



August 28, 2009

VIA OVERNIGHT DELIVERY

Ms. Charlene Frizzera
Acting Administrator
Department of Health and Human Services
Attention: CMS-1413-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments on CMS-1413-P

Dear Acting Administrator Frizzera:

Thank you for the opportunity to comment on the Proposed Medicare Payment Policies under the Physician Fee Schedule and other Revisions to Part B for Calendar Year (CY) 2010 (CMS-1413-P).¹ Although we recognize the enormity of the task that the Centers for Medicare & Medicaid Services (CMS) faces each year in developing and finalizing the Medicare Physician Fee Schedule (MPFS) and respect the efforts of the agency and its many dedicated staff members, we respectfully disagree with several of the provisions in the CY 2010 MPFS proposed rule. Specifically, this letter addresses CMS's proposed changes with respect to (i) the equipment utilization rate assumption applicable to all equipment with a purchase price over \$1 million; (ii) the elimination of the malpractice expense component for radiation oncology; and (iii) the proposed policy with respect to physicians' services and the sustainable growth rate (SGR) system MPFS -21.5 percent update. We believe that these proposed changes — individually and in combination — pose a serious threat to the delivery of high quality and accessible cancer care, particularly to the use of radiation therapy in treating prostate cancer.

I. Access to Integrated Cancer Care

Access to Integrated Cancer Care (AICC) is an alliance of multi-specialty physician group practices and industry partners organized for the purpose of promoting and protecting the fundamental right of patients with cancer to access an integrated and comprehensive program of diagnosis, treatment, comfort and support of the highest quality. AICC's efforts include the

¹ 74 Fed. Reg. 33520 (Jul. 13, 2009).

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coordination of data collection regarding utilization and outcome analysis, the education of legislators on the benefits of comprehensive cancer care provided through multi-specialty physician group practices, and interaction with regulatory agencies to preserve patient access to this integrated model of care.

Through AICC, 35 multi-disciplinary physician group practices, comprising 875 specialists committed to diagnosing, staging, and providing definitive or palliative treatment for cancer patients, along with industry leaders that provide critical services and technologies to help deliver the most effective treatments to these patients, have lent their voice to communicate to CMS the dramatic, adverse impact that CMS's proposed policies as applied to radiation therapy services would have on the delivery of cancer care. The physician practices supporting this effort range in size from nine to 102 physicians and are located in 18 states drawn from every region of the country. They furnish care in urban and suburban settings, and many of the physician practices serve patients in rural communities.

AICC's goal is simple — to preserve access to the highest quality, integrated care to patients with cancer. Our grave concern, as we detail in Part III below, is that CMS's proposed policies as applied to radiation therapy services would result in reimbursement cuts of as much as 30 to 40 percent (and, potentially, nearly 60 percent when factoring in the proposed change to the Medicare conversion factor according to the SGR formula) that would seriously jeopardize the ability of multi-specialty physician groups to provide such care. This fear is not based on mere conjecture, but rather on comprehensive data AICC has collected from 875 physicians from across the country whose multi-specialty group practices provide integrated cancer care to 185,000 cancer patients annually and, in 2009, will see more than ten percent of all newly diagnosed cases of prostate cancer in the United States.

The integrated model of cancer care is critical for the treatment and wellbeing of the patients of the medical practices participating in AICC, as well as for all Medicare beneficiaries. As such, representatives from the Large Urology Group Practice Association (LUGPA), the American Association of Clinical Urologists (AACU), and industry, among others, have come together to support physician group practices that have integrated physicians of different specialties into a team approach for therapy of cancer, which include not only genito-urinary cancers, but those of other organ systems as well (breast and brain cancers to name but two). When cancer care is furnished in an integrated physician office setting, patients benefit from the convenience of having most, if not all, of their cancer care services available in a single location that is close to home and with which they are familiar. The value of the integrated care model might have been best summarized by a practice in Houston, Texas that responded to the AICC Survey:

Most of our physicians have been in private practice for over 15 years. They have seen and experienced many different styles of practice and find that the most beneficial style for the patient is that of totally integrated urologic care. This type of care sees the patient from diagnosis through treatment, including post treatment care and follow up. The patient has the benefit of being followed by a group of physicians (urology, pathology, radiation oncology) who are in the same practice, accessing the same records, participating in active communication, and utilizing the ability to

work and communicate together as a “comprehensive treatment team,” delivering the most efficient and comprehensive treatment.

CMS’s proposed policies as applied to radiation therapy services, if finalized, would result in reimbursement cuts that would be devastating for the delivery of integrated cancer care in the multi-specialty physician practice setting. As we show in Part II, there are a series of legal infirmities with CMS’s proposal that warrant further study before CMS decides to finalize such severe cuts. In Part III, we share in detail the results of the AICC Survey that obtained input from 875 physicians across the country who treat cancer patients in their group practices and have come to rely on integrated delivery of radiation therapy as a critical component of their patient’s treatment regimen. Finally, in Part IV we present a series of recommendations for CMS’s consideration as alternatives to finalizing the proposed cuts in reimbursement.

II. Legal Infirmities with CMS’s Proposals in the CY 2010 Medicare Physician Fee Schedule Proposed Rule

CMS has proposed several modifications to the assumptions underlying its calculation of the relative value units (RVUs) attributable to procedures for the CY 2010 MPFS. We focus in this comment letter exclusively on CPT Code 77418 (IMRT), but many of the concerns AICC identifies in these comments are applicable to other procedure codes as well. Although we discuss numerous policy issues herein, we first discuss whether CMS’s proposals satisfy requirements imposed by statute for the development of the MPFS.

A. CMS’s Proposal to Increase the Equipment Utilization Assumption from 50 Percent to 90 Percent is Legally Flawed

In the Omnibus Budget Reconciliation Act of 1989, Congress mandated that the Secretary of the Department of Health and Human Services (HHS), through CMS (then the Health Care Financing Administration),² develop a resource-based relative value scale for establishing payments under Part B for physicians’ services. Later, in the Balanced Budget Act of 1997 (BBA), Congress set forth parameters within which CMS must remain when determining the practice expense (PE) RVUs to assign to individual procedure codes. Specifically, the BBA required that, in developing such units, CMS:

- (A) utilize, to the maximum extent practicable, generally accepted cost accounting principles which (i) recognize all staff, equipment, supplies, and expenses, not just those which can be tied to specific procedures, and (ii) use actual data on equipment utilization and other key assumptions;
- (B) consult with organizations representing physicians regarding methodology and data to be used; and

² In this comment letter, for the reader’s convenience, CMS and its predecessor, the Health Care Financing Administration, are both referred to as CMS.

(C) develop a refinement process to be used during each of the 4 years of the transition period.³

Regrettably, in developing its proposals for the CY 2010 MPFS, CMS failed to comply with this Congressional mandate.

1. CMS is Relying on Data that is Inapplicable to Radiation Therapy

CMS relied on surveys described in the March 2009 Report to the Congress of the Medicare Payment Advisory Commission (MedPAC) (referred to herein as the MedPAC Report) as the basis for its proposed change to the equipment utilization rate assumption from the current 50 percent usage rate to a 90 percent usage rate for all equipment priced over \$1 million.⁴ CMS asserts that the surveys described in the MedPAC Report provide the “strong empirical evidence to justify” a change in the equipment utilization rate assumption—for all “high cost” equipment—that CMS lacked prior to the issuance of the MedPAC Report.

It is not plausible that the data upon which MedPAC relies *to make recommendations to Congress regarding payments for diagnostic imaging* is adequate to support CMS’s proposed 90 percent equipment utilization rate assumption for equipment used to furnish IMRT and other forms of radiation therapy. The MedPAC Report discussed a single, MedPAC-sponsored survey that focused on the usage rates for only two types of equipment: computed tomography (CT) and magnetic resonance imaging (MRI).⁵

Type of Equipment	MedPAC Report of Average Hours Utilized	Equipment Utilization Rate (based on 50-hour week)
MRI	46	92%
CT	45	90%
IMRT	Did not study	Did not study

In addition, MedPAC reviewed data from a survey that it had not sponsored that calculated only CT usage for certain non-hospital CT providers. Yet, despite this shortcoming in the data, CMS is proposing to apply the results of two very limited studies of CT and MRI equipment utilization to all equipment priced over \$1 million. Also troubling is the fact that the results of the MedPAC-sponsored survey described in the MedPAC Report, by MedPAC’s own admission, “are not nationally representative,” but instead represent only six markets.⁶ The use of this data to establish equipment utilization rates for “high cost” imaging equipment is problematic in its

³ Pub. Law 105-33, section 4505(d).

⁴ 74 Fed. Reg. 33520, 33532.

⁵ Report to the Congress, Medicare Payment Policy, Medicare Payment Advisory Commission (March 2009), available at http://www.medpac.gov/documents/Mar09_EntireReport.pdf at 108.

⁶ Id.

own right, but its use to establish the equipment utilization rate assumption for radiation therapy equipment unquestionably does not meet the statutory mandate that CMS “use actual data on equipment utilization.”⁷

Congress clearly intended that the PE RVUs be data-driven and developed with industry input regarding the data that underlies the assigned RVUs. In fact, Congress required the Comptroller General to evaluate CMS’s proposed implementation of the BBA mandate⁸ and to report to certain Congressional committees on: (1) the adequacy of the data used in preparing the rule, (2) categories of allowable costs, (3) methods for allocating direct and indirect expenses, (4) the potential impact of the rule on beneficiary access to services, and (5) any other matters related to the appropriateness of resource-based methodology for practice expenses.⁹ The Comptroller General was required to consult with representatives of physician organizations with respect to matters of both data and methodology.¹⁰

With respect to the equipment utilization assumption, CMS has not obtained valid data that is representative of the actual experiences of the health care providers who furnish radiation therapy to cancer patients. Moreover, when proposing the change from a 50 percent equipment utilization rate assumption to a 90 percent equipment utilization rate assumption, CMS did not consult with organizations representing physicians regarding the data to be used. Therefore, the proposed CY 2010 MPFS calculations of PE RVUs for intensity-modulated radiation therapy (IMRT) and other radiation therapy procedures are not rooted in any meaningful data analysis and, therefore, do not satisfy the requirements of section 4505 of the BBA.

2. Actual Data on Radiation Therapy Equipment Utilization is Available and Does Not Support CMS’s Proposals

In the CY 2010 MPFS proposed rule, CMS welcomed additional empirical data relating to equipment utilization rates, because the “[Physician Practice Information Survey] did not produce information that can inform the utilization rate assumption discussion.”¹¹ Not only is such data available, it indicates that the current CMS equipment utilization rate assumption of 50 percent for radiation therapy equipment is accurate and should not be changed.

The American Society for Therapeutic Radiology and Oncology (ASTRO) commissioned an independent survey to determine the daily utilization rates of the most costly equipment used to provide radiation therapy at freestanding radiation oncology centers (the ASTRO Commissioned Study, hereafter referred to as the “ACS”).¹² The ACS analyzed survey response data from 102 radiation therapy suppliers located in all regions of the country (Northeast, South/Southeast, Midwest, and West) and in all settings (urban, suburban and rural). Practice size varied among

⁷ Pub. Law 105-33, section 4505(d).

⁸ The Secretary was required to issue a proposed rulemaking to solicit public comment on how CMS would implement a system of assigning PE RVUs in accordance with the BBA mandate.

⁹ Pub. Law 105-33, section 4505(c).

¹⁰ *Id.*

¹¹ 74 Fed. Reg. at 33532.

¹² The survey was conducted in July 2009 by **dmrkynetec**, a leading global provider of market research, and the results reported to ASTRO in August 2009.

the survey respondents from less than 50 to over 200 patients treated per day.¹³ Survey respondents utilize a range of equipment to provide radiation therapy services to Medicare beneficiaries and other patients. The ACS found that radiation therapy equipment utilization rates range from 18 percent to 63 percent, with a median utilization rate of 42 percent and a mean utilization rate of 40.7 percent, based on a 10-hour day (or 50-hour week).¹⁴ Each of these types of equipment has a purchase price of over \$1 million and, therefore, is assumed by CMS in its CY 2010 MPFS proposal to be utilized 90 percent of the time, or 45 of 50 available hours during a standard week. Clearly, this is not the case.

The equipment utilization rate for even the most utilized equipment studied, the 4-6 MV linear accelerator, is far below CMS's proposed equipment utilization rate assumption of 90 percent, and it is much closer to the current 50 percent utilization rate assumption. With knowledge that "actual data" exists to support an equipment utilization rate of 50 percent (or less) with respect to radiation therapy equipment, CMS may not, within its existing statutory authority, finalize its proposal to increase the equipment utilization rate assumption to 90 percent. We note that the MedPAC report supports this conclusion. MedPAC explicitly recognized that its recommended change to the equipment utilization rate assumption "would require a change in statute because the [BBA] requires CMS to use 'actual data' on equipment use to calculate PE RVUs."¹⁵

B. Impact of the Proposals on Reimbursement for IMRT

As noted above, AICC is concerned primarily with CMS's proposals regarding: (1) the equipment utilization rate assumption applicable to all equipment with a purchase price over \$1 million; (2) the elimination of the malpractice expense component for radiation oncology; and (3) the physicians' services and SGR system MPFS -21.5 percent update. When combined with the changes in PE RVUs scheduled according to the four year MPFS implementation schedule, these proposals, if finalized, will result in a decrease in the Medicare reimbursement rate for IMRT (CPT Code 77418) of over 60 percent, depending on the location where the service is furnished. For example, using the current conversion factor (36.0666) under the CY 2010 MPFS, IMRT furnished in Tucson, Arizona, would have been reimbursed at \$448.42. Under the proposed CY 2010 MPFS, factoring in only the proposed equipment utilization change, but ignoring the SGR negative update and elimination of medical malpractice expenses, the same service would be reimbursed at \$250.83, representing a 44.1 percent decline in expected reimbursement. Similarly, reductions of 44.0 percent and 44.2 percent would be seen in Melville, New York, and Leawood, Kansas, where, using the same parameters described above, IMRT reimbursement would decrease from the current projection of \$604.58 per unit of service to \$338.45 and from \$412.33 per unit of service to \$230.24 per unit of service, respectively.

¹³ Equipment Utilization Study, Prepared for American Society for Therapeutic Radiology and Oncology, **dmrkynetec**, August 2009 at 5.

¹⁴ Id.

¹⁵ Report to the Congress, Medicare Payment Policy, Medicare Payment Advisory Commission (March 2009), available at http://www.medpac.gov/documents/Mar09_EntireReport.pdf. at 109.

1. AICC Cannot Determine How CMS Arrived at Its Impact Estimates

The decreases described above deviate from CMS's estimate of the impact of its proposals. In the Regulatory Impact Analysis section of the proposed rule, for the radiation oncology specialty, CMS estimated impacts of -5 percent and -1 percent attributable to its proposed changes to the equipment utilization assumption and the malpractice expense elimination, respectively.¹⁶ According to CMS, other proposed policies affecting the PE RVU calculation, primarily the incorporation of PE data from the Physician Practice Information Survey (PPIS), would result in an additional 12 percent decrease in reimbursement for radiation oncology.¹⁷ Ignoring the SGR update that would decrease reimbursement by 21.5 percent across the MPFS, AICC is unable to ascertain how CMS arrived at its impact conclusions for PE RVUs.¹⁸

For CY 2009, IMRT (CPT Code 77418) was assigned 14.2 PE RVUs in a non-facility setting (transitioned), and 0.13 malpractice expense RVUs. Based on the four-year phase in schedule for the revaluation of MPFS services that is to be completed in CY 2010, physicians and other suppliers anticipated a fully-implemented RVU assignment of 12.88 PE RVUs for CY 2010 and were able to plan accordingly for the resulting 9.3% reduction in reimbursement. However, CMS proposes to assign only 7.16 PE RVUs (rather than the 12.88 fully implemented proposed PE RVUs) and no malpractice expense RVUs for IMRT for CY 2010. This dramatic decrease in PE and malpractice expense RVUs was not (and could not have been) anticipated by physicians and other suppliers. Thus, the industry has had no time to alter its business practices or care models to address this significant cut in reimbursement.

Relative to the fully implemented CY 2010 amounts, without considering the SGR adjustment, the proposed changes in equipment utilization rate assumption and malpractice expense RVUs represent a 44.4 percent decrease from the transitioned RVUs.¹⁹ MedPAC, in its Report to the Congress, also identifies the impact of the CMS proposals (ignoring the SGR adjustment) as a decrease of 44 percent. Thus, when the fully implemented change in MPFS is combined with the proposed change in PE RVUs, the actual effective reduction in PE RVUs proposed by CMS for CY 2009 to 2010 is 49.6 percent, and when all proposed and planned changes are coupled with the proposed change in SGR, results in *net decreased reimbursements of over 60 percent*. The table below illustrates the effect of the change in MPFS, along with the proposed reductions in PE RVUs, malpractice RVUs and SGR on reimbursements in four sample zip codes (assuming no change in GPCI for 2009 to 2010):

¹⁶ 74 Fed. Reg. 33520, 33661-33662.

¹⁷ *Id.* at 33661.

¹⁸ We assume that the 1 percent projected impact of the elimination of malpractice expense RVUs is attributable to the elimination of 0.13 malpractice expense RVUs from the CY 2009 MPFS non-facility, fully implemented RVU assignment of 13.01 RVUs (total) to CPT Code 77418 (IMRT).

¹⁹ These proposed changes represent a 38.7 percent decrease from the fully implemented RVUs that physicians and suppliers had planned for under the phase in.

Zip Code	11747	17043	66211	85715
City, State	Melville, NY	Lemoyne, PA	Leawood, KS	Tucson, AZ
2009 Fees	\$ 665.95	\$ 569.41	\$ 454.32	\$ 493.98
Proposed Fee	\$ 262.80	\$ 223.66	\$ 179.82	\$195.11
% Δ	60.5%	60.7%	60.4%	60.5%

The impacts calculated by CMS appear inaccurate on their face, and, because of a lack of transparency in CMS’s calculation of the impact of its proposals, AICC was unable to replicate CMS’s estimates in its own analysis. In order to provide meaningful comments regarding this and other aspects of CMS’s proposals, in August 2009, AICC surveyed multi-specialty physician group practices to better ascertain the true impact of CMS’s proposals, both financially and with respect to beneficiary access to cancer care. The results of the AICC Survey are discussed below in Part III.

2. CMS’s Rationale for Eliminating the Malpractice Expense RVUs for Radiation Oncology is Without Merit

As required in section 1848(c) of the Social Security Act (the Act), CMS must review no less than every five years the RVUs assigned to services paid under the MPFS.²⁰ In the CY 2010 MPFS proposed rule, CMS proposed to implement the second review required by the statute. CMS described in detail the steps it took to obtain and analyze data related to professional malpractice premiums. Unfortunately, with respect to radiation oncology, this process did not result in an accurate assessment of the actual malpractice expense incurred in the provision of IMRT and other forms of radiation therapy.

In the prior update of the malpractice RVUs, CMS did not update the RVUs for the technical components (TCs) of procedures because of its inability to obtain data concerning malpractice costs associated with this portion of the service. Instead, CMS based the malpractice RVUs for TC services (and the TC portion of global services) on historically allowed charges.²¹ For the CY 2010 MPFS proposals, CMS has again relied inappropriately on an analogy to diagnostic imaging in eliminating the malpractice RVUs from CPT code 77418 and other codes representing radiation therapy.

CMS, through its contractor, obtained malpractice premium data for medical physicists from an insurance company that provides liability insurance *to imaging facilities*.²² This data indicates that medical physicists have very low malpractice premiums relative to treating

²⁰ Social Security Act, §1848(c)(2), 42 U.S.C. §1395W-4(c)(2).

²¹ 74 Fed. Reg. at 33541.

²² Id.

physicians.²³ CMS then made a radical leap in logic to use medical physicist malpractice premium data as a proxy for the malpractice premiums paid by all entities providing TC services, regardless of the type of service supplier (for example, physician practice or freestanding imaging center) or the type and risk of the service provided.

Singling out IMRT for discussion, CMS states in the proposed rule that:

“Medical physicists are involved in complex services such as [IMRT]. . . . Based on the complexity of these services, we believe that medical physicists would pay one of the highest malpractice premium rates of the entities furnishing TC services and that using their data as a proxy (in the absence of actual premium data) to develop malpractice RVUs for TC services would be more realistic than our current approach for these entities.”²⁴

CMS also stated that the use of medical physicist malpractice premium data would better reflect the level of malpractice premiums related to the provision of TC services than a crosswalk to the malpractice premium data of physician specialties.²⁵ AICC strongly disagrees. In making these assumptions and applying medical physicist malpractice premium rates to all suppliers of radiation therapy services, CMS has failed to consider that malpractice premium rates may differ between non-facility settings, for example, between a freestanding diagnostic imaging center and a physician office setting.

Most significantly, CMS ignores the important role of the physician in the provision of TC services such as radiation therapy. The mere fact that a medical physicist is involved in the furnishing of IMRT services does not negate the fact that significant physician work, including staff training time, supervision, and quality assurance activities, is involved with the furnishing of TC services and, specifically, with the furnishing of radiation therapy. Under scope of practice laws across the entire country, a medical physicist may only provide radiation therapy services under the supervision of a licensed physician. Moreover, the supervising physician ultimately would be professionally liable for any negligence of the medical physicist under a vicarious liability theory. Thus, in a physician office setting and, in particular, in a physician practice that furnishes integrated cancer care, *physician* malpractice premium data would be the best proxy for determining the malpractice expense RVUs for radiation therapy TC services.

Finally, as part of its proposal to use medical physicist malpractice premium data universally for all TC services, CMS stated its belief that “it is unlikely that actual malpractice premium rates for these entities would exceed those for medical physicists.”²⁶ CMS provides no evidence that it compared malpractice premium rates for other types of non-physician practitioners, including technicians and others involved in the furnishing of complex diagnostic imaging, radiation therapy, or any other TC service, to confirm this assumption. Moreover, CMS obtained only malpractice premium data for medical physicists who furnish services *in imaging centers*. Without clear proof that this is an appropriate proxy for the development of malpractice RVUs for all TC services paid under the MPFS, it is inappropriate for CMS to finalize this proposal.

²³ Id.

²⁴ Id. at 33541-33542.

²⁵ Id. at 33542.

²⁶ Id.

III. AICC's August 2009 Survey of 875 Physicians Whose Multi-Specialty Group Practices Provide Cancer Care to Medicare Beneficiaries Shows that CMS's Proposals, If Implemented, Will Be Devastating for the Delivery of Integrated Cancer Care.

In order to provide CMS with meaningful and useful comments with respect to the impact of its proposals, AICC conducted a nationwide survey of physicians who provide patients with comprehensive cancer care within multi-specialty physician group practices (the AICC Survey). AICC received responses from 875 physicians in 35 multi-specialty physician practices across the country. Responses were received from small, medium and large size groups (ranging from nine to 102 physicians) in 18 states covering all regions of the country — Northeast, South/Southeast, Midwest and West.²⁷ Combined, the physicians who responded to the AICC Survey treat more than 185,000 cancer patients annually and see over 22,000 new cases of prostate cancer each year. In 2009, this will amount to more than one out of every 10 newly diagnosed cases of prostate cancer in the United States.²⁸ In at least a half dozen states, the physicians who responded to the AICC Survey are expected to see anywhere from 20 percent to more than 60 percent of all newly diagnosed cases of prostate cancer in the state in 2009.²⁹ On an annualized basis, the multi-specialty physician groups that responded to the AICC Survey report that they will furnish 8,600 patients with radiation therapy at one of their medical practice locations in 2009.

Impact on Access to High Quality Care. The primary purpose of the AICC Survey was to determine what impact CMS's CY 2010 MPFS proposals can be expected to have on physician practice operations and beneficiary access to high quality care. All of the responding physician practices stated that they believe the quality of cancer care in their respective localities will suffer if CMS implements its proposed cuts in reimbursement for radiation therapy. In addition, 80% of responders — encompassing urban, suburban and rural communities — anticipate that they will have to reduce availability of radiation therapy if CMS implements its proposed cuts.³⁰

The AICC Survey went further and asked the responding multi-specialty physician group practices to identify what specific steps their medical practices anticipate having to take if CMS implements one or more of the three proposed cuts that would impact reimbursement levels for

²⁷ Specifically, AICC received responses from multi-specialty physician group practices in Alabama, Arizona, California, Colorado, Florida, Illinois, Indiana, Kansas, Maryland, Missouri, Nevada, New Jersey, New York, Ohio, Oklahoma, Oregon, Pennsylvania and Texas.

²⁸ According to the American Cancer Society, approximately 192,280 new cases of prostate cancer will be diagnosed in the United States this year. See http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_are_the_key_statistics_for_prostate_cancer_36.asp.

²⁹ See, e.g., Alabama (36%); Illinois (24%); Ohio (33%); New Jersey (63%); New York (33%); Texas (36%). These figures are based on a comparison of the number of newly diagnosed cases of prostate cancer that AICC responders see annually with the American Cancer Society's state-by-state projection of new cases of prostate cancer for 2009. See American Cancer Society, "Cancer Facts and Figures: 2009," at p. 5, available at <http://www.cancer.org/downloads/STT/500809web.pdf>.

³⁰ We examine later in this section the specific adverse effects anticipated by multi-specialty physician practice groups servicing patients in rural communities.

radiation therapy.³¹ Eighty-seven percent of responding physician practices indicated that they would have to close or reduce the number of hours of operation of one or more of their radiation therapy facilities. Nearly 30 percent of the responding medical practices reported that the next closest available radiation oncology provider to the responding physician practice with at least equivalent quality equipment was at least 11-25 miles away; nearly two-thirds of those responding practices reported that the next closest available radiation oncology provider with at least equivalent quality equipment was more than 25 miles away. Patients with cancer needing radiation therapy, at best, would have trouble scheduling required radiation therapy appointments and, at worst, could find themselves unable to receive treatment within a reasonable distance from their work and homes. As CMS is well aware, many Medicare beneficiaries have limited transportation options due to frailty or lack of assistance from family and other caregivers, a challenge that is exacerbated when it comes to IMRT that typically requires treatments five days a week for upwards of eight weeks.

In addition to expanding dramatically the distance that many patients would have to travel for comparable cancer care, those responding to the AICC Survey identified a series of other adverse affects likely to be felt by multi-specialty physician group practices and their patients if CMS finalizes its proposed policies as applied to radiation therapy services:

- 97 percent of the responding physician practices expect that they would have to reduce the hours of or layoff non-physician staff.
- 34 percent of the physician practices surveyed expect that they would have to reduce the number of physicians providing integrated cancer care and other health care services to their patients.
- Although in many cases radiation therapy services would be available within 25 miles to patients who were no longer able to receive the services from a surveyed multi-specialty physician group practice, 20 percent of the responding practices indicated that the equipment and technology at the other available facilities is inferior to what is available in the physician's medical practice.
- 88 percent of the responding practices would delay scheduled equipment upgrades, resulting in reduced access to cutting edge technology often not found in the facility setting.
- 91 percent of the responding practices anticipate having to reduce the amount of indigent care that they furnish, as well as reduce community outreach and charitable efforts.
- Five physician practices stated that they may have to discontinue their medical practice operations altogether, jeopardizing cancer care to over 10,000 patients in five states.

³¹ To repeat, those proposed cuts involve (i) the change in the equipment utilization rate assumption from 50% to 90% for all equipment with a purchase price over \$1 million; (ii) the elimination of the malpractice expense component for radiation oncology; (iii) and the proposed policy with respect to physicians' services and the SGR system MPFS -21.5 percent update.

Significantly, these detrimental affects on access to high quality cancer care were not driven exclusively by the -21.5 percent adjustment to the SGR. Seventy-two percent of the responding multi-specialty physician group practices anticipate that they will have to reduce hours and/or layoff non-physician staff, even if CMS were only to finalize the change in the utilization rate assumption from 50 percent to 90 percent for equipment valued over \$1 million. Likewise, 69 percent of the responding practices anticipate that the change in utilization rate assumption, standing alone, would result in delays in scheduled upgrades in radiation therapy equipment and/or reductions in the amount of pro bono and indigent care services as well as community outreach and charitable efforts that their practices are able to offer.

Impact on Access to Cancer Treatment in Rural Areas. CMS's proposals do not take into account the effect that drastic cuts in reimbursement for radiation therapy services would have on the delivery of cancer care in rural areas. CMS took MedPAC's conclusion that access to CT services in rural areas would not be impacted adversely by the proposed cuts in reimbursement and, without any substantiation, leapt to the conclusion that there would be no problem in rural areas with access to *any* services furnished using equipment valued over \$1 million.³² The MedPAC Report, however, says nothing about whether patients in rural locations will be able to continue receiving the highest quality cancer care if multi-specialty physician group practices are forced to reduce availability of radiation therapy treatment in those areas. The MedPAC Report on which CMS relied was clear in its narrow focus on diagnostic imaging:

According to our analysis of data from the American Hospital Association's 2006 AHA annual survey of hospitals, 95 percent of rural hospitals provide CT services in their community.... Therefore, if rural areas do not have physician offices or freestanding centers with MRI and CT machines, most of these communities have access to such services through a hospital.³³

Notwithstanding MedPAC's findings with respect to beneficiary access to CT services in rural communities, data collected from the AICC survey strongly suggests that there should be cause for concern about the availability of radiation therapy in rural areas if CMS's proposed cuts take effect. Among the survey responses AICC received were responses from multi-specialty physician practices that furnish care, at least in part, in rural communities. On an annual basis, these practices reported treating 8,200 cancer patients, seeing 1,940 new diagnoses of prostate cancer, and furnishing radiation therapy to 1,210 patients. All of these practices anticipate having to reduce the availability of radiation therapy if CMS implements its proposed cuts in reimbursement. Each group reported that based on the change in the utilization rate assumption from 50 to 90 percent alone, it would have to take one or more of the following actions — reduce hours of and/or layoff staff, delay scheduled upgrades in radiation therapy equipment, close one or more practice locations, and reduce pro bono and indigent care services.

These results are particularly distressing coming from multi-specialty practices that furnish cancer care in rural settings, given that fewer alternatives exist for patients to receive comparable care. As a responding practice that furnishes services to patients who live in rural locations in Illinois reported, "CMS's proposed cuts will force patients to drive an additional 50 miles for each treatment," because the group will be forced to close the doors of its facility servicing

³² 74 Fed. Reg. at 33532.

³³ Report to the Congress, Medicare Payment Policy, Medicare Payment Advisory Commission (March 2009), available at http://www.medpac.gov/documents/Mar09_EntireReport.pdf at 110.

patients in rural communities. Similarly, a multi-specialty physician group practice furnishing treatment for all types of cancer (and regardless of patient ability to pay) to patients living in rural communities in Western New York reports that if CMS's proposed cuts take effect the group would likely have to narrow its focus to treatment of prostate cancer alone and would have to scale back significantly on its pro bono or indigent care services, leaving patients in this rural area with the option of driving more than an hour to Buffalo or as much as two or three hours to Cleveland in order to receive comparable cancer care.

In short, CMS should not dismiss legitimate concerns regarding beneficiary access to radiation therapy services in rural areas based on data indicating that *CT services* may be available in rural communities through a hospital. The AICC Survey bears out this very point.

If CMS finalizes the proposed rate cuts, it should expect that in both rural and urban settings one of the principal casualties will be the integrated model of comprehensive cancer care offered in multi-specialty physician group practices. From across the country, AICC Survey responders identified specific ways in which their integrated model of cancer care would suffer.

One group in the New York Metropolitan area stated, "our practice was founded on providing cutting edge technology to our patients and expanding this access to underserved communities...these cuts will jeopardize our ability to provide state of the art care in areas in which such care is desperately needed."

A practice in Central Pennsylvania furnishing care to patients in rural communities anticipates patients having to "travel longer distances daily to receive care" and the practice having greater difficulty in recruiting new urologists to the community.

A practice in Austin, Texas echoed the concern about physician recruitment, explaining that CMS's proposed cuts, if implemented, "would be devastating in attracting top physicians to the field of cancer medicine and in allowing community investment and bringing technology to the community."

A practice in Akron, Ohio was particularly concerned about elderly patients and their families having to navigate more cumbersome physical layouts at the local hospital's radiation therapy center and not benefiting from direct supervision of treatment by the patients' own urologist, as occurs in the multi-specialty physician group practice setting.

A practice in Baltimore, Maryland anticipated severe impacts on cancer patients, including less time with physicians and dramatic reductions in critical charity care for indigent populations, particularly in the African American community where incidents of prostate cancer are dramatically higher than in other communities.

In short, the quality of integrated cancer care across the country will suffer dramatically if CMS implements its proposed policies as applied to radiation therapy.

IV. Recommendations

For the reasons discussed above and in this section, AICC urges CMS not to finalize its proposals to (i) increase the equipment utilization rate assumption from 50 percent to 90 percent for all equipment with a purchase price of over \$1 million; (ii) eliminate the malpractice expense RVUs from radiation therapy TC codes due to the use of limited medical physicist malpractice premium data; and (iii) apply a -21.5 percent adjustment under the SGR system for CY 2010. Specifically, we recommend the following:

- CMS should not finalize the change in the equipment utilization rate assumption;
- CMS should not change the way CMS calculates malpractice expense RVUs for TC services;
- CMS Should not implement the full -21.5 percent adjustment under the SGR system for CY 2010;
- CMS should let Congress pass final health care reform legislation before implementing any of the proposals discussed in this letter; and
- CMS should not finalize any of the proposals discussed in this letter until it has completed properly the regulatory impact analysis required by law.

For ease of reference, our rationale for each of these recommendations is summarized below.

A. Do not finalize the change in the equipment utilization rate assumption.

The data upon which CMS relied to support its proposal to increase the equipment utilization rate assumption is limited, applicable only to CT and MRI, and contradicted in the ACS with respect to radiation therapy equipment. Specifically, the MedPAC report and recommendations upon which CMS relies did not address radiation therapy equipment or, for that matter, any “high cost” equipment used to furnish services other than CT or MRI. With recent, independent data indicating that CMS’s current equipment utilization rate assumption of 50 percent is correct with respect to equipment used to furnish radiation therapy services, CMS should not finalize a proposal that has such a significant impact on the ability of physicians and other suppliers to furnish radiation therapy services to Medicare beneficiaries. Perhaps most important, CMS’s proposal to change the equipment utilization rate assumption utilized to calculate PE RVUs violates the statutory mandate set forth by Congress in the BBA, as detailed above in Part II.A. At a minimum, CMS should independently study the utilization of equipment used to furnish radiation therapy before implementing a policy that affects integrated cancer care for all Medicare beneficiaries.

Also, section 1848(c)(2)(B)(ii) of the Act requires the Secretary, to the extent the Secretary determines to be necessary, to adjust the number of RVUs for MPFS services to take into account changes in medical practice, coding changes, *new data on relative value components*, or the addition of new procedures. The data from the ACS must be considered prior to making a change to the PE RVUs for radiation therapy codes.

B. Do not change the way CMS calculates malpractice expense RVUs for TC services.

Section 1848(c)(2)(C)(ii) of the Act requires CMS, using the authority delegated to it by the Secretary of HHS, to determine a number of malpractice relative value units for MPFS services based on the malpractice expense resources involved in furnishing the service. CMS's proposal to apply to radiation therapy services provided in a physician office setting data regarding the malpractice premiums for medical physicists who furnish services in imaging facilities does not satisfy this statutory requirement. It is outside the scope of CMS's authority to determine the number of malpractice RVUs for radiation therapy TC procedure codes without considering the actual resources involved in furnishing radiation therapy.

C. Do not implement the full -21.5 percent adjustment under the SGR system for CY 2010.

As described above, the cumulative proposals for the CY 2010 MPFS will have a severe and detrimental impact on beneficiary access to local, high quality, integrated cancer care provided in the physician office setting. CMS should consider all available options within its statutory authority to eliminate or reduce the impact of the SGR adjustment for CY 2010. CMS proposed to remove physician-administered drugs from the list of items and services included in "physicians' services" subject to the SGR system adjustment calculation. CMS also should consider removing other items and services not paid under the MPFS, such as clinical diagnostic laboratory tests. In addition, CMS should work with Congress to revise the SGR system to address only those physicians' services for which physicians actually control increases in cost.

D. CMS should let Congress pass final health care reform legislation before implementing any of the proposals discussed in this letter.

With health care system reform the top domestic Administration priority, and with Congress poised to address many of the issues addressed in the CMS proposals, it is prudent for CMS to wait for Congress to act on health care reform.

Based upon MedPAC recommendations, Congress has curtailed growth in physician-administered advanced imaging such as CT, PET and nuclear scans. More recently, the House Tri-Committee proposal that comprises H.R. 3200 reflects a 75 percent equipment utilization rate assumption for imaging equipment, rather than the current 50 percent assumption, when computing the practice expense *for imaging services*.

Moreover, the Obama Administration has taken a number of steps this year to replace the SGR formula for updating Medicare physician payments. As with proposed reductions in advanced imaging, Congress is addressing the growth in spending on physician services. House proposals would establish a new Medicare physician payment formula. Senate negotiators have scaled back the Medicare physician payment relief in the compromise package to a one-year temporary halt to the payment cuts being produced by the SGR formula. The legislative situation remains fluid, but as the full Senate debates legislation this fall, this physician payment topic will be an important part of the debate.

As described above, physician payment levels are being addressed as part of the health system reform debate. Multiple Congressional committees have held countless hearings on these topics. At a time of intense legislative negotiation on the proper physician services provisions, CMS should not implement regulatory changes that trump the legislative process.

E. CMS should not finalize any of the proposals discussed in this letter until it has completed properly the regulatory impact analysis required by law.

Despite being required in the Regulatory Impact Analysis section of the proposed rule to do so, CMS did not address the impact of the proposed changes on small businesses, and does not propose any measures for mitigating negative impact. Under the Regulatory Flexibility Act (“RFA”) of 1980 (P.L. 96-354) and the Small Business Regulatory Enforcement Fairness Act (“REFA”) of 1996 (P.L. 104-121), government agencies must analyze how proposed regulations would affect small businesses, must attempt to mitigate negative regulatory impact on small businesses, and must address these factors in the Regulatory Impact Analyses accompanying proposed regulations. The majority of physician practices are considered small businesses, and the changes embodied in the proposed CY 2010 MPFS would have a significant negative impact on these small businesses.

By taking the steps suggested in this letter, CMS can mitigate the negative impact that the proposed policies would have on the many small businesses that furnish radiation therapy services as part of Medicare beneficiaries’ integrated cancer care. Because most physician practices that furnish integrated cancer care are small businesses, determining *not* to finalize the proposals discussed in this letter, or instead finalizing more appropriate, data-driven policy changes, would help mitigate the effect of the proposed regulations on small businesses. The RFA and REFA require CMS to undertake such mitigation efforts, and CMS should heed these statutory mandates.

In closing, we would like to thank CMS for providing us with this opportunity to comment on the Proposed Medicare Physician Fee Schedule for CY 2010. Please feel free to contact Dr. Deepak Kapoor, Chairman of AICC’s Executive Board, at (516) 931-0041 if you have any questions or if AICC can provide additional information to assist CMS as it considers these issues.

Respectfully submitted,

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On behalf of the AICC Executive Board

cc: Jonathan Blum
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