

Radiation Therapy Alliance

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Vantage Oncology, Inc.

August 31, 2009

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

Re: Proposed Rule (CMS-1413-P): Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010

Dear Ms. Frizzera:

The Radiation Therapy Alliance (RTA), an organization that represents for-profit, freestanding radiation therapy facilities including 21st Century Oncology, OnCure Medical Corporation, Physician Oncology Services, L.P., Radiation Oncology Services of America and Vantage Oncology, Inc., appreciates the opportunity on behalf of their physicians and staff at over 200 freestanding radiation therapy facilities in 21 states to comment on the 2010 Proposed Physician Fee Schedule Rule as it relates to proposed changes affecting radiation therapy.

The RTA would like to express its serious concern to CMS that the Proposed Rule could not only result in a significant decrease in access to freestanding radiation therapy centers overall, but in several states the Proposed Rule puts a significant number of freestanding radiation therapy centers at risk for closure. If these facilities were to close, it would result in substantial increases in drive time for patients and, as evidenced by peer reviewed literature, would reduce patient access to radiation therapy.

The focus of this letter relates to (1) the proposal by CMS to use information from the Physician Practice Information Survey (PPIS) to update the specialty-specific PE/HR data used to develop PE RVUs and (2) the overall impact of the CY 2010 Proposed Physician Fee Schedule Rule on freestanding radiation oncology centers and the related Medicare beneficiary impact. In addition to the new PPIS data, CMS's new proposed equipment utilization policy also will have a large and harmful impact on radiation therapy. The RTA commented on the proposed equipment utilization policy previously (see attached letter to CMS).

This letter will address several specific issues:

1. The significant impact of the PPIS on radiation therapy codes causes CMS to fail their stated objective of stability and predictability of the PE portion of the PFS payments.
2. RTA's evidence is that the PE/HR values used in the CY 2010 PFS Proposed Rule are significantly understated and, equally important, not clearly explained or described.
3. RTA survey of practice expense per hour (PE/HR) indicate that the actual PE/HR at freestanding facilities may be 400% higher (\$227.43 (CMS) vs. \$1031 (RTA)) than the PE/HR reported in the proposed rule.
4. Results from a unique analytical model developed by the RTA indicate that the proposed cuts to radiation oncology have the potential to significantly impact the number of freestanding radiation oncology centers and reduce access to radiation therapy treatments by cancer patients in numerous markets.

According to the National Cancer Institute (NCI), 1,479,350 men and women in the U.S. will be diagnosed with cancer in 2009¹. About 60 percent of treatment plans include radiation therapy.² As discussed in greater detail below, several studies have shown the importance of the availability and proximity of radiation therapy facilities on quality cancer care.^{3,4,5,6} Radiation therapy generally involves repeated daily visits for periods up to eight weeks. Increasing the distance patients must travel for cancer treatment not only imposes a burden on cancer patients, but also can impact patient compliance (e.g. the utilization of post-operative radiation therapy) and even the choice of treatment (e.g. the choice of mastectomy over breast conservation).

1. The Impact of the PPIS on radiation therapy codes is significant

In the CY 2010 PFS Proposed Rule, CMS proposes to use a new PE/HR based on the Physician Practice Information Survey (PPIS). The PPIS was conducted by the AMA in 2007 and 2008 and was analyzed by the AMA and The Lewin Group, which also calculated the PE/HR for physician specialties.

Radiation oncology will face an average 17 percent cut in PE RVUs as a result of the proposed rule. CMS acknowledges the significant impact that the PPIS has on Practice Expense RVUs for radiation oncology. According to CMS, "the PE RVU impacts are primarily attributable to the proposed incorporation of PE data from the Physician Practice Information Survey (PPIS)" In fact, however,

¹ National Cancer Institute. *SEER Cancer Statistics Review 1975-2006*. www.cancer.gov. Retrieved 8/28/09, from http://seer.cancer.gov/csr/1975_2006/results_single/sect_01_table.01.pdf

² National Cancer Institute. (4/20/2007). Questions and Answers About Radiation Therapy. <http://www.cancer.gov/cancertopics/radiation-therapy-and-you/page2>

³ Ballas, Leslie K., M.D. (2006). Radiation Therapy Facilities in the United States. *Int. J. Radiation Oncology Biol. Phys.*, Vol. 66, No. 4, pp. 1204-1211.

⁴ Celaya, Mario O. (2006). Travel distance and season of diagnosis affect treatment choices for women with early-stage breast cancer in a predominately rural population (United States). *Cancer Causes Control*, Vol. 17, pp. 851-856

⁵ Punglia, Rinaa S. (2006). Effect of Distance to Radiation Treatment Facility on Use of Radiation Therapy After Mastectomy in Elderly Women. *Int. J. Radiation Oncology Biol. Phys.* Vol. 66, No. 1, pp. 56-63.

⁶ Schroen, Anneke T. (2005). Impact of Patient Distance to Radiation Therapy on Mastectomy Use in Early-Stage Breast Cancer Patients. *Journal of Clinical Oncology*. Vol. 23, No. 28, pp. 7074-7080.

because this data is blended between hospital based and freestanding in the rule, it belies the actual, much larger and more damaging, effect from the rule on freestanding centers.

An analysis conducted by Christopher Hogan at DirectResearch on behalf of the RTA demonstrates the dramatic impact of the new PPIS data on specific CPT codes affecting radiation oncology. For example, for conventional radiation therapy codes (77402-77416), the use of the new PPIS data is responsible for more than 1/3 of the gross cuts under the Proposed Rule. Overall, these particular codes receive roughly a 14% net cut under the Proposed Rule. As discussed in the attached letter, the proposed equipment utilization policy is the other primary cause of the reduction in reimbursement for these codes.

For other “standard of care” codes such as intensity-modulated radiation therapy (IMRT; CPT code 77418), the PPIS data results in an estimated 9% cut on top of the effects of the estimated 25% cut from the equipment utilization policy. In other cases, such as for image-guided radiation therapy (IGRT; CPT code 77421), the PPIS data is responsible for virtually the entirety of the cut (around 8%) unrelated to the final phase-in year of the “bottom up” PE methodology. Although the final year of the phase-in of the “bottom up” PE methodology has a mixed result for radiation oncology codes generally, for some codes critical to the provision of radiation therapy, the phase-in results in yet *further* cuts (e.g. *another* roughly 10% cut for 77421 and 77418 for a total of a 44% cut for IMRT and 19% for IGRT under the Proposed Rule).

Furthermore, the -17 percent impact of the PE RVUs for radiation oncology actually masks the dramatic reductions in payments that CMS proposes for the services that are the foundation of radiation oncology. As shown in the table below, the proposed changes would result in an average reduction in payment of more than 35 percent for the family of radiation treatment delivery services described by CPT codes 77401 through 77418.

Code	Description	2008 Allowed Services	2009 Total Pay	2010 Proposed Total Pay	% Change in Total Pay from 2009 to 2010
77401	Radiation treatment delivery	58,714	\$1,905,851	\$889,400	-53.3%
77402	Radiation treatment delivery	1,105	\$149,849	\$122,351	-18.4%
77403	Radiation treatment delivery	22,422	\$2,676,747	\$2,183,450	-18.4%
77404	Radiation treatment delivery	8,189	\$1,075,072	\$862,420	-19.8%
77406	Radiation treatment delivery	981	\$129,849	\$105,436	-18.8%
77407	Radiation treatment delivery	2,488	\$527,634	\$505,201	-4.3%
77408	Radiation treatment delivery	7,791	\$1,244,807	\$1,042,491	-16.3%
77409	Radiation treatment delivery	2,656	\$467,469	\$382,214	-18.2%
77411	Radiation treatment delivery	1,036	\$181,220	\$149,086	-17.7%
77412	Radiation treatment delivery	5,135	\$1,055,651	\$903,786	-14.4%
77413	Radiation treatment delivery	660,382	\$136,713,801	\$117,183,267	-14.3%
77414	Radiation treatment delivery	476,227	\$109,410,391	\$91,719,225	-16.2%
77416	Radiation treatment delivery	91,998	\$21,235,549	\$17,817,952	-16.1%
77417	Radiology port film(s)	284,243	\$4,612,809	\$3,280,211	-28.9%
77418	Radiation tx delivery, imrt	1,183,644	\$611,747,937	\$340,666,355	-44.3%
Total			\$893,134,637	\$577,812,844	-35.3%

2. Data from the RTA shows that the PE/HR numbers used in the rule are understated and not clearly explained or described.

The American Society of Therapeutic Radiology and Oncology (ASTRO), the American College of Radiation Oncology (ACRO) and the Association of Freestanding Radiation Oncology Centers (AFROC) provided the combined survey data used in the PPIS for radiation oncology. Although the RTA comprises a significant portion of the radiation therapy centers in the country, it is not a specialty society and, therefore, is not privy to the ASTRO/AFROC data or the specifics of Lewin's analytical adjustments of such data to formulate the PE/HR conclusions contained in the proposed rule. Moreover, our understanding is that even the radiation oncology specialty societies are only able to analyze Lewin's manipulation of *their* data, but are not able to analyze (a) hospital based data, even though the ultimate PE/HR is a blend of hospital based data and freestanding data, or (b) other specialty society data, even though significant overstatements of PE/HR for those specialties would have a direct effect on the radiation oncology specialty because of budget neutrality rules. This lack of transparency is inconsistent with the NPRM process.

Evidence that the calculation of PE RVUs is not understandable or intuitive due to failure of CMS to provide sufficient transparency:

- Table 2 of the Proposed Rule shows almost no change in the PE/HR for radiation oncology yet the reduction of the PE RVU changes on the total allowed charges for radiation oncology is 17 percent (Table 39). On the other hand, the PE/HR for emergency medicine decreased 3 percent but the impact of the PE RVU changes on their total allowed charges is +2 percent. RTA does not understand these discrepancies and would ask CMS to consider whether or not this is an appropriate result.
- Under the current methodology, CMS calculates an indirect practice cost index (IPCI) at the service level "to ensure the capture of all indirect costs." However, we cannot understand the impact of this step on radiology oncology services. Data from CMS indicates that the IPCI for radiation oncology increased from 1.02 in 2009 to 1.0546 in 2010. In general, we believe an IPCI greater than 1.00 should result in higher indirect PE RVUs, especially since radiation oncology services are provided predominantly by the specialty of radiation oncology. Therefore, it is not clear why the PE RVUs have declined so dramatically.

Nonetheless, there still are a number of issues that raise concerns in publicly available information and analyses thereon related to the rule, including the following:

- Weighting. In its final report on PPIS data submitted for the rule⁷, The Lewin Group acknowledges an "unweighted" PE/HR for freestanding radiation oncology centers of \$712.22. However, due to a concern that practices with a larger amount of physicians were more likely to be sampled, The Lewin Group weighted the survey observations by the number of physicians in the practice. As a result, the PE/HR dropped from \$712.22 to \$508.67. The RTA has no way to verify whether the weighting by The Lewin Group was appropriate or properly administered.

⁷ The Lewin Group, Inc., "Physician Practice Information Survey (PPIS) Data Submitted for 2010 Non-MD/DO and Health Professionals Practice Information," 18 June 2009.

- Blending. Table 2 of the proposed rule shows a final PE/HR for radiation oncology of \$126.66 in indirect PE/HR and, therefore, a total PE/HR of \$227.43 for indirect and direct. According to the Lewin Group, the final PE/HR for radiation oncology blends a total PE/HR of \$508.67 for radiation oncologists in freestanding centers with a total PE/HR of \$62.25 for hospital based radiation oncologists. While we understand the intention of the blend is to develop an overall average radiation oncology PE pool, this effectively cuts the PE/HR for freestanding centers yet again by over 55 percent. Moreover, we encourage CMS to review its most current data for the blending methodology as it is our belief that a growing share of radiation oncology services are provided outside of hospitals.
- Decrease in Direct PE RVUs. CMS shows a decrease in the direct PE/HR percentage from 50% to 44% in the proposed rule. On top of this, CMS imposes a scaling factor of 0.508 for direct costs under the current PE methodology. This calculation methodology completely disregards the detailed cost accounting database created by the AMA/Specialty Society Relative Value Scale Update Committee (RUC) and substantially disadvantages services with higher reportable direct costs. The RTA believes the level of reimbursement for a service should reflect the costs, including direct costs, associated with providing that service. Here again we would urge attention to our earlier comment on the equipment utilization factor of the direct PE.

3. RTA survey of PE/HR indicates actual PE/HR far greater than CMS reports

The RTA would like to better inform CMS regarding the actual practice expense costs incurred at the centers it represents. As such, the RTA has conducted a thorough analysis of actual practice expense costs at their facilities. The methodology and results are discussed below.

Methodology

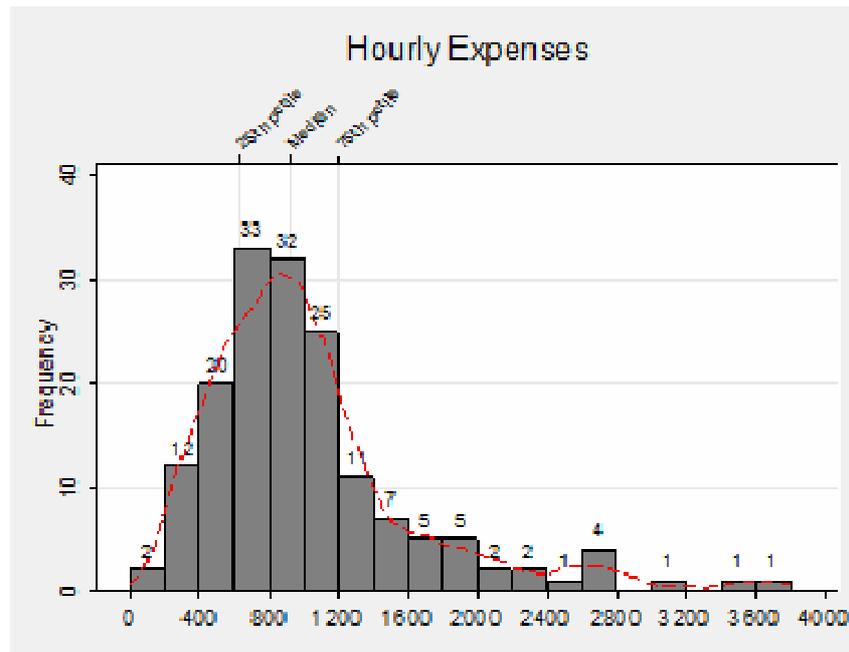
Each of the five member companies of the RTA calculated PE/HR costs, for the period January 2009 - June 2009. Excluded from the analysis was any facility for which there is not full period data. Facilities with estimated patient volumes less than 6 per day were also eliminated.

The calculation of average hourly expenses is as follows:

1. Total Operating Expenses + Depreciation - Physician Salaries = Total Expenses
2. Total Expenses / Business Days = Average Daily Expenses
3. Average Daily Expenses / Daily Hours of Operation = Average Hourly Expense

Results

Of the 164 facilities for which we have data, the mean hourly expense is \$1031/hour and the median is \$912/hour. 75 percent of the facilities have average hourly expenses greater than about \$600/hr. The following chart illustrates the distribution of responses among the surveyed facilities. Consistent with CMS methodology, each facility was assumed to operate 10 hours per day.



4. The proposed cuts to radiation oncology have the potential to significantly affect patient access to radiation therapy by placing at risk a significant number of freestanding centers.

RTA believes that the impact of the proposed rule on radiation oncology is very significant and if finalized we expect that it would result in reduced access to radiation treatment for patients. The sheer orders of magnitude of the proposed reductions give credence to this claim. We recognize CMS is accustomed to hearing such claims, however, and therefore we provide concrete analytics to assist CMS in understanding the potential impact of the proposed rule on patient access due to facility closures. We present results from a conservative analysis using a complex mapping analysis that identifies and quantifies the projected at-risk locations in the U.S. in terms of regions where facility closings are most likely and where patients would be most adversely affected.

The data and methodology employed in this analysis are described in Appendix 1 of this letter along with a series of state maps which illustrate the location of facilities at greatest risk for closing and the impact that such closing would have on patient access. For brevity, we have only included maps representing a few states.

The RTA model analyzes radiation treatment data (volumes and location), information on the location of all free-standing and hospital-based radiation treatment facilities, and data on the 65+ population by zip code. Of the 1,047 identified freestanding clinics, 320 of them resided in the 1st decile. These facilities are projected to treat less than 13 patients per day. RTA member companies believe that at current CMS reimbursement rates, in general and on average, a facility with these treatment volumes are most likely at-risk for closure if these treatment volumes are sustained over time. Should CMS finalize the proposed PFS rule, any of these first decile facilities -- at a minimum -- could be projected to close.

Recognizing that in a market where two nearby facilities both projected to fall in the first decile may not both face a risk of closing (one may close and the other may absorb the additional patients), we further conservatively restrict our analysis by allocating treatment volumes at first decile facilities to

the closest nearby facility and recalculating the number of facilities projected to treat less than 13 patients per day. This step reduces the number of projected high-risk facilities from 320 to 294.

Results

There are numerous ways to calculate the potential impact of this rule on patient access and patient choice. Here we highlight two types of results from the model:

1. States with large number or percentage of facilities projected to be at high-risk for closing:

According to the RTA model, the following 15 States listed in Table 1 are at-risk for facing 10 or more freestanding (FS) facility closings or a majority of FS facilities closing in the State (or both):

Table 1. States with a High Number or Share of FS Facilities At-Risk to Close

State	# of FS facilities projected to be at high-risk for closing	% of State's FS facilities projected to be at high-risk for closing
AZ	14	27%
CT	7	88%
DE	3	75%
FL	15	15%
ID	4	100%
IL	39	53%
IN	10	37%
LA	20	65%
MA	22	88%
MD	21	54%
ME	6	100%
NC	33	69%
NH	8	100%
UT	9	100%
VA	20	83%

These high number of potential facility closings in a single state raise the possibility of significant local market disruptions and the potential for a significant limit to patient and doctor choice for radiation treatment thereby reducing competition for quality care in a market. In six states (Illinois, Louisiana, Massachusetts, Maryland, North Carolina and Virginia) over twenty facilities are projected to be at risk for closing, which also represent a majority of the freestanding facilities. In Idaho, Maine, New Hampshire and Utah all of the freestanding facilities are at risk for closing.

The proposed rule and potential closing of centers also has a negative impact on the driving distance for patients to the remaining open centers. One may reasonably ask why this is so critical? As we point out in our prior comment, patients undergoing radiation therapy are required to make daily trips to their oncology center for anywhere from four to eight weeks at a time. Many are older and, in light of their diagnosis, in a more weakened state. Some must rely on family or friends for transportation to and from the facility.

Peer-reviewed academic research has demonstrated that increased driving distances have a statistically significant negative impact on patient access to radiation therapy. Therefore, the potential impact of the proposed rule on patient access and thereby patient care will be large in several states.

For example, a study conducted by researchers at Dartmouth College Medical School of breast cancer patients in New Hampshire conclude, “New Hampshire women with early-stage breast cancer were less likely to choose [breast conserving surgery] BCS if they live further from a [radiation treatment facility] RTF ($P < 0.001$). Of those electing BCS, radiation was less likely to be used by women living >20 miles from a RTF ($P = 0.002$) and those whose diagnosis was made during winter ($P = 0.031$).” The study concludes, “Women living more than 20 miles from a radiation treatment facility are not only less likely to have breast conserving surgery, but, if they do so, they are significantly less likely to receive post-operative radiation that would reduce their risk of recurrence.”

Schroen, et al. (2005) also study travel distances for breast cancer patients and find that the location of a radiation therapy facility has a strong influence on mastectomy rates. “In multivariate analysis, mastectomy use was independently influenced by XRT distance after adjusting for age, race, T stage, and diagnosis year... Opportunities for increasing breast-conservation rates through improved [radiation therapy] XRT access exists,” they write.

These studies confirms evidence presented by Stafford, et al. (1998)⁸, Nattinger, et al. (2001)⁹, Athas, et al. (2000)¹⁰ and Punglia, et al. (2006) regarding the effect of travel distance on the choice of radiation treatment for breast cancer patients.

RTA believes the key interpretation of this modeling exercise is as follows:

1. Of the approximately 1000 freestanding radiation oncology facilities in the country, roughly one-third can be considered at-risk for closing should the proposed rule be finalized.
2. Those at-risk facilities are not uniformly distributed across the country with adequate alternative facilities available in close proximity for all patients. Rather, there are numerous states where a disproportionate share of the at-risk facilities is located and where a patient's next closest radiation therapy facility (freestanding or hospital based) presents a drive time that will pose an additional serious health risk.
3. Increasing the distance patients must travel for radiation therapy treatment have been shown in academic research to have a significant impact on cancer treatment practices. The proposed CMS policy would adversely affect patient care due to the expected closings of “at-risk” risk facilities.

⁸ Stafford D, Szczyz R, Becker R, Anderson J, Bushfield S (1998) How breast cancer treatment decisions are made by women in North Dakota. *Am Journal of Surgery* 176(6):515–519

⁹ Nattinger AB, Kneusel RT, Hoffmann RG, Gilligan MA (2001) Relationship of distance from a radiotherapy facility and initial breast cancer treatment. *J National Cancer Inst* 93(17):1344–1346

¹⁰ Athas WF, Adams-Cameron M, Hunt WC, Amir-Fazli A, Key CR (2000) Travel distance to radiation therapy and receipt of radiotherapy following breast-conserving surgery. *Journal of National Cancer Inst* 92(3):269–271

Conclusion

We thank CMS for the opportunity to comment on the CY 2010 Physician Payment Rule and to express our concerns relating to the use of the PPIS data, the equipment utilization policy and the combined impact of these proposed policies on Medicare beneficiaries.

We would like to summarize and conclude our comments with the following recommendations:

1. The large impact of the proposed rule will have a significant effect on the ability of many radiation therapy facilities to continue to operate. We urge CMS to postpone the implementation of the 2010 proposed rule, including the use of PPIS and to disclose the information needed to replicate the PE RVUs and simulate alternative approaches that better reflect actual practice expenses for radiation oncology.
2. As discussed in the RTA's previous letter to CMS, we believe there is no factual basis for adopting a 90% utilization rate assumption for radiation oncology equipment and we have provided data indicating that the mean and median utilization rate among RTA facilities is below 50%.
3. The consequence of the proposed cuts to radiation oncology may be severe for patients. A conservative, analytical analysis undertaken by the RTA concludes that the proposed cuts could result in at least one-third of all free-standing facilities facing serious risk of closure and the resulting impact on many patients would be increased drive distances and time to the remaining open centers that offer the same treatment.

We would be happy to discuss further or provide to CMS the details of the RTA's PE/HR survey and/or the patient access study. If you have additional questions regarding these issues and the views of the RTA please contact Andrew Woods, Executive Director of the Radiation Therapy Alliance, at (202) 661-7949.

Sincerely,



Dr. Christopher Rose

Chair, Radiation Therapy Alliance Policy Committee

Attachment

1. August 24, 2009 Letter from RTA to CMS, re: CMS-1413-P & equipment utilization proposal

Appendix 1

Appendix 1 contains a description of the data and methodology employed in the RTA model to analyze the projected impact of proposed cuts on patient access. Following the description we provide a set of maps of five states to illustrate the projected impact of the proposed rule on facility closings and patient access.

Data

Data required to build the model came from a number of independent sources and fell into three major categories: (1) Radiation Treatment Facility data; (2) Radiation Treatment data; and (3) Population data.

Radiation Treatment Facility Data:

Hospital Based Centers – Name and Location information for hospital based centers came from CMS. CMS classifies having the oncology service of Radiation Therapy when there are more than 10 Medicare outpatient claims for delivery of Radiation Therapy during 2008.

Freestanding Centers – Name and location information regarding freestanding centers was acquired from Verispan and are also from 2008 data.

Treatment Volume:

Estimated annual radiation treatment volume is based on historical claims from CMS as well as claims from commercial payors. Outpatient procedure projections are based on data from Thomson Claims Database and the CMS 100% Beneficiary Standard Analytical File - Outpatient (SAF-O). Age and sex-specific use rates are calculated from the database and the SAF-O for each Physician's Current Procedural Terminology (CPT®) procedure code. Projected population counts by age are provided by Claritas, Inc. The database and SAF-O databases provide CPT-4 level procedure records. Treatment volume is then projected to geographical units, (States, Counties, zipcodes, etc) by multiplying the expected use rates by CPT code for each age and sex cohort to the members of the population in each respective cohort in the target population.

Population Data

Population data used to size population 65 and older in each zip code was obtained from the U.S. Census.

Model

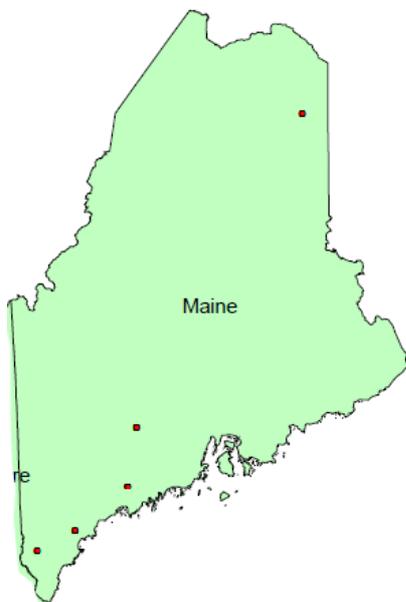
The RTA model projects radiation treatments per facility from a treatment allocation algorithm. Based on zip code population estimates, we assign treatments to facilities in a 2 step process. First, the number of freestanding treatments associated with patient zip codes geographically located within 10 miles (straight line distance) was allocated pro rata to the number of freestanding Clinics within the 10 mile distance. If no clinics were located within 10 miles, we located the closest freestanding Clinic and allocated treatments pro rata to all freestanding clinics within 1.5 times the distance of the closest clinic to the particular patient zip centroid. Second, the same allocation methodology was carried out for hospital based treatments.

Once all treatments were allocated, Centers were organized into deciles. Deciles were assigned to freestanding clinics and separately for hospital based Clinics. Each freestanding or hospital based decile contains the same number of treatments per day as other freestanding or hospital based deciles respectively. Clinics assigned to the 1st decile are the ones that have the fewest number of projected treatments per facility. The number of clinics in each decile was calculated along with the mean, minimum and maximum number of annual treatments per facility.

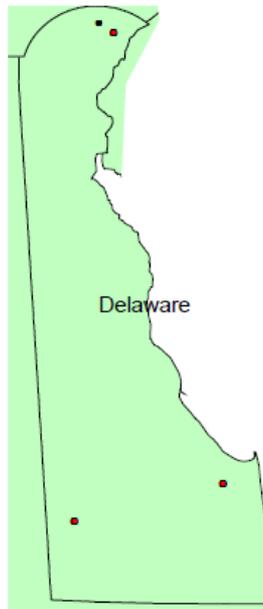
Map Presentations

Following are five maps, one from each of the following states: Maine, Delaware, New Hampshire, North Carolina and Arizona. The map indicates the location of the free-standing radiation therapy facility projected to be at high-risk to close (red dots). The black dots represent the location of the other free-standing facilities in the state.

Maine



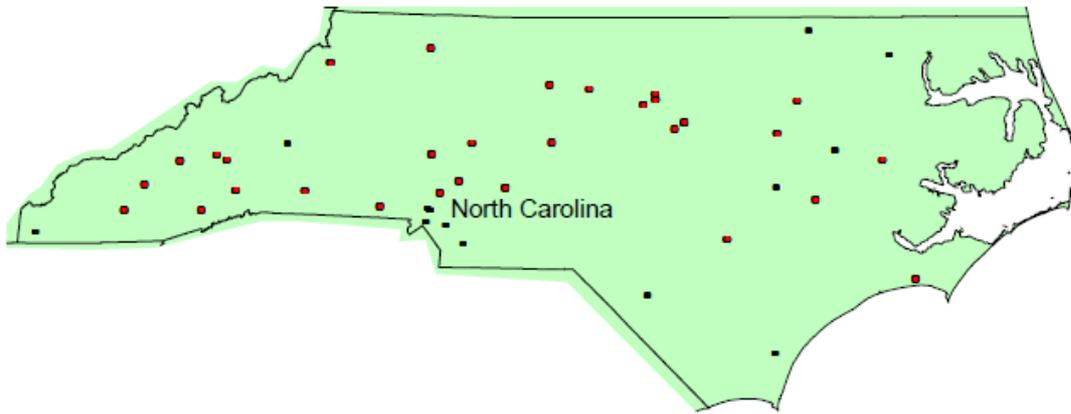
Delaware



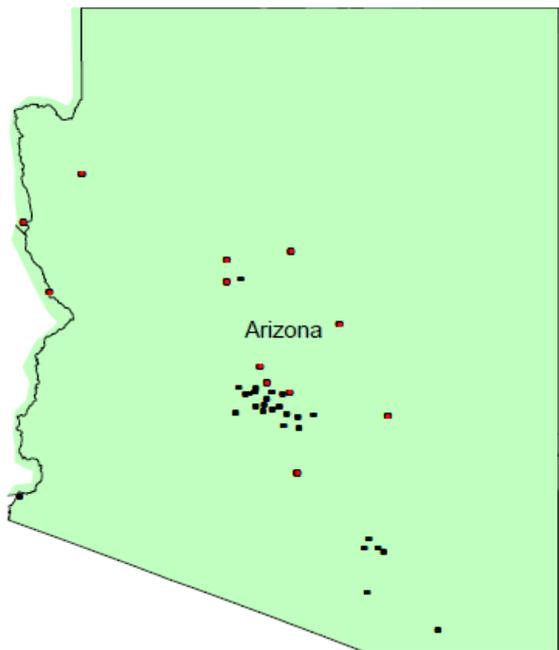
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North Carolina



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August 24, 2009

Ms. Charlene Frizzera
Acting Administrator
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Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

Re: Proposed Rule (CMS-1413-P): Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010

Dear Acting Administrator Frizzera:

The Radiation Therapy Alliance, an organization including 21st Century Oncology, OnCure Medical Corporation, Physician Oncology Services, L.P., Radiation Oncology Services of America and Vantage Oncology, Inc., appreciates the opportunity on behalf of physicians and staff at over 200 freestanding radiation therapy facilities in 21 states to comment on the 2010 Proposed Physician Fee Schedule Rule as it relates to proposed changes affecting radiation therapy. The focus of this letter relates only to the proposed increase in the utilization rate assumption for equipment costing over \$1 million from 50 percent to 90 percent. A comprehensive letter from the Radiation Therapy Alliance is forthcoming on other significant issues and the overall effect of the Proposed Rule on freestanding radiation therapy centers and their patients. A complete description of the Radiation Therapy Alliance (RTA) is presented at the end of this letter.

This letter will address three issues:

1. The proposed CMS policy on equipment utilization is based on a MedPAC recommendation regarding utilization rate as it relates to diagnostic imaging equipment. We comment on the appropriateness of basing policy change for radiation therapy equipment on a recommendation for diagnostic imaging equipment. We believe that the evidence supporting the MedPAC recommendation--which is limited to diagnostic imaging only--does not support CMS's choice to extend the rule to equipment used for radiation therapy.

2. The proposed change to the utilization rate assumption will have a major impact on key reimbursement rates for radiation therapy at freestanding facilities far greater than the 5 percentage point impact referenced in the Proposed Rule for all radiation oncology services. In fact, the utilization rate assumption is generally responsible for 100% of the net decline for conventional radiation therapy treatment codes relative to 2009 rates and is responsible for almost 60% of the total decline in reimbursement for IMRT treatment relative to 2009 reimbursement rates.
3. Evidence from a comprehensive survey of equipment utilization rates that we conducted at 198 radiation therapy facilities across the country indicates the mean utilization rate for radiation therapy equipment was 44 percent. The median utilization rate was 43 percent. 75 percent of the facilities had utilization rates below 56 percent.

We now summarize the proposed regulatory change and discuss these three issues in greater detail.

CMS Proposed Change to Equipment Utilization Rate Assumption

In the CY 2010 Proposed Physician Fee Schedule Rule CMS states, “[W]e are proposing to change the equipment usage assumption from the current 50 percent usage rate to a 90 percent usage rate for equipment priced over \$1 million.” (74 FR 33532). In justifying the proposed change, CMS relies exclusively on a recommendation from MedPAC (March 2009). In turn, the MedPAC recommendation relies on a 2006 survey of utilization of MRI scanners and CT machines by NORC and a 2007 survey by IMV Medical Information Division of CT machines.

1. RTA is concerned with the overly broad application of the MedPAC recommendation

We are very concerned that CMS has proposed a broad change in the equipment utilization rate assumption for all medical equipment costing more than \$1 million based on data and recommendations pertaining to only one category of machines: diagnostic imaging. As MedPAC notes in their March 2009 report, evidenced by CMS as a justification for the new policy, in a section titled, “Changing payments for expensive imaging services”:

“The Commission recommends that Medicare adopt a normative standard in which providers are assumed to use costly **imaging** machines at close to full capacity (45 hours per week or 90 percent of the time that providers are assumed to be open). Such a normative standard would discourage providers from purchasing expensive **imaging** equipment unless they had sufficient volume to justify the purchase. The Secretary should start by adopting a standard of 45 hours per week for all **diagnostic imaging** machines that cost at least \$1 million and should explore applying this standard to **imaging** equipment that costs less.” (Report to Congress: Medicare Payment Policy, March 2009, xv-xvi, emphasis added).

Clearly, MedPAC was focused only on diagnostic imaging equipment yet CMS has broadened their proposal far beyond this category of equipment. MedPAC's concern with the utilization rate assumption for diagnostic imaging equipment appears motivated by two factors: (1) survey results (NORC 2006 and IMV 2008) indicating that imaging equipment is frequently used at least 45 hours a week and (2) concern about rapid growth of volume of diagnostic imaging services resulting from increased deployment of imaging equipment.¹ As discussed below, these concerns do not come to bear for radiation therapy equipment.

Radiation Therapy is Not Diagnostic Imaging

Radiation therapy differs from diagnostic imaging in several important respects, including:

The Kind of Radiation Used and Its Intended Effect. Radiation therapy utilizes daily applications of high doses of ionizing particles (low or high energy photons, electrons, protons, and alpha particles) to kill cancer cells. Diagnostic imaging uses much lower doses of lower energy photons (~1/10,000 the dose of radiation used for therapy), ultrasound, or magnetic resonance to identify and characterize anatomic abnormalities for the purpose of diagnosing disease and to assess the results of therapeutic interventions.

The Skill Set of Radiation Oncologists vs. Radiologists. Radiation therapy requires an extreme degree of targeting accuracy. Patient treatment must be reproducible day after day. This imposes upon the radiation therapy team a requirement for repetitive quality assurance which is met by daily to weekly ancillary localization studies called simulation and image guidance. Although the quality of diagnostic imaging is impacted by patient motion, the issue of reproducibility is not as dire. Thus the necessity for absolutely reproducible patient positioning is less important and the time requirement to assess the location of the abnormality is much less.

The Type of Care Provided to a Patient. A diagnostic radiologist performs his or her service in support of the efforts of a referring treating physician. Diagnostic imaging is a discrete service delivered as a single event and a patient may see many diagnostic imagers over their lifetime on a once a service basis. Radiation therapy, on the other hand, generally involves repeated daily patient visits over four to eight weeks. Radiation oncologists, like the other treating physicians of the cancer team, interact directly with patients throughout the entire episode of cancer care. They continue to follow their patients with malignant disease for periods of time up to five years after the course of care to assess response, to detect potential recurrences in a timely manner and to ameliorate side effects of treatment.

2. Large impact of the increase in equipment utilization on reimbursement for radiation therapy

¹ MedPAC states (page 107-108), "The Commission is concerned about the diffusion of costly imaging machines because more machines are associated with higher overall volume."

CMS, in the proposed rule, indicates that the overall average impact of the rule on radiation oncology is a -19 percent reduction and the impact of the increased utilization rate assumption accounts for a decrease in PE RVUs of -5 percent for radiation oncology.² This average aggregate impact analysis significantly under-estimates the impact on free-standing facilities overall and the portion of the cut attributable to the change in equipment utilization rate.

Analysis conducted by Christopher Hogan at DirectResearch on behalf of the RTA, ASTRO and ACRO estimates the approximate impact of the change in the utilization rate assumption on specific, CPT codes affecting radiation oncology. For some codes, the equipment utilization policy is primarily responsible for the entirety of the total change relative to 2009 rates.

For conventional radiation therapy (non-IMRT), the utilization rate change generally accounts for all of the net change for codes 77402—77416. In other words, absent this change, some codes would have received an increase for 2010 but are now facing a reduction. For example, for CPT code 77409, PE RVUs were scheduled to increase by about \$31.38 due to the final year of the phase in of the new "bottom up" PE method. As a result of the proposed rule, the new utilization rate assumption reduces that amount by about \$38.64 and the new PPIS data will reduce the PE amount by about \$20.91.

Other "standard of care" codes also are significantly impacted by the equipment utilization policy. For example, according to the analysis, approximately 58 percent of the \$225 reduction in payment for 77418, radiation therapy delivery with IMRT, is a result of the utilization rate change.

RTA believes that these significant reductions in reimbursements relative to 2009 caused by the change in utilization rate assumption without out any specific evidence to cite or clear rationale is concerning and inappropriate.

3. RTA equipment utilization study

While the RTA believes that there is no rationale for changing the utilization rate assumption from 50 to 90 percent for radiation therapy, we also recognize that a lack of evidence in favor of a change does not itself prove that status quo is the correct assumption. To inform CMS about utilization rates for equipment used in the treatment of radiation therapy, RTA has conducted a careful and extensive analysis of actual utilization rates at each of the 200 facilities it represents. The methodology and results are discussed below.

Methodology

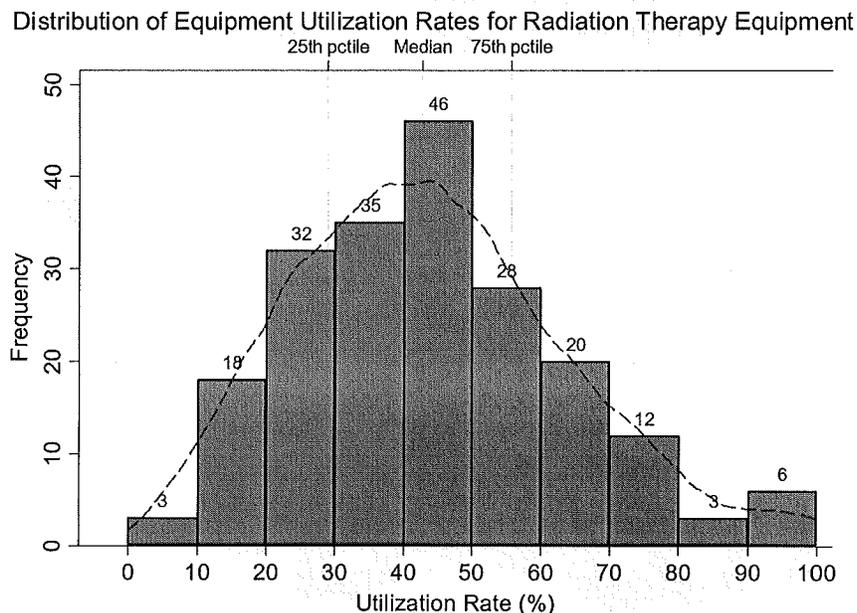
² Specifically, CMS notes, "For two specialties, [Independent Diagnostic Testing Facilities] IDTFs and Radiation Oncology, the impact of our proposed change in the utilization rate for expensive equipment is also significant. We estimate that for these two specialties, the utilization rate change will result in impacts of -2 percent and -5 percent (respectively) ... [T]he change in the utilization rate for expensive equipment does not substantially reduce overall payments for other specialties."

1. Each facility conducted a day-long “stop watch” analysis to determine the average treatment time (in minutes) for conventional radiation therapy treatment and IMRT treatment. The definition of “in use” for the equipment was that the equipment was not available for use by another patient.
2. Each facility then counted the number of treatments of conventional radiation therapy and of IMRT that were performed at that facility, per machine during the previous 12 months.
3. Based on the average treatment times and the total number of treatments, RTA estimated the total number of hours of treatment in each facility. Based on the CMS assumption of a 10-hour day, a facility-specific equipment utilization rate was then constructed.

Results

Utilization rates for 203 linear accelerators were collected and are summarized below. Data are drawn from facilities in 21 states and include facilities in urban, rural and suburban areas. The mean equipment utilization rate for the facilities surveyed was 44 percent and the median utilization rate was 43 percent. 75 percent of the facilities had utilization rates below 56 percent. If you exclude facilities with low utilization rates (below 25 percent), the mean rises to 49.6 percent and the median rises to 46.7 percent.

The graph below contains a histogram of the data (the solid bars) and a kernel density estimation (the red dotted line). The kernel density estimation represents the estimated distribution for the full population of radiation therapy equipment. Clearly the data closely approximates a normal distribution.



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Caveats

A few caveats to note about the data. For 83 of the observations, data was only available for 10 months, instead of 12. We normalized the results appropriately. In addition, 3 facilities reported utilization rates slightly above 100%. This could be the result of the confluence of two factors: facilities operating more than 10 hours day and estimated treatment times from the observation day being higher than the actual average treatment time during the previous year. We truncated those utilization rates to 100% in the data. We excluded from our data facilities that were in operation less than 10 months.

About the Radiation Therapy Alliance

Radiation Therapy Alliance is a 501(c)6 organization formed in 2009 by five companies that own multiple freestanding radiation therapy facilities. The members of the RTA are Vantage Oncology, 21st Century Oncology, Oncure, Physician Oncology Services, and Radiation Oncology Services of America. Collectively, they own and operate over 200 facilities in 21 states. RTA is committed to collecting and disseminating the highest quality research related to the operations and efficacy of freestanding radiation therapy.

Conclusion

We thank CMS for the opportunity to comment on the Proposed CY2010 Physician Payment Rule and the proposed increase in equipment utilization rate assumption from 50 percent to 90 percent. As described above, the RTA strongly believes that CMS should not finalize the proposed rule as it relates to equipment utilization. We would be happy to provide CMS with additional details about the utilization rate survey that we have conducted and would urge CMS to consider only utilization rate data related specifically to radiation therapy equipment when setting policy affecting radiation oncology.

If you have additional questions regarding this issue and the views of the RTA please contact Andrew Woods, Executive Director of the Radiation Therapy Alliance, at (202) 661-7949.

Sincerely,



Dr. Christopher M. Rose

Chair, Radiation Therapy Alliance Policy Committee