

September 8, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-1631-P, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016

Dear Acting Administrator Slavitt:

The Radiation Therapy Alliance (RTA) appreciates the opportunity to submit comments regarding the 2016 Physician Fee Schedule (PFS) Proposed Rule. The RTA represents 296 freestanding facilities in 35 states and 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, Association of Freestanding Radiation Oncology Centers (AFROC), Large Urology Group Practice Association (LUGPA), and Vantage Oncology.

Summary

The RTA is very concerned about the potential impact of the Proposed Rule on the freestanding radiation sector for a number of reasons. First, CMS's proposal to increase the equipment utilization rate to 70 percent is not supported by evidence. In fact, as described in this letter, the evidence indicates that the equipment utilization rate for linear accelerators among freestanding facilities is between 46.7 percent and 56.0 percent.

Second, CMS's proposal to exclude the separate cost of on-board imaging equipment is misinformed. CMS should consider new invoice data regarding the price of on-board imaging equipment that we understand to have been recently provided by an equipment manufacturer.

Third, treatment vaults on average are currently undervalued by approximately \$121,000, and mandatory service contract costs are undervalued by approximately \$96,000. CMS should consider the well-documented evidence provided by the RTA in the form of

submitted invoices regarding updated costs for the treatment vault and equipment service costs. The agency has consistently ignored this evidence for no articulated reason.

Fourth, while the RTA recognizes the appeal of establishing “simple,” “intermediate,” and “complex” conventional radiation treatment codes as well as “simple” and “complex” IMRT treatment delivery codes, the establishment of these codes is not rationally informed because it fails to consider the impact of the wide payment disparity for these codes relative to reimbursement in the hospital outpatient setting.

Finally, the lack of transparency in creating and setting the values for new consolidated codes makes it extremely difficult to comment meaningfully on major changes to an entire set of codes. CMS continues to rely on the work of the RUC, which it acknowledged in last year’s rule is not transparent and which the Government Accountability Office recently criticized for lack of transparency ([GAO-15-434](#)). To add to the problem, CMS applies its own refinements that are not sufficiently detailed.

The RTA urges CMS to 1) maintain a utilization rate of 50 percent for equipment inputs for radiation delivery codes; 2) keep on-board imaging as an independent item; 3) update equipment service costs and vault costs to reflect the evidence submitted by the RTA on December 31, 2013; and 4) consider alternative criteria for the definition of simple and complex IMRT treatments.

The remainder of this letter is organized as follows. Section I summarizes the overall impact of the Proposed Rule on freestanding radiation oncology. Section II discusses the proposed change in equipment utilization. Section III discusses CMS’s assumed costs for on-board imaging and other equipment inputs associated with treatment delivery. Section IV relates to improved criteria for simple and complex IMRT.

I. Impact of Proposed Rule

According to Table 45 of the Proposed Rule, the impact of CMS’s proposed policy changes would result in a 3 percent decline in allowed charges for radiation oncology in 2016. As we have noted in previous comment letters, this impact analysis combines the effects of the Proposed Rule on freestanding and hospital-based radiation oncology. The disaggregated effects of the Proposed Rule indicate that the impact to freestanding facilities is –6 percent while the impact on hospital-based providers is +5 percent. The negative impact on freestanding radiation oncology is larger than any category of care detailed in Table 45. This is the second consecutive year that freestanding radiation oncology has faced the largest proposed cuts in the PFS.

The large proposed cuts in reimbursement to freestanding radiation oncology providers for CY 2016 come on top of deep cuts in reimbursement rates by CMS over the last decade.

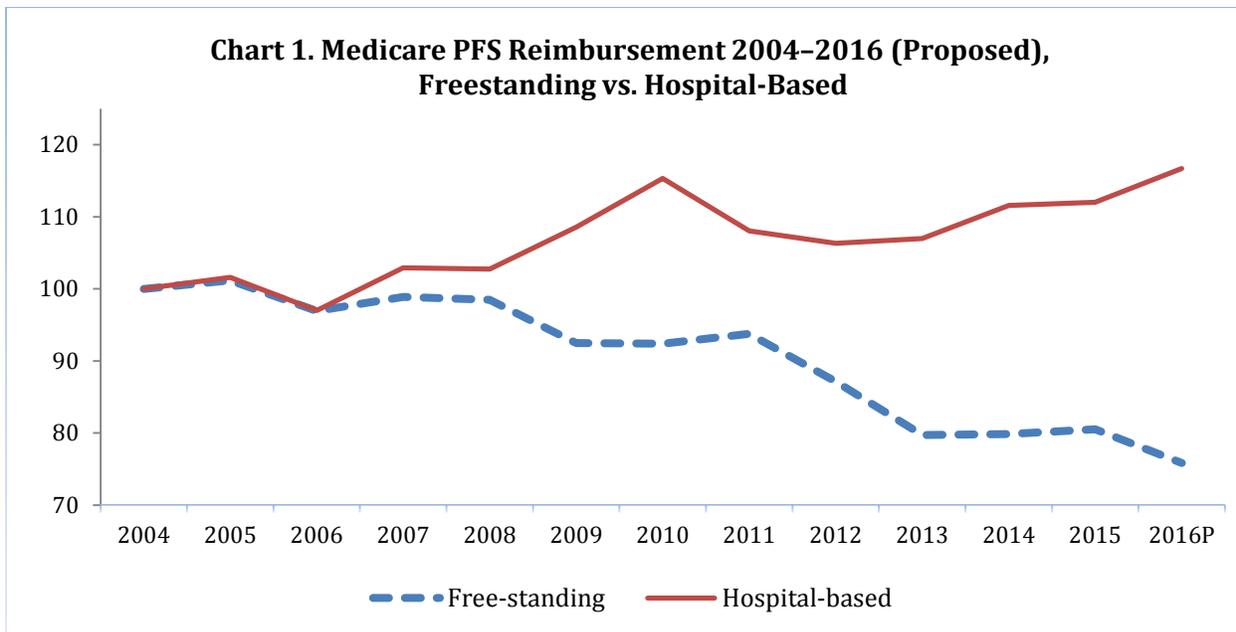
Avalere Health estimates that the cumulative change in reimbursement to freestanding radiation oncology has been –21 percent from 2005 to 2015 (assuming constant 2014 utilization). If CMS finalizes the cuts in the Proposed Rule, the aggregate impact on reimbursement will be –25 percent since 2005.

Certain frequently billed CPT codes will experience an even more dramatic decline in reimbursement. For example, a new code, CPT 77385 (IMRT treatment delivery, simple), will be reimbursed 30 percent less than the code it will replace, CPT 77418. Frequent and dramatic proposed cuts (even if not finalized) have had significant adverse effects on the industry and were a factor in the bankruptcy of one major provider in recent years.

Moreover, the net impact of the proposed changes will be particularly large for the care of prostate and breast cancer patients. According to Avalere Health, the impact of the Proposed Rule on an average episode of care for a prostate cancer patient treated with IMRT will be –25 percent and for a breast cancer, –19 percent. Combining these new cuts with cuts from previous years, the reimbursement for an average episode of care for prostate cancer treated with IMRT in the freestanding setting will be just 64 percent of the reimbursement for the same care in the hospital outpatient setting (\$17,118 vs. \$26,825). For breast cancer, the payment disparity will be 68 percent (\$11,056 vs. \$16,210).

Finally, the Proposed Rule further exacerbates the disparity in reimbursement across settings, contrary to the objective advocated by MedPAC and pursued by Congress for site-neutral payment policies. Avalere Health estimates that radiation oncologists in a freestanding clinic, who are currently paid 90 percent of the hospital outpatient rate, will be paid 80.3 percent of the outpatient rate if the Proposed Rule is finalized.

Changes in the Indirect Practice Cost Index (IPCI) in recent years have contributed to the widening disparity in reimbursement across settings. The IPCI, a factor in PE methodology that adjusts for variations in indirect costs across specialties, moves counter to the RVUs for treatment delivery codes. As a result, when reimbursement for a treatment delivery code is cut, the IPCI increases reimbursement for other radiation oncology codes. Because hospital-based physicians do not bill for delivery codes, hospital-based radiation oncologists experience an increase in reimbursement for their frequently billed codes when reimbursement for a treatment delivery code is cut. Chart 1 illustrates the cumulative impact of reimbursement changes since 2004 for freestanding and hospital-based radiation oncology. In the Proposed Rule, a dramatic increase in the IPCI for radiation oncology (from 1.05 to 1.25) is the primary driver of the increase in payments to reimbursement codes frequently billed by hospital-based radiation oncologists.



Note: Both freestanding and hospital-based reimbursement under the PFS are indexed to 100 in 2004 to show the relative change in reimbursement (assuming constant FY2014 utilization).

II. Proposal to Increase Equipment Utilization Rate to 70 percent

The Proposed Rule adjusts the equipment utilization rate assumption to 70 percent, phased in over two years. The RTA disagrees with this proposed change and believes that the actual utilization rate of linear accelerators is nearest to 50 percent, as CMS currently assumes. We offer the following evidence in support of this view.

- 1. A survey of 242 facilities shows a mean utilization rate of 46.7 percent.** In August 2015, the RTA distributed a survey to member facilities as well as facilities in the US Oncology network to determine equipment utilization rates. There were 242 responses. The questionnaire gathered information regarding facility location, number of linear accelerators, number of hours per week that the facility treats patients, number of treatments per linac during the first six months of 2015, the maximum number of patients that can be scheduled per hour per linac, and the amount of time per day that the facility does not treat patients (staff lunch time and machine warmup time).

See Table 1 for a summary of the survey results. The survey shows that the average number of hours that a facility is open per week is 46.5. The average number of treatments per day per linac is 20.3; the median is 19.9; and the 25th and 75th percentiles are 12.7 and 26.7, respectively. Clearly there is a wide range in average daily utilization across surveyed facilities.

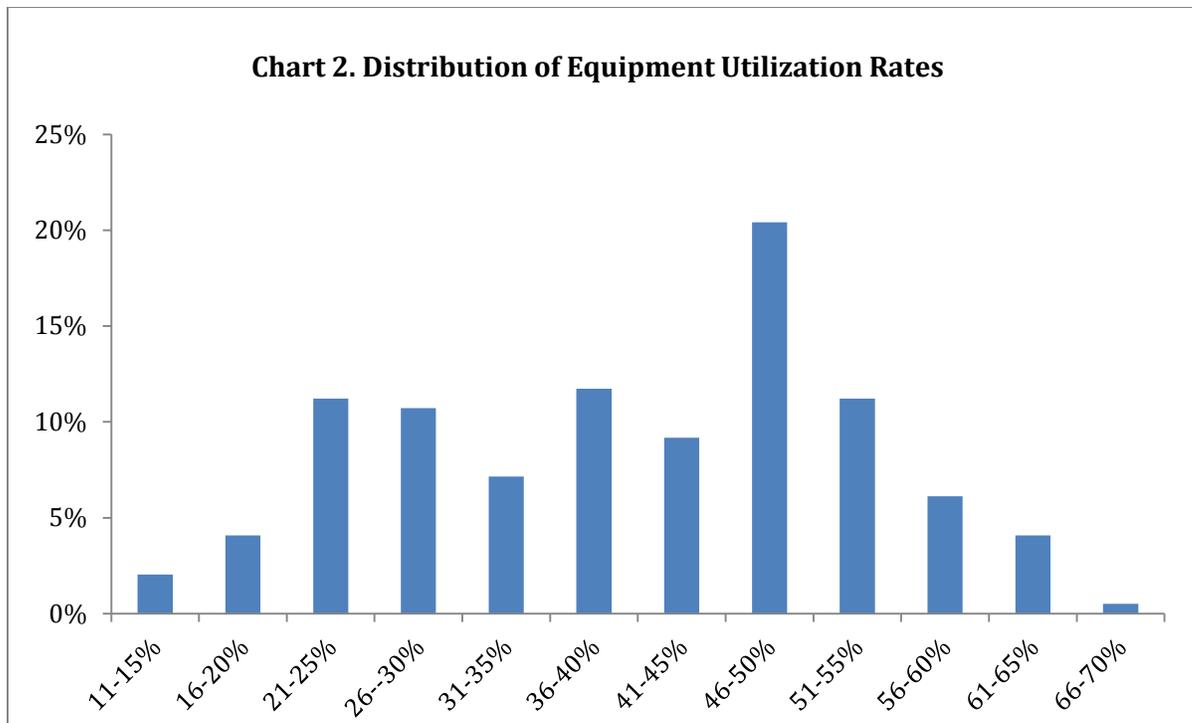
Table 1. Results of RTA Facility Survey

<i>Treatments per linac per day (January–June 2015)</i>	
Average	20.3
Median (50th percentile)	19.9
25th and 75th percentile range	12.7–26.7
<i>Average equipment utilization rate</i>	
Average utilization rate assuming 50 hours/week	46.7%
Average utilization rate assuming actual facility hours	56.0%

Survey data were also used to estimate an equipment utilization rate by dividing the average number of treatments performed per week by the total potential number of treatments that a facility could perform per week. The denominator was calculated two ways: 1) assuming a 50-hour week (consistent with current CMS methodology), and 2) using the actual total observed hours a facility was open per week. In both cases the number of hours was multiplied by the maximum number of patients that can be scheduled per hour per linac. The data indicate an equipment utilization rate of 46.7 percent in the first case and a utilization rate of 56.0 percent in the second case. A sensitivity analysis that excluded the tails (5th and 95th percentiles) did not alter the results.

The RTA believes that for the purpose of estimating an equipment utilization rate, the most appropriate assumption for facility operating hours is 50 hours per week (which yields a utilization rate of 46.7 percent). Because the intent is to estimate the facilities' operating potential, it is appropriate for CMS to base this number on the maximum possible number of hours that a facility can feasibly be open, not the actual number of hours a facility is open. If, for example, a facility closes 30 minutes early because of low patient supply, this decision should not affect the utilization rate since that facility has the potential to treat patients in that time slot. In fact, survey results indicate that 20 percent of facilities surveyed were open more than 52 hours per week.

Chart 2 illustrates the wide disparity in equipment utilization rates across facilities. Each vertical bar represents the share of the facilities that reported equipment utilization rates within a given 5-point range. As noted in Table 1, the mean is 46.7 percent. These data, based on an assumed 50-hour work week, vary significantly. For example, at the 25th percentile, the equipment utilization rate is 26 percent, and at the 75th percentile, the equipment utilization rate is 60 percent. Two-thirds of all linacs have a utilization rate lower than 50 percent, and one-third of all linacs have a utilization rate between 46 percent and 55 percent.



Based on these data, any increase in the assumed utilization rate is wholly inappropriate. Facilities with equipment utilization rates well below the current rate would be particularly harmed by the Proposed Rule, and the survey indicates that there are many such facilities. Over one-fourth of all linacs in the survey had equipment utilization rates less than or equal to 35 percent. Conversely, only 3 percent had utilization rates equal to or greater than the proposed 70 percent.

2. An equipment utilization rate model yields a rate of 45–52 percent. The RTA supports an analytical framework proposed by AFROC to impute an equipment utilization rate based on CMS claims data. This analysis relies on CMS utilization data for radiation therapy delivery codes from 2014 along with the CMS crosswalk to proposed codes and volumes—CPT 77385 (855,692 treatments), CPT 77386 (435,203 treatments), CPT 77402 (24,627 treatments), CPT 77407 (24,092 treatments), and CPT 77412 (858,980 treatments)—along with 2015 proposed treatment times for these codes (29, 44, 14, 19, and 23 minutes, respectively). Together, these data yield an estimate of the total number of treatment minutes for Medicare FFS in the freestanding setting per year (64.5 million). To estimate an average number of treatment minutes per linear accelerator, this number is divided by an estimate of the share of all treatments that are Medicare FFS (0.5) and by an estimated number of linear accelerators in the freestanding setting (1,830). Finally, this number is divided by the total number of available minutes per year (150,000). Based on this framework, the implied equipment utilization rate is 47 percent. A

sensitivity analysis indicates that this result can range from 45 percent to 52 percent by varying the estimated number of linacs (1,830–1,922) and the share of treatments that are Medicare FFS (45–50 percent).

A variety of public sources underpin the assumptions in this model. We use the American Society for Radiology Technicians (ASRT) survey data (which CMS cites in the Proposed Rule) to estimate the average number of linacs per facility (2.0 in our base case and 2.1 in our sensitivity analysis). From the CMS physician billing public use database, which we use to create a proxy for the number of facilities, we identify 917 unique locations. The total available hours (the denominator in the utilization rate calculation) is drawn from the CMS assumption that facilities operate 10 hours a day, 5 days a week, 50 weeks a year.

3. *Clinical trends suggest that the equipment utilization rate has not increased.*

Finally, three recent clinical trends refute CMS's view that the utilization rate has increased. First, there has been a dramatic decline in diagnoses of prostate cancer following the recommendation of the U.S. Preventive Services Task Force (USPSTF) against routine PSA screenings for prostate cancer. An April 2015 study published in *The Journal of Urology* found that when comparing PSA testing rates before and after the USPSTF final determination, the testing rate among men aged 60–69 dropped from 19.3 percent to 7.7 percent ([Werntz 2015](#)). Evidence published in the same journal in June 2015 indicated a 28 percent decline in the year following the USPSTF announcement ([Barocas et al. 2015](#)). The *Journal of the American Board of Family Medicine* published a study in July 2015 that found a 14 percentage point drop in PSA screenings for men aged 75 and older between 2008 and 2013 ([Li et al. 2015](#)).

Second, a dramatic increase in recent years in “watchful waiting” among men diagnosed with prostate cancer also points toward a lower, not higher, equipment utilization rate. A July 2015 study in the *Journal of the American Medical Association (JAMA)* examined medical records for 10,000 men across 45 urology practices from 1990 through 2013 and found a dramatic rise in watchful waiting ([Cooperberg and Carroll 2015](#)). Among low-risk prostate cancer patients older than 74, the rate of watchful waiting more than tripled (from 22 percent to 76 percent) between 2000–2004 and 2010–2013. Moreover, the *JAMA* study explicitly indicates that the rise of watchful waiting among low-risk prostate cancer patients is accompanied by a statistically significant decline in radiation therapy.

Third, a recent trend in clinical practice for some radiation oncologists includes an increased reliance on hypofractionation, which utilizes fewer fractions of radiation at higher doses. Evidence published in the *International Journal of Radiation Oncology* in December 2014 indicates that hypofractionation for breast cancer

patients increased nearly 10 percentage points (3.8 percent to 13.6 percent) from 2006 to 2010 ([Reshma et al. 2014](#)).

These three trends—fewer PSA tests and prostate cancer diagnoses, a large increase in the number of prostate cancer patients who are forgoing active treatment, and an increase in hypofractionation for breast cancer and other patients—can only reduce, not increase, equipment utilization.

4. *CMS's rationale for raising the equipment utilization rate for linear accelerators lacks adequate support and a cogent explanation.* CMS explains its equipment utilization rate proposal thus:

We developed the 70 percent rate based on a rough reconciliation between the number of minutes the equipment is being used according to the new recommendations versus the current number of minutes based on an analysis of claims data. . . . We believe . . . 70 percent is more accurate than the default utilization assumption of 50 percent. (78 FR 41772)

This rationale is problematic. First, a “rough reconciliation” is an inadequate basis for proper rulemaking given the significant impact that a change in the equipment utilization rate has on reimbursement to providers. Affected codes constitute the majority of reimbursement to radiation oncologists, and the first-year impact alone exceeds \$55 million. The second-year effect will be of similar magnitude.

Second, CMS's assertion that an analysis of claims data supports its position is refuted by the claims data analysis we offer above (as well as the survey results). On top of this, CMS offers no information regarding its methodology for the analysis it claims supports CMS's position and thus has denied the public any meaningful opportunity, in fact any ability at all, to comment on that methodology or its results. The agency's failure to offer sufficient empirical justification for the proposed change violates the requirements of the Administrative Procedures Act.

And finally, CMS employs a single “default utilization assumption” for virtually all equipment reimbursed by the PFS (except MRI and CT). To deviate from that assumption only for select items, and only to reduce reimbursement, unfairly distorts reimbursement across the entire PFS.

In addition, the RTA believes, based on an analysis by Avalere Health that attempts to replicate the impact of the proposed rule, that CMS inappropriately applied the proposed change in utilization rate for the linear accelerator to other equipment as well. The Proposed Rule clearly states that the change is being proposed only for the linear accelerator: “we are proposing to adjust the equipment utilization rate assumption for the

linear accelerator” (78 FR 41771), and “we are proposing to use a 70 percent assumption based on recognition that **the** item” (78 FR 41772, emphasis added). The RTA urges CMS to ensure that in withdrawing the proposed change in the equipment utilization rate for the linear accelerator, the agency restore the 50 percent utilization rate to all equipment.

III. Proposal to Remove On-Board Imaging as an Independent Item for Radiation Treatment Codes

In the Proposed Rule, CMS states:

Because the invoices used to price the capital equipment [for radiation delivery] included “on-board imaging,” the cost of that equipment is already reflected in the price per minute associated with the capital equipment. Therefore, we have not included it as a separate item in the proposed direct PE inputs for these codes, even though it appeared as a separate item on the PE worksheet included with the RUC recommendations for these codes. (78 FR 41770)

The RTA opposes this change and urges CMS to continue to include the cost of on-board imaging as a separate item. In addition, the RTA urges CMS to include other capital costs indicated (but ignored) in invoices previously supplied by the RTA to CMS.

- 1. *The impact of this proposal is significant.*** Among the three changes that CMS is proposing to the RUC recommendations for CY 2016 (removing the value for on-board imaging, reducing the treatment minutes, and increasing the utilization rate), the removal of the separate price for on-board imaging has the largest impact, reducing aggregate payments by over \$60 million. (The combined effect of all three changes reduces reimbursement for treatment delivery codes by 19.1 percent relative to the RUC-based recommendations.)
- 2. *New invoices provided to CMS support keeping on-board imaging as a separate item.*** RTA understands that at least one manufacturer of linear accelerators has provided CMS with recent invoices reflecting the cost of the linear accelerator and the separate cost of on-board imaging. While the RTA is not privy to these data directly, we urge CMS to accept these new data and to use those costs as PE inputs for delivery codes.
- 3. *CMS should not cherry-pick invoice data to only reduce reimbursement.*** We believe that if CMS would like to “augment” the RUC recommendations with additional changes regarding the value of equipment used in radiation treatment delivery codes, CMS must consider all recent invoice data that it has received. In particular, CMS should—regardless of its decision regarding the cost of on-board imaging—update PE inputs for radiation oncology delivery codes in two respects:

treatment vault price and service costs for the linear accelerator to reflect invoice data previously submitted on behalf of the RTA.

On December 31, 2013, the RTA, through a contract with Avalere Health, submitted invoice data that clearly indicate that the cost of the radiation treatment vault and the service cost associated with the linear accelerator are misvalued. (A copy of the cover letter from Avalere to CMS is attached as Exhibit 1.) As we noted in our January 27, 2014, comment letter to CMS on the CY 2014 Final Rule, “The data indicate that CMS’s assumed cost of \$773,104 for putting a vault system in place is currently undervalued by over \$121,000. The median cost (based on 4 recent vault costs) was \$894,806 compared to the cost assumed by CMS, \$773,104.” The RTA requests that CMS consider all suitable invoice data that it has received and update the cost of the vault to \$894,806. In addition, the RTA continues to urge CMS to depreciate the vault over seven years rather than fifteen years because the vault is integrally linked and custom-designed to the linear accelerator, which has a seven-year useful life. These changes should be reflected in CPT codes 77385, 77386, 77387, 77402, 77407, and 77412.

With regard to the service costs for equipment associated with treatment delivery codes, the RTA has also previously provided information regarding the true cost of this component of the delivery of care. As we noted in our January 2014 letter, “The annual cost of service contracts for actual linear accelerators ranges from \$170,000 to nearly \$250,000, with a median cost of \$228,723. Compared to the calculated maintenance cost in the PERVU process [estimated to be \$132,089], the actual service contracts are approximately \$96,634 higher per year.” These maintenance contracts are critical to the safe operation of the linac. Because the PE methodology for treatment of equipment maintenance cost is based on a fixed percentage of the cost of the equipment, the simplest approach for adjusting that assumption would be to add a separate line item, with a one-year life, to the PERVU methodology to reflect the amount by which maintenance costs are underestimated (\$96,634). These changes should be reflected in CPT codes 77385, 77386, 77387, 77402, 77407, and 77412.

IV. Improved Criteria for Simple and Complex IMRT Delivery Codes

Revisions by the CPT Editorial Board have resulted in CPT 77418 (“Intensity modulated treatment delivery”) being deleted and replaced by 77385 (“IMRT delivery; simple”) and 77386 (“IMRT delivery; complex”). While the RTA recognizes that the time required for IMRT delivery can vary, the descriptors used to bifurcate CPT 77418 are overly simplistic. Specifically, CPT 77385, the new IMRT simple code, is for all prostate and breast cancer patients regardless of the complexity posed by individual cancers.

The designation of IMRT as “simple” for all prostate and breast cancer and “complex” for every other cancer is incorrect and does not reflect differences in work, capital, and labor inputs to deliver the therapy. In reality, there exist both simple and complex cases of prostate and breast cancer. Clearly, treatments directed at a single site of disease with relatively robust adjacent normal tissues are treated more easily by current IMRT techniques. However, when there are multiple tumor targets with sensitive adjacent normal targets, the treatment trajectories and modulation required to achieve dose coverage with normal tissue sparing require considerable more effort, time, and personnel intervention. The RTA believes that it would be more appropriate to define 77386 to include the treatment of any cancer for which there is also lymph node treatment. According to ICD-10 diagnostic codes, which take effect in October 2015, any patient with C77.X secondary diagnosis treated with IMRT would be treated appropriately with CPT 77386. Within the ICD-9 framework, this can also be achieved through the inclusion of 196.X secondary diagnosis. Both C77.X and 196.X indicate “secondary and unspecified malignant neoplasm of lymph nodes.”

The wide disparity in payment for simple IMRT vs. complex IMRT in the freestanding setting and lack of payment differential in the hospital outpatient setting runs counter to the objectives of site neutrality and will increase the incentive for industry consolidation between hospitals and freestanding providers who bill a disproportionate share of simple IMRT delivery codes. The reimbursement disparity of CPT 77385 and CPT 77386—intended to reflect the variation in necessary resources between “simple” and “complex” IMRT treatment—is nonexistent in the hospital outpatient PPS because both simple and complex IMRT share a single APC. Bifurcating IMRT reimbursement in one setting while maintaining a single reimbursement rate for both CPT codes in a different setting is likely to induce unintended consequences in the delivery of care, further exacerbate payment disparities across settings, and encourage further industry consolidation among freestanding providers that perform a disproportionate share of simple IMRT.

V. Conclusion

The RTA thanks CMS for the opportunity to comment on the CY 2016 PFS Proposed Rule. As we have explained in previous correspondence and discussions with CMS, the simple economics of operating a freestanding radiation oncology facility necessitates adequate reimbursement to cover the large fixed costs associated with financing the construction and equipment necessary to provide critical treatments to oncology patients. Current reimbursement rates are insufficient to finance a new facility, yet the number of Medicare beneficiaries is projected to increase sharply in the coming decade. At current rates, only facilities that have older equipment and are debt free or have extraordinarily high patient volumes can remain viable. And even these facilities cannot afford to upgrade to new

technologies as they become available. Given these realities, the RTA urges CMS not to finalize proposed cuts to freestanding radiation oncology.

CMS's proposal to increase the equipment utilization rate is unfounded, and the proposal to eliminate the separate cost for on-board imaging conflicts with recent invoice data provided by a major equipment manufacturer on the cost of the linear accelerator and on-board imaging.

More broadly, the RTA continues to advocate for fundamental payment reform for freestanding radiation oncology 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,

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

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



To: Centers for Medicare & Medicaid Services
Center for Medicare Management
Hospital and Ambulatory Policy Group
Division of Practitioner Services

From: Eric Hammelman
Avalere Health

Date: December 31, 2013

Re: Invoices for radiation treatment vaults and service costs associated with linear accelerators

Please find attached to this email a list of invoices supplied by members of the Radiation Therapy Alliance (RTA) for a radiation treatment vault, CMS equipment code ER056, currently used as an input in CPT codes 77402-77416, 77418, and 77373. The RTA contracted with Avalere Health to collect invoices from member facilities and supply the invoices to CMS.

Radiation Treatment Vault

There are four (4) separate vault invoices included with this submission. For each vault, we have provided a summary sheet, a description of the cost allocation process, a summary sheet of the individual invoices, and each separate invoice. In addition, Avalere is also supplying an Excel spreadsheet to assist CMS in identifying the specific section of the packet with each element.

In addition to considering these invoices as updated input prices for the CPT codes listed above, members of the RTA believe the costs associated with the radiation treatment vault should be included with CPT 77372, SRS linear based. This treatment requires the use of a linear accelerator, which in turns requires the use of a radiation treatment vault.

Linear Accelerator Service Contracts

Separately, the RTA is also submitting nine (9) invoices for the service contracts related to linear accelerators. Currently, linear accelerators are used in CPT codes 77402-77416, and 77418, under CMS equipment codes ER009, ER010, and ER089. The RTA has previously supplied CMS with invoices regarding the purchase costs of these linear accelerators.

The manufacturers of linear accelerators offer service contracts to maintain the equipment in proper working order. This maintenance is necessary to ensure the safe and proper usage of the machines. In most circumstances, the cost associated with maintenance in the first year after purchase is included in the price of the linear accelerator, but subsequent years' maintenance require the purchase of additional service contracts.

While the RTA recognizes that the CMS methodology for calculating the per-minute input cost of all equipment used in the Practice Expense Relative Value Unit (PE RVU) process incorporates a five (5) percent maintenance factor, there is concern that this adjustment factor does not reflect the full maintenance cost of this specialized machine. Avalere estimates that the maintenance factor adjustment for the linear accelerator used in CPT code 77418, CMS equipment code ER089, is approximately \$1.761 per minute. Using the CMS assumption that the equipment is used for 75,000 minutes per year, this would suggest a total annual maintenance cost of \$132,089 for the linear accelerator is currently accounted for in the CMS PERVU process.

As demonstrated by the attached invoices, the annual cost of service contracts for actual linear accelerators ranges from \$170,000 to nearly \$250,000, with a median cost of \$228,723. Compared to the calculated maintenance cost in the PERVU process, the actual service contracts are approximately \$96,634 higher per year.

The RTA believes the annual marginal cost associated with the service contracts of \$96,634 should be part of the input cost for all radiation therapy treatment codes (CPT codes 77402-77416, and 77418). While there are three separate equipment codes for different types of linear accelerators on the current PE input list, only one of these machines (ER089) is currently sold in the US. As such, the service costs associated with this machine reflect the service costs associated with all radiation treatment codes.

CMS could use several different approaches to adjusting the input prices to reflect the service costs associated with linear accelerators.

- One option would be to add the total marginal cost of the service contracts to the price of the linear accelerator. Since the expected life of a linear accelerator is 7 years, but the first year of service costs is included in the purchase price of the machine, CMS could add an incremental \$579,804 to the price of linear accelerator.
- Another option would be to create a separate input item related to the service contracts. Since the contracts are purchased each year, the useful life of the new input would be 1 year. To avoid potentially "double-counting" these costs, CMS could remove the maintenance factor from the new input and use the incremental \$96,9634 as the cost, or it could remove the maintenance factor from both the new input as well as the linear accelerator and use the entire service cost of \$228,723.

Please note that the price information contained on these invoices should be treated confidentially under the Trade Secrets Act. We have redacted all customer names.

Please let me know if I can provide any assistance in understanding or interpreting the attached invoices. I also have the ability to request additional information from the providers who supplied the invoices, if needed. I can be reached via phone at (202) 207-1303 or via email at ehammelman@avalerehealth.net.

Thank you,

Eric Hammelman