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Integrating Science and Technology into Patient Care
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September 8, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS–1631–P
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Acting Administrator Slavitt:

The American College of Radiation Oncology (ACRO) is pleased to offer its comments to the Centers for Medicare and Medicaid Services (CMS) on the Proposed Rule: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 (CMS-1631-P).[1] ACRO represents radiation oncologists in the socioeconomic and political arenas. With a current membership of approximately 1,000, ACRO is dedicated to fostering radiation oncology education and science; improving patient care services; studying the socioeconomic aspects of the practice of radiation oncology; and encouraging education in radiation oncology.

ACRO appreciates this opportunity to comment on the proposed regulations. This letter will comment on the following issues:

- Overview of the CY 2016 Physician Fee Schedule Proposed Rule
- Proposed Rule Widens Payment Differential for Hospitals and Freestanding Centers
- Proposed Rule Contains Massive Cuts for the Treatment of Prostate and Breast Cancer
- Equipment Utilization Assumption Should Be Maintained at 50 Percent
- Treatment Delivery/Imaging Codes Should Be Updated Holistically with Most Recent Data
- Need for a New Payment System

[1] Federal Register, 80 FR 41686 (July 15, 2015)

Overview of the CY 2016 Physician Fee Schedule Proposed Rule

The impact of the Proposed Rule to the overall radiation oncology specialty is – 3%. As in past years, however, the Physician Fee Schedule combines the effect on freestanding and hospital-based providers, thereby masking the effect on freestanding providers. The impact of the Proposed Rule to freestanding providers is – 6%.

The disaggregated effects of the rule to the different settings are reflected in the tables below.

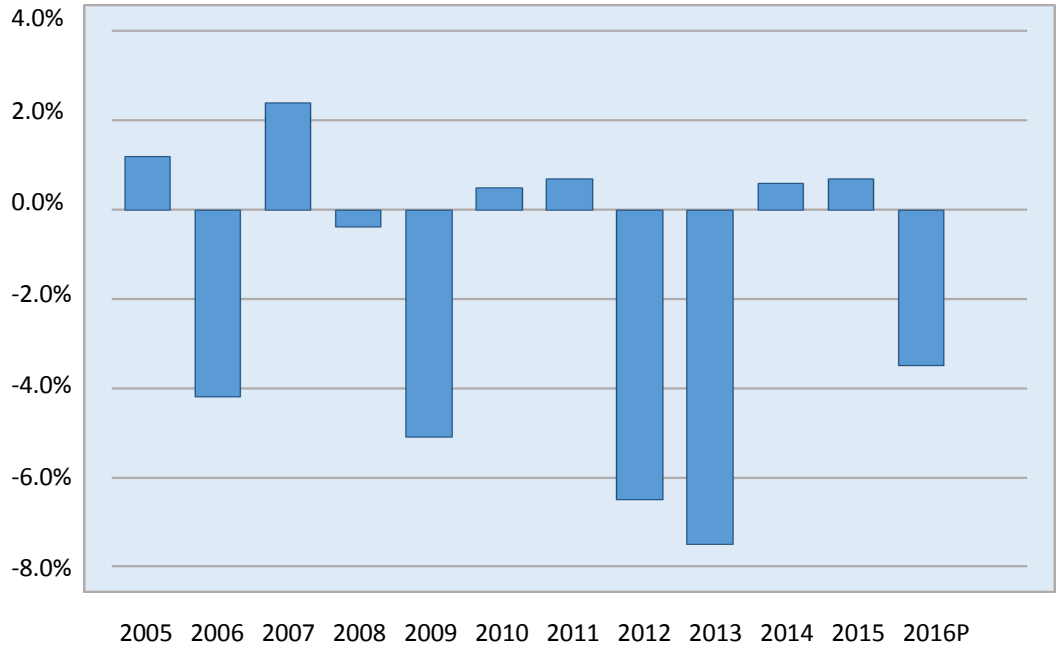
Impact of Proposed CY 2016 PFS Rule on Total Allowed Charges (By Setting, in Millions)			
	CY 2015 Payments	**CY 2016 Payments**	**% Change**
Total	$1,785.2	$1,723.2	-3.48%
Facility	$414.2	$431.7	+4.24%
Non-Facility	**$1,371.1**	**$1,291.5**	**-5.80%**

Cumulative Cuts to Radiation Oncology Over the Last Several Years are Significant

As ACRO has continued to note for CMS, the cumulative cuts to radiation oncology over the last several years has been significant. An independent analysis of Medicare payments for radiation oncology from 2005 to 2016 and using 2013 utilization data reveals several important points:

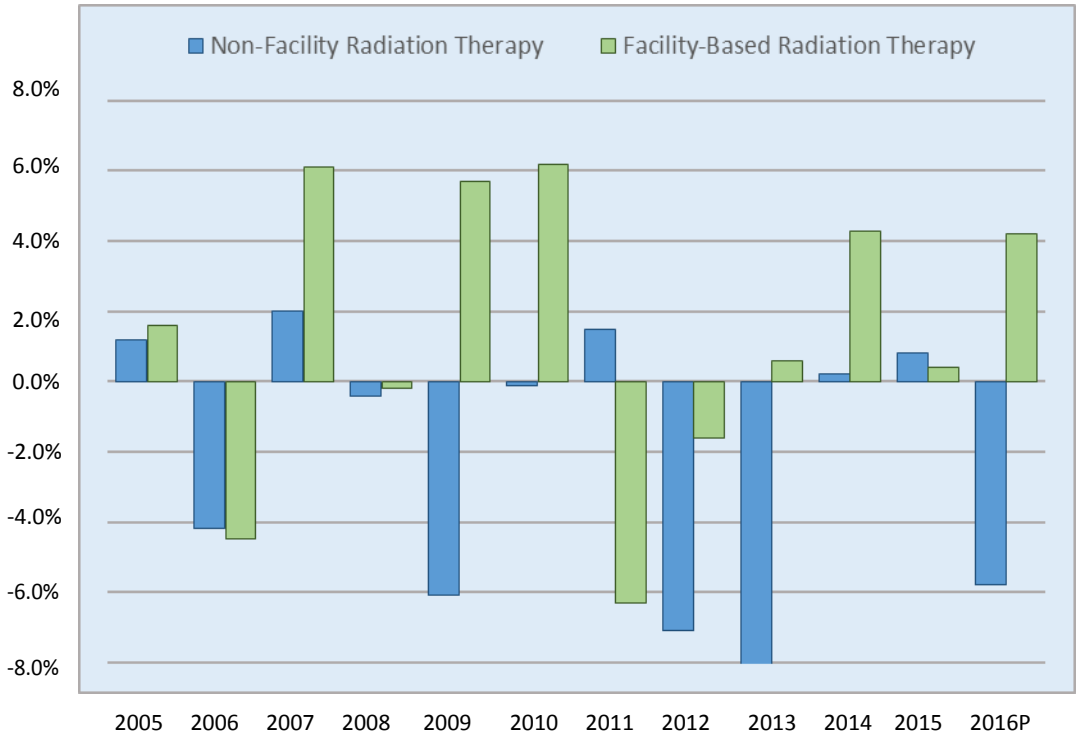
- Payments for Radiation Oncology Have Been Significantly Reduced
    - Using constant utilization, payments for radiation oncology have declined -19.7% between 2005 and 2016. ***(See Chart 1)***

Chart 1
Change in Radiation Oncology Payments
(All Settings)



- Freestanding Settings Have Received the Brunt of the Cuts
  - Non-facility payments have declined -24.2% between 2005 and 2016, while facility-based payments have increased +16.7%. ***(See Chart 2)***

Chart 2
Change in Radiation Oncology Payments
(Non-Facility and Facility Settings)



Proposed Rule Widens Payment Differential for Hospitals and Freestanding Centers

On top of actual cuts to freestanding radiation therapy centers, a key contributor to the widening site-of-service payment differential for radiation therapy in the hospital and freestanding settings relates to the Indirect Practice Cost Index (IPCI). The IPCI is the method that CMS uses to reallocate indirect costs for each CPT code to account for variations in specialty-reported indirect costs. The IPCI uses multiple inputs, including:

- the number of services billed,
- the associated physician minutes for each service,
- the indirect PE/HR for each specialty based on the PPIS, and
- the indirect costs calculated from the direct costs and the work RVU

Previous work by Avalere has found that increases in zero-minute services (e.g. radiation therapy treatment delivery services) results in a lower IPCI for the specialty. Conversely, reducing the input costs for zero-minute services results in a higher IPCI. A higher IPCI benefits all radiation oncologists through higher PERVUs, whereas cuts to radiation therapy treatment delivery services only cut freestanding radiation oncology.

Due to the net cuts to radiation treatment delivery codes in the Proposed Rule, the radiation oncology ICPI increases significantly from 1.05 to 1.25. It is for these reasons that most of the non-treatment delivery radiation therapy codes see increases of roughly 4 – 8%. The IPCI effect masks the cuts to the treatment delivery codes and also is a significant reason for the increase in payments to hospital based radiation oncology providers.

According to Avalere Health, in 2015, payments to freestanding centers are about 10% less than those to the HOPD setting in aggregate. The 2016 PFS Proposed Rule would exacerbate this differential to 20% and could result in further bankruptcies and accelerated purchasing of freestanding offices by hospital purchasers (and, therefore, higher costs to the Medicare program and its beneficiaries).

CMS's continued inequitable treatment of freestanding radiation therapy centers will not only disadvantage Medicare patients, it ultimately will cost the program more as has been evidenced with cardiology services. In its June 2013 Report to Congress, MedPAC noted "A survey conducted by the American College of Cardiologists found that the share of cardiologists who are employed by hospitals tripled between 2007 and 2012, from 11 percent to 35 percent (American College of Cardiology 2012).[2] This migration of services has been a direct result of recent Medicare payment cuts to freestanding cardiology services and will cost Medicare more due to the higher payment rate for cardiology services in the HOPD setting.[3] Further cuts to freestanding radiation therapy services will have the same result.

[2] Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System, June 2013, page 33

[3] San Francisco Chronicle, Private Cardiologists Selling to Hospitals, 24 November 2012

Proposed Rule Contains Massive Cuts for the Treatment of Prostate and Breast Cancer

These cuts would be particularly onerous to patients with breast and prostate cancer, the leading sites of all new cancer cases (excluding skin cancer) and the second leading cause of death. The Proposed Rule cuts payments for a total course of care for prostate and breast cancer patients by 25% and 19%, respectively.

Table 2						
	2015		2016		**Percent Change**	
Episode Type	Hospital Outpatient	Freestanding	Hospital Outpatient	Freestanding	**Hospital Outpatient**	**Freestanding**
Prostate IMRT	$22,108	$19,428	$22,849	$14,649	**+3.4%**	**-24.6%**
Breast IMRT	$15,711	$13,651	$16,210	$11,056	**+3.2%**	**-19.0%**

From a site-of-service perspective, the payments to freestanding centers are 36% and 32% less, respectively, than in the hospital setting.

Table 3						
	2015		2016		**Freestanding As Percent of Hospital**	
Episode Type	Hospital Outpatient	Freestanding	Hospital Outpatient	Freestanding	**2015**	**2016**
Prostate IMRT	$22,108	$19,428	$22,849	$14,649	**87.9%**	**64.1%**
Breast IMRT	$15,711	$13,651	$16,210	$11,056	**86.9%**	**68.2%**

Equipment Utilization Should Be Maintained at 50 Percent

In the CY 2016 PFS Proposed Rule, CMS proposes to increase the equipment utilization rate for radiation therapy treatment equipment from 50% to 70%. CMS argues that since a single kind of linear accelerator is used as an input for all conventional and IMRT treatments that it can assume an increase in the equipment utilization assumption, although CMS concedes that this notion is "not itself rooted in empirical data."

In this comment letter, ACRO provides the following qualitative reasons to support a 50% equipment utilization rate.

- ***Unused Patient Slots***
    - Some of the scheduling slots for patients will go unused in order to accommodate patients who need to come either at the beginning or end of the work day.
    - Cancer patients are routinely treated with combined modality therapy requiring absence from treatment on certain days because of scheduling conflicts. Backfilling these missed appointments is not possible.

- Cancer patients frequently have symptoms related to their disease or co-morbidity, especially if they are aged or being treated with palliative intent, and cancel therapy at the last minute because of these symptoms. Backfilling of these lost appointments is not possible.

- ***Patient Needs***
  - It is common for a patient to be required to come off the treatment table to drink water to enlarge the bladder or defecate to empty the rectum in order to reproduce the set up in the simulator.

- ***Treatment Modality***
  - CMS assumes utilization of a single "high-tech" linac for simple and complex treatment delivery. Additional time between treatments (outside specific patient pre- and post-service time) is required for transition of modalities.

- ***Other Treatments***
  - Although the radiation treatment vault is usually used for conventional and IMRT treatments with the companion linear accelerator, sometimes it is used for orthovoltage and HDR treatments with either a portable high dose brachytherapy automated radioactive applicator/source or a portable low energy kilovoltage photon tube. When this occurs, the linear accelerator cannot be used.

- ***Additional Linear Accelerators***
  - Although a single treatment device is assumed for all conventional and IMRT treatment codes, there are technical differences among accelerators and some treatment machines are better suited to treat specific cancer cases than are others. Consequently, radiation oncology practices often require multiple accelerators with varying capabilities in order to treat optimally a wide distribution of cases and patients. For example:
    - An accelerator equipped only with planar x–ray image guidance would be less capable than volumetric CT image guidance of delivering radiation therapy accurately to a prostate cancer without implanted fiducial markers.
    - Fixed gantry modulation may deliver a less precise radiation dose distribution than arc-based modulation for a highly complex tumor in the brain and near critical, radiosensitive organs.
    - Treatment of a highly mobile lung tumor may result in frequent tumor miss by the radiation beam unless the beam is coordinated to the patient's respiratory motion using respiratory gating technology.

  - Furthermore, a radiation oncology practice must maintain an equipment capacity in excess of its absolute need in order to continue delivering radiotherapy for patients if a treatment machine breaks down. A key element to the success of radiation therapy

for the usual patient is the delivery of many treatments over a period of several weeks without interruption. Multiple clinical studies have demonstrated the harmful impact of treatment delays upon tumor control across many cancer types. This clinical circumstance is very different from diagnostic imaging, where there is much greater latitude to delay an imaging procedure if a CT scanner or MRI is in need of repair.

Treatment Delivery/Imaging Codes Should Be Updated Holistically with Most Recent Data

In the CY 2013 PFS Proposed Rule, CMS proposed to make significant reductions to certain radiation treatment delivery codes (77418 and 77373) based solely on the time assumed to perform those services. ACRO objected to this approach to rate-setting and strongly requested CMS update the valuations for these codes holistically using all available data. The use of such data reduced the proposed cuts to these codes by half in the CY 2013 PFS Final Rule.

ACRO continues to urge CMS to use all recently available data when updating radiation therapy services under the Physician Fee Schedule. In particular, ACRO notes that two sets of data were submitted by the Radiation Therapy Alliance (RTA) in response to the CY 2014 PFS Final Rule, including (1) updated costs relating to the radiation treatment vault and (2) costs relating to regular services costs for the linear accelerator.[4]

Radiation Treatment Vault

ACRO believes that CMS continues to undervalue payments to freestanding radiation therapy providers due to outmoded vault costs. Indeed, the last time the radiation treatment vault data was updated was 2004. On December 31, 2013, the RTA, through a contract with Avalere Health, submitted updated equipment costs pursuant to the process CMS established in the CY 2011 PFS. 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 vault costs submitted on December 31, 2013) was $894,806 compared to the current cost assumed by CMS, $773,104. **ACRO requests that the updated vault cost be included for all relevant treatment delivery and imaging codes. Also, as detailed in ACRO's previous comment letters, we believe for multiple reasons that the vault system is a direct expense and, because it is integral to the linear accelerator, should be depreciated in a similar manner and therefore treated as a seven-year asset.**

Service Costs for the Linear Accelerator

ACRO believes that CMS continues to undervalue payments to freestanding radiation therapy providers due to outmoded service costs associated with the linear accelerator. For years, CMS has under-reimbursed for these service costs with its 5 percent maintenance cost assumption utilized in the PFS practice expense methodology (and first established in 1998).

The RTA has analyzed the average annual maintenance cost for a linear accelerator and finds that this also is undervalued based on nine (9) invoices submitted to CMS on December 31, 2013.

[4] Radiation Therapy Alliance, Comment to CMS on the CY 2014 PFS Final Rule, 27 January 2014. Retrieved here on August 21, 2015: http://www.radiationtherapyalliance.com/images/payment-policies-revisions-letter.pdf

According to Avalere Health:

> *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… [Based on invoices submitted to CMS], 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.*

ACRO requests CMS 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). ACRO requests that the updated service costs be included for all relevant treatment delivery and imaging codes. In the 2015 PFS Final Rule, CMS noted "Rather than assertions that a particular maintenance rate is typical, multiple invoices containing equipment prices that are accompanied by maintenance contracts would provide support for a maintenance cost other than our currently assumed 5 percent."[5] ACRO believes the RTA submission is responsive to CMS' request and urges CMS utilize these data.

Removal of On-Board Imaging as a Cost Input

CMS also seeks comment on the "apparent contradiction between technical component billing for image guidance in the context of the inclusion of a single linac with integrated imaging guidance technology being included for all external beam treatment codes." CMS notes that the RUC recommendations incorporate the same capital cost of image guidance equipment (a linear accelerator, or linac), for all radiation treatment delivery codes, including the codes that describe IMRT and Stereotactic Radiation Treatment delivery services. Imaging is not separately billable for 77385 and 77386 while it is separately billable for 77402, 77407 and 77412.

Image guidance is assumed to be utilized with every IMRT treatment delivery, given the complexity of the treatment field created by IMRT and therefore the need to assure its accurate placement onto diseased tissue. These cases are typically curative and have a clinical need to deliver high radiation doses near sensitive organs. Image guidance cannot be assumed with conventional treatment delivery, as these services encompass a much broader distribution of simple to complex cases with highly variable clinical demands for total radiation dose, dose distribution and accuracy of beam placement. Therefore, the clinical decision to use image guidance for these cases is also variable. Because all capital and work costs related to guidance are not included in the payment for conventional treatment delivery, we believe both a separate technical and professional fee for the IGRT service is merited in the setting of conventional treatment when IGRT is indicated clinically.

ACRO supports statements made by the American Society for Radiation Oncology (ASTRO) relating to the inclusion of the image guidance equipment for the new radiation treatment delivery codes/IGRT code. ACRO agrees the CMS proposal to ignore the significant capital equipment cost associated with image guidance/on board imaging is disappointing and not appropriate. ACRO also believes CMS may not have fully understood the complicated and detailed RUC

[5] 79 FR 67557

recommendations for this large radiation oncology treatment delivery/IGRT family of codes. **ACRO urges CMS to include the most up-to-date documented cost of on-board imaging equipment into CPT codes 77385, 77386 and 77387 and we understand that radiation therapy manufacturers are in the process of supplying this updated data to CMS.**

CMS' "Refinements" to RUC recommended Times for Treatment Delivery/Imaging Codes

CMS' established policies for non-highly technical equipment assumes that certain equipment and equipment items are less likely to be used during all of the pre-service or post-service performed by clinical labor staff on the day of procedure and are typically available for other patients even when one member of clinical staff may be occupied with a pre-service or post-service task related to the procedure. CMS' proposal to conform to so-called "highly technical" radiation oncology equipment (i.e. the linear accelerator, the radiation treatment vault, the water chiller, the power conditioner and the laser) to this policy in order to reduce the RUC recommended times for these services by 2 minutes per equipment item for the family of treatment delivery and imaging codes is inappropriate. **Because none of these equipment items are available for other patients during pre-service and post-service time, ACRO disagrees with the CMS refinements and urges CMS to support the RUC recommended times for these services.**

Need for a New Payment System

Freestanding radiation therapy centers, more akin to a "facility" than a physician office, do not fit well within the current Physician Fee Schedule. The nature of free-standing (non-facility) radiation oncology centers render them more analogous to facility-based radiation oncology centers, ambulatory surgical centers or dialysis centers than to a typical physician's office. For example, freestanding radiation therapy center capital costs (reimbursed primarily through Medicare PFS "technical component" payments) are in the millions of dollars, while most physician office costs are in the hundreds of thousands. The high-technology nature of radiation therapy services often makes it difficult for the current fee-for-service system to properly value such services and the narrower set of service makes freestanding radiation therapy centers significantly more vulnerable to volatile changes relative to other specialties.

These points are evidenced by the consistent payment errors for radiation therapy services contained in the last several Physician Fee Schedule regulations, including:

- 2010 Physician Fee Schedule
    - Confusion of "radiation therapy" services with "diagnostic imaging" which resulted in inappropriate proposed cuts of up to 19 percent to the specialty.
        - This was fixed in the 2010 Final Rule.
- 2011 Physician Fee Schedule
    - Incorrect calculations for radiation treatment management code resulted in additional 15 percent reduction for work RVUs.
        - This was fixed with a technical correction.
- 2012 Physician Fee Schedule
    - Missing page of direct cost inputs for key radiation therapy delivery code resulted

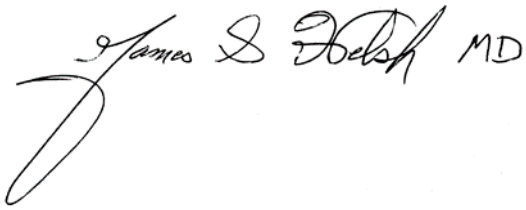
in an inappropriate 3 percent reduction to practice expense RVUs.
    - This was fixed in the 2013 Final Rule.
- 2013 Physician Fee Schedule
    - Missing and outmoded direct cost inputs for key radiation therapy delivery code resulted in cuts of 15 percent to the specialty in the Proposed Rule.
        - Cuts were mitigated by half with corrected data in the 2013 Final Rule.
- 2014 Physician Fee Schedule
    - Proposed rule capped certain radiation therapy services in the physician office setting through the use of 2013 APCs in the Hospital Outpatient PPS, resulting in an 8 percent cut to freestanding facilities.
        - This was not finalized in the 2014 Final Rule.
- 2015 Physician Fee Schedule
    - Proposed rule proposed not to pay for the radiation treatment vault as a practice expense directly attributable to the care of the patient, resulting in a 5 percent cut to freestanding facilities.
        - This was not finalized in the 2015 Final Rule.

Given the aforementioned volatility in payments, we continue to believe radiation therapy centers would be more appropriately reimbursed under a separate, bundled payment methodology. ACRO continues to express an interest in working with CMS on payment reform in the months and years ahead.

Conclusion

ACRO's comments on the Physician Fee Schedule regulations seek to ensure ongoing access to high-quality, state-of-the-art radiation oncology services. Maintaining patient access is crucial to quality healthcare delivery since most of our patients require services five days a week for many weeks of life-saving therapy. Patient accessibility and continuity through a complete course of therapy are key components of the care continuum. We hope that our comments highlight our sincere interest in making radiation oncology services cost-effective, fairly reimbursed, and readily accessible to cancer patients. We look forward to continuing to work with CMS to guarantee quality oncology services can be provided by our specialty to every Medicare patient.

Sincerely,



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Sincerely,

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