

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 21st 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.

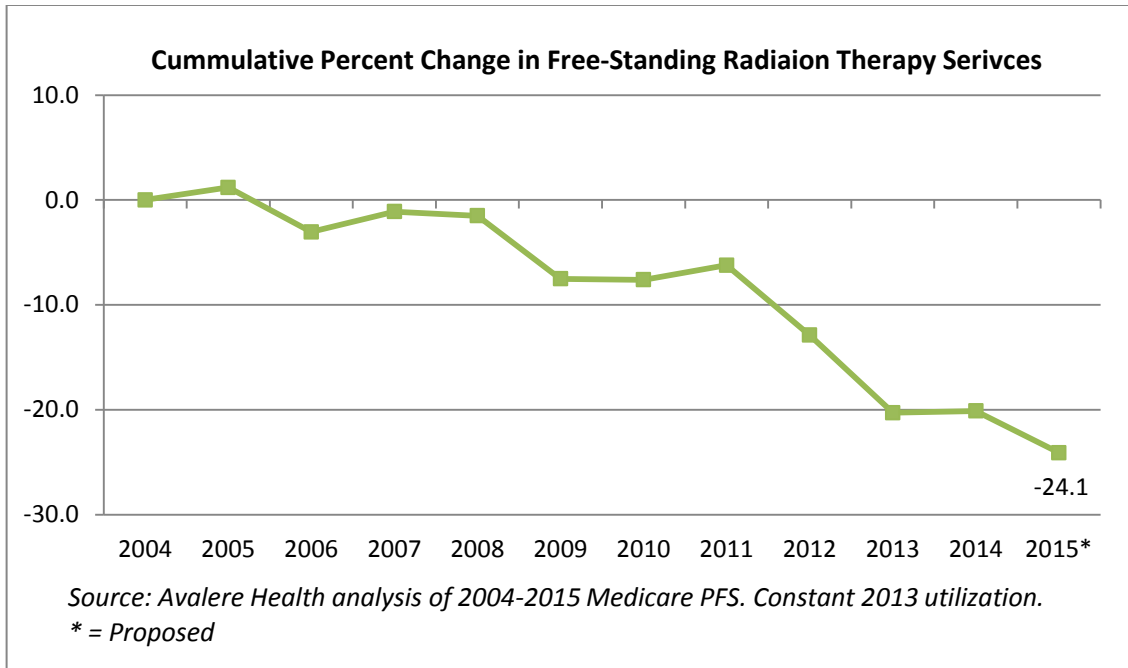
The remainder of this letter details the impact of the Proposed Rule—as best we can in light of the unknown factor noted above— on free-standing radiation oncology providers, explains why the radiation therapy vault should remain a direct PE, expresses our serious concern with CMS's proposal to delay 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.

I. 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 Tenant 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) | \$428.88 | \$370.54 |
| (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) | \$226.93 | \$192.52 |
| (9) Adjusted Direct | Steps 2-4 | = (6)+(7)+ (8) | \$252.95 | \$218.54 |
| (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) | 6.33 | 5.37 |
| (14) Adj. direct cost converted | Step 5 | = (11)+(12) +(13) | 7.06 | 6.10 |
| (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 | 9.49 | 8.20 |
| (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) | 10.04 | 8.75 |
| (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) | 3.98 | 3.70 |
| (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 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