012 Medicare utilization rates.



2014 P* = Proposed CY 2014 PFS Reimbursement

The impact of the proposed cuts to freestanding radiation therapy providers is disparate across treatment modalities and, as a result, diseases. For example, the proposed rule would cut reimbursement for breast and lung cancer by approximately 16%. To calculate the impact of the Proposed Rule on the treatment of particular cancers, Avalere Health analyzed the Medicare 5% sample to determine the average billing pattern for a non-palliative course of treatment using 3D CRT for various cancer types. Table 3 summarizes the impact for five cancers.

Table 3. Conventional Radiation (3D CRT) Course of Average, Non-Palliative Treatment

Cancer	2013	2014 Proposed	% Change
Breast	$ 12,679	$ 10,692	–15.7%
Genitourinary (Uterus, Cervix, Bladder)	$ 13,782	$ 11,608	–15.8%
Lung	$ 13,988	$ 11,782	–15.8%
Skin	$ 10,344	$ 8,764	–15.3%
Head & Neck	$ 12,828	$ 11,109	–13.4%

Note: Analysis excludes cases with fewer than 25 fractions of radiation. Reimbursement reflects average treatment patterns observed in the 2007–09 Medicare 5% sample.

While freestanding radiation oncology providers have experienced significant cuts since 2008, hospital-based radiation oncology has experienced an increase in payment during this time. The large proposed cuts in reimbursement for many cancers treated in the freestanding setting would increase the disparity in reimbursement between the freestanding and hospital-based settings. This widening gap would further incentivize market consolidation through hospitals' acquisition of physician practices and freestanding facilities, a trend that CMS notes with concern in the Proposed Rule. This trend, which we already observe occurring with regularity in the radiation therapy industry, drives more patients to the higher-cost setting and has the net effect of contributing to the overall rise in government and private health care spending nationally.

An analysis by Avalere Health, summarized in Table 4, compares the average reimbursement in the hospital outpatient setting with reimbursement for the same course of treatment in the freestanding setting. The analysis examines 2013 Medicare reimbursement and Medicare reimbursement as it would be under the CY 2014 PFS Proposed Rule. Across all radiation treatment episodes analyzed, the average Medicare reimbursement in the freestanding setting in 2013 was 90.8% of the reimbursement in the hospital outpatient setting. Under the PFS and HOPPS Proposed Rules, that disparity would increase nearly 12 percentage points, with PFS rates equivalent to 79.1% of hospital outpatient rates on average. It is inappropriate and unsustainable for hospital outpatient payments to be 25% greater than payments for the same service in the freestanding setting.

Table 4. Reimbursement for Radiation Therapy Episodes: Freestanding vs. Hospital Outpatient						
	2013: Total Episode Payments			***2014 <u>Proposed</u>: Total Episode Payments***		
	Hospital Outpatient	**Free-standing Clinic**	**Free-standing % of Hospital**	**Hospital Outpatient**	**Free-standing Clinic**	**Free-standing % of Hospital**
All radiation therapy episodes	$11,059	$10,043	90.8%	$11,172	$8,833	79.1%
All curative case episodes*	$17,224	$15,720	91.3%	$17,482	$14,003	80.1%
IMRT, all episodes	$18,666	$16,686	89.4%	$19,481	$15,591	80.0%
IMRT, curative case episodes*	$23,112	$20,618	89.2%	$24,048	$19,315	80.3%
3D-CRT, all episodes	$7,313	$6,772	92.6%	$7,080	$5,504	77.7%
3D-CRT, curative case episodes*	$11,611	$11,052	95.2%	$11,223	$8,939	79.6%

*Curative case episodes are generally considered treatment courses consisting of greater than 25 radiotherapy fractions, or treatment sessions.

<u>RTA Comments on the OPD/ASC Cap in the 2014 PFS Proposed Rule</u>

1. **The Radiation Therapy Alliance strenuously opposes the OPD/ASC cap proposal.** Beyond the large and potentially disruptive financial impact of this proposed policy, we believe that the policy is inappropriate for the following reasons:

    - <u>It is not appropriate to compare reimbursement rates for specific services under different payment methodologies</u>. The data and methodologies underlying the construction and determination of payment are complex and vary significantly across payment rules. For example, an increase in RVUs for one CPT code in the PFS results in a decrease in reimbursement for other codes due to the budget-neutrality constraint. As such, there is no assurance in the PFS that the payment for a given service is adequate. Different methodological constraints apply to the OPPS and ASC payment rules, and a mix-and-match across payment rules would likely exacerbate any misvalued reimbursement rates.

    - <u>The proposed OPD/ASC cap is complex and insufficiently detailed in the Proposed Rule</u>. An extraordinary amount of time and effort was required to understand and replicate the proposed cap. The Proposed Rule did not clearly enumerate which codes would be affected and by which factor they would be capped. CMS failed even to provide a single concrete

example of the cap methodology. Such a major policy change, affecting perhaps $500 million in payment reallocations across the PFS, should be more carefully detailed.

- Unlike hospitals and ASCs, a physician office or freestanding radiation oncology facility does not have sufficient diversity of services to offset an underpayment for a given CPT. Hospitals and ASCs have a relatively weak incentive to ensure that every payment is appropriately valued. Some rates may be too low and others too high, but for most hospitals, these errors offset one another. If, however, a given service is underpaid in the OPPS or ASC schedule and that rate is then applied to the PFS, a physician practice may not have sufficient payments from other services to offset the underpayment.

- The OPPS payment schedule contains an outlier payment adjustment that does not exist in the PFS. This outlier policy results in a lower payment rate for ordinary services. If that lower OPPS rate is then imposed on the PFS without any corresponding outlier payment policy, the PFS rate would be reduced even further.

- Contrary to the expressed objective of excluding certain "low volume" services, certain codes capped by the OPD/ASC cap policy would be paid at the ASC rate schedule even when there are no or low ASC volumes. This is because CMS only evaluates the low-volume threshold exemption with regard to OPPS volumes. In fact, roughly 60 of the 211 capped codes have no or very low ASC volumes but would be paid at the ASC rate. We believe that the low reimbursement rate in the ASC setting may be a cause for the low volume of services performed in this setting, as it may not be financially viable to provide these services at such a low rate of reimbursement.

- Because the OPD/ASC cap policy only reduces certain isolated codes, it exacerbates the disparity in payment across settings. Table 4 illustrates this effect clearly, and the RTA believes that such a trend is wholly inconsistent with the objectives of site neutrality and would cause further consolidation in the radiation therapy industry.

- It is not appropriate to use 2013 OPD/ASC rates to determine 2014 RVUs for non-facility services under the PFS. The proposed OPD/ASC cap relies on 2013 reimbursement rates in the OPPS and ASC setting for capping certain services in the PFS in 2014. This intertemporal application of payment rates means that CMS is proposing to utilize outdated OPPS and ASC rates to pay physicians at the same time that the agency is proposing updated and revised rates in other settings. The RTA is deeply troubled that CMS would knowingly apply outdated reimbursement rates in the PFS that the agency expressly rejects in the OPPS Proposed Rule. We also believe that this raises fundamental questions about the long-term sustainability of this policy.

2. **If CMS insists on an OPD/ASC cap proposal, the RTA strongly urges CMS to, at a minimum, utilize rates set forth in the 2014 OPPS and 2014 ASC Final Rules.** While this adjustment would fail to address the inappropriate nature of cross-walking individual reimbursement rates across fee

schedules, it would eliminate the intertemporal distortions resulting from the Proposed Rule's use of 2013 OPPS and ASC rates.

Other RTA Comments

1. **The RTA supports the proposed price adjustment for the laser diode probe.** The CY 2014 PFS Proposed Rule indicates that CMS is proposing to adjust the price for the laser diode probe (ER040), which had a direct PE input database price of $7,678, to the corrected price of $18,160 (as noted in the CY 2013 PFS Final Rule with comment period (77 FR 68922)). The RTA raised this issue with CMS in our December 31, 2012, comment letter to the 2013 PFS Final Rule. We thank CMS for proposing to make this adjustment to the price of the laser diode probe.

2. **The RTA appreciates the continued inclusion of the radiation treatment vault as a direct expense.** In the CY 2013 PFS Final Rule, CMS asked commenters if it is appropriate to treat the radiation treatment vault as a direct expense, "since it is difficult to distinguish the cost of the construction of the vault from the cost of the construction of the building." Since last year, the RTA has used various means—its CY 2013 PFS Final Rule comment letter, separately submitted vault data, and a site visit to a freestanding radiation therapy center near Baltimore—to present data and evidence to CMS explaining the clear reasoning for continuing to treat the vault as a direct expense. In addition, we have proposed that CMS update the assumed vault price to reflect more current paid invoice data and depreciate the vault over 7 years instead of the current 15 years. We reiterate this suggestion here. The radiation treatment 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, making it appropriate to assume the same useful life for both equipment items. The RTA appreciates CMS's decision to maintain the vault as a direct cost input for radiation treatment delivery codes.

Conclusion

We thank CMS for the opportunity to comment on the 2014 PFS Proposed Rule. We are extremely concerned that the proposed OPD/ASC cap will have a significant adverse impact on the ability of freestanding radiation oncologists to continue providing access to quality care for our patients. An overall reduction in Medicare reimbursement of nearly 8% and cuts to the treatment of breast, lung, and other cancers of nearly 16% would be very harmful to patient care. We reiterate that these cuts are impacting only freestanding radiation oncologists, not hospital-based providers. We urge CMS to withdraw this proposal for the reasons outlined above. Absent that decision, CMS should utilize 2014 OPD/ASC rates, rather than 2013 rates.

More broadly, the RTA continues to advocate for fundamental payment reform and believes strongly that freestanding radiation therapy providers would be excellent candidates for episode-based, bundled payments with an appropriate registry. We will continue to work with policymakers to pursue the goal of establishing payment stability and improved incentives for quality care, and we always welcome the opportunity to discuss the opportunities for payment reform with CMS.

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