

# **NPAF** National Patient Advocate Foundation

The Patient's Voice | *since 1996*

## **EXECUTIVE BOARD**

**Nancy Davenport-Ennis**

CEO, President

Patient Advocate Foundation

**Christian Downs, MHA, JD**

Board President

Executive Director

Association of Community Cancer Centers

**Leah Locke-Arnett, RN, BSN, MHCA**

Board Secretary

Associate Director

University Health Services

University of Texas at Austin

**John L. Murphy**

Board Financial Officer

Saguenay Capital, LLC

**Edward G. Connette, Esquire**

Immediate Past President

Essex Richards, PA

**Bruce Avery, MD**

Hematology-Oncology Knoxville

**Alan J. Balch, Ph.D.**

Vice President

Preventive Health Partnership

**Rene S. Cabral-Daniels, JD, MPH**

Vice President of Grant Programs

Williamsburg Community Health Foundation

**Martha E. "Meg" Gaines, Esquire, LL.M.**

Clinical Professor of Law,

University of Wisconsin Law School

**Dennis A. Gastineau, MD**

Director, Human Cell Therapy Laboratory

Divisions of Transfusion Medicine & Hematology

Mayo Clinic

**Venus Ginés, MA**

Founder & CEO

Dia de la Mujer Latina, Inc.

**The Honorable Phil Hamilton**

Virginia House of Delegates

**Lovell A. Jones, MD, PhD**

Director, Center for Research on Minority Health

Department of Health Disparities Research

University of Texas

MD Anderson Cancer Center

**Pearl Moore, RN, MN, FAAN**

CEO (Ret.)

Oncology Nursing Society

**Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI**

President, Clinical Services & Chief Medical Officer

HCA / Hospital Corporation of America

**Roy Ramthun, MSPH**

President

HSA Consulting Services

**Reed V. Tuckson, MD, FACP**

Executive Vice President and

Chief of Medical Affairs

UnitedHealth Group

## **SCIENTIFIC BOARD**

**Robert M. Rifkin, MD, FACP**

Chair, PAF Scientific Board of Directors

Director, Cellular Therapeutics

Rocky Mountain Blood & Marrow Transplant Program

Rocky Mountain Cancer Centers

**Pamela S. Becker, MD, PhD**

Associate Professor of Medicine/Hematology

Institute for Stem Cell and Regenerative Medicine

University of Washington

**David Brizel, MD**

Professor of Radiation Oncology

Associate Professor of Head and Neck Surgery

Duke University Medical Center

**F. Marc Stewart, MD**

Professor of Medicine, University of Washington

Fred Hutchinson Cancer Research Center

**Lori Williams, PhD, DSN<sup>1</sup>, RN, AOCN**

University of Texas

MD Anderson Cancer Center

August 27, 2009

## **VIA FEDERAL EXPRESS**

Charlene Frizzera

Acting Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attn: CMS-1413-P

7500 Security Boulevard

Baltimore, MD 21244-1850

Re: **CMS-1413-P: Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2010**

Dear Administrator Frizzera:

We are pleased to offer comments on the Physician Fee Schedule (PFS) proposed rule<sup>1</sup> and give a voice to patient needs and concerns. The advocacy activities of the National Patient Advocate Foundation (NPAF) are informed and influenced by the experience of patients who receive counseling, case management, and co-payment relief services from our companion organization, the Patient Advocate Foundation (PAF), which specializes in mediation for access to care, job retention, and relief from debt crisis resulting from a diagnosis of a chronic, debilitating or life-threatening disease. In 2008, PAF received over 9.5 million contacts on-line and by telephone requesting information and/or direct professional intervention in the resolution of access disputes and it initiated the provision of direct services to 48,800 individuals. Twenty two percent of the individuals receiving direct professional intervention from PAF were Medicare beneficiaries and the majority of those were individuals dealing with a diagnosis of cancer. PAF provided assistance to Medicare beneficiaries from all 50 states.

Medicare beneficiaries are assigned to PAF Senior professional navigators, who negotiate the full spectrum of social services, federal and state programs, and private sector resources, providing needed services in a coordinated process to

<sup>1</sup> 74 Fed. Reg. 33519 (July 13, 2009).

ensure that no patient is without treatment or resources after being diagnosed with chronic, debilitating, or life-threatening diseases. When appropriate, PAF navigators assist in locating pharmaceutical assistance by facilitating application to pharmaceutical manufacturers' and foundations' patient assistance programs.

The PAF Senior professional navigators helped resolve debt crisis issues for slightly more than 24% of the Medicare beneficiaries served in 2008. Sadly, typical issues included inability to pay for food, housing, utilities, transportation, non-covered medical supplies, and burial expenses. Approximately 28% of PAF's Medicare cases concerned medical co-payment issues and another 28%, pharmaceutical co-payment issues, under either Part B or Part D, illustrating the toll that high prescription drug costs and cost-sharing obligations can take on Medicare beneficiaries, particularly those with cancer. PAF also assisted beneficiaries with coding and billing errors, premium assistance, benefit exclusions, formulary denials, chemotherapy denials, and clinical trial denials. This note to PAF from a patient with commercial insurance sums up the Foundation's mission.

1

**BECKY SANDERSON**

Colon Cancer  
Conwary, AR

“Not only does the PAF Colorectal CareLine actually help people but your staff actually cares, which means so much when you're so overwhelmed by cancer and all that comes with it. I needed help with interpretation of insurance policies – read mine and thought I understood it only to find out there was no coverage for cancer treatment (other than surgery). No average person can understand how, at least mine, was written. Help from advice, support and financial (for medication and travel expenses) as given. Just knowing I had someone to call was great!”<sup>2</sup>

## **DETAILED DISCUSSION OF PROPOSED RULE PROVISIONS**

Effective January 1, 2010, the proposed rule projects the PFS conversion factor will be \$28.3208. This is a 21.5% decrease from the current 2009 rate of \$36.066. CMS must use the flawed SGR formula which underlies this across-the-board payment cut unless Congress overrides the mandate. It has therefore included the SGR reduction in its Impact Analysis and the payment rates detailed in the proposed rule. Because NPAF expects Congress to avert the SGR cut, the discussion below ignores this aspect of the proposed rule.

### **Practice Expense Methodology**

CMS has proposed two significant changes to the methodology used to develop the practice expense relative value units (PE RVUs) assigned to procedures eligible for reimbursement under the PFS. The combined effect of the changes is a massive reimbursement cut of 19% for radiation oncology, and lesser – but still troubling – cuts of 6% for medical oncology and 11% for radiology. Largely as a result of the proposed PE

---

<sup>2</sup> PAF Patient Data Analysis Report for 2008, 54 (published with permission from Ms. Sanderson).

changes, about 20% of the \$2.4-\$3 billion in payment reductions in the PFS proposed rule would affect services provided to patients with cancer.

Neither the payment reductions facing radiation and medical oncology nor the latest round of proposed cuts to reimbursement for the diagnostic imaging services crucial to cancer staging and treatment planning are consistent with patient care demands, the commitment to curing cancer made by President Obama in his February 24, 2009 address to Congress, or the Administration's decision to include \$6 billion in its fiscal 2010 budget to support cancer research. The proposed payment reductions come at a time when many oncology practices and radiation treatment centers already are cutting back on the charity care they provide because of deteriorating collections associated with higher cost-sharing obligations under commercial insurance policies, lost insurance coverage because of unemployment, and the like. Because of the implications of the proposed reimbursement changes for patient access, NPAF is of the view that CMS needs to rethink its approach to the proposed PE methodological changes.

As we understand it, the first of the proposed PE methodology changes affects direct PE under the bottom-up methodology and involves a significant revision to the assumption that CMS has made about equipment utilization since the PE RVUs were implemented. Since it began setting PE RVUs, CMS has assumed all equipment needed for patient care is used 50% of the time. It is now planning to take the position that any equipment costing over \$1 million is used 90% of the time. Doing so significantly reduces the direct PE RVUs assigned to equipment-heavy technical component (TC) services central to radiation oncology and the diagnostic imaging used in the therapeutic treatment and management of cancer. The revised utilization rate assumption that CMS has integrated into the calculation of the payment rates detailed in the 2010 PFS proposed rule accounts for about a quarter (almost 6%) of the disastrous reimbursement cut projected for radiation oncology and a portion of the cut facing radiology.

The second PE methodological change CMS is proposing relates to the data used to determine the specialty-specific PE/hour central to building indirect PE RVUs and setting the proportion of direct and indirect PE assigned to each specialty. CMS anticipates replacing the cost data from the American Medical Association (AMA) Socioeconomic Monitoring System surveys in 1995-1999 and the supplemental surveys submitted pursuant to the Balanced Budget Refinement Act of 1999 (BBRA)<sup>3</sup> in 2003-2005 with data collected through the more recently completed AMA Physician Practice Information (PPI) survey and the supplemental Lewin survey of non-physician health professionals. Both surveys are based primarily on financial data from 2006. The Lewin survey covers radiation oncologists working in freestanding cancer centers.

When the PPI survey data (hereafter used as shorthand for the combined AMA/Lewin dataset) is used and the PFS budget neutrality requirement applied, the end result is a dramatic and, in our view inappropriately skewed, redistribution of Medicare reimbursement to primary care at the expense of specialists, including those oncologists responsible for providing cancer care to millions of Medicare beneficiaries. The decision to build the fee schedule presented in the proposed rule using PPI survey data is

---

<sup>3</sup> Pub. L. 106-113.

responsible for approximately three-quarters (about 12%) of the reimbursement reduction facing radiation oncology, almost the entire payment cut facing medical oncology and a significant portion of the cut facing providers of diagnostic radiology services.

The financial implications of the staggering reimbursement cuts facing cancer care in 2010 because of the proposed changes in the PE methodology are staggering. We fear that from an access to care perspective, any increases in care affordability that flow from reduced co-payments under the proposed rule will be far outweighed by reduced physical access to care as physicians and cancer centers close or consolidate practice locations. Physician practices and freestanding cancer centers are small businesses. Based on NPAF's conversations with representatives of this community, we do not believe they can absorb revenue reductions of the magnitude contemplated by the proposed rule in a single year. Similarly, we fear they will not be able to continue providing the level of patient care that Medicare beneficiaries fighting cancer deserve. These realities are all the more disturbing because the changes underlying the cuts reflect what appear to be flawed assumptions and unreliable data.

The discussion of PE issues that follows describes some of the real-world implications of the PE methodology changes outlined in the PFS proposed rule, addresses the legal and conceptual concerns NPAF has with the approaches CMS has proposed, and makes recommendations for modifications needed before the PFS is finalized.

#### Impact of Proposed PE Changes on Radiation Oncology

Based on the data presented in Table 39 of the PFS proposed rule,<sup>4</sup> overall Medicare reimbursement to radiation oncology would be reduced 19%. Payment cuts for different radiation therapy (RT) procedures vary widely, with the reduction for IMRT treatment delivery being the deepest at 44%.<sup>5</sup> A comparison of payment rates under the 2010 PFS proposed rule with those in the 2010 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule<sup>6</sup> reveals that, in many instances, payments for the same RT services will be radically higher in the *hospital* than they are in freestanding community-based cancer treatment centers. For example, the Medicare reimbursement for a course of prostate IMRT (40 fractions) in a hospital outpatient department in 2010 is slated to be \$23,415, but the TC payment for a freestanding cancer center would only be \$15,480. For head and neck IMRT, the hospital payment rate would be \$24,418 but the TC rate at a freestanding center would be \$15,891. The story is the same for a number of other treatment regimens as well. Such significant site-of-service differentials raise concerns about the appropriateness of the proposed changes to the PE methodology since, as we understand it, the cost of equipment, staff and other overhead are similar in both settings. They also could signal a potential increase in the total costs incurred by Medicare for

---

<sup>4</sup> 74 *Fed. Reg.* at 33661.

<sup>5</sup> The enormous proposed reduction in payment for IMRT treatment delivery is particularly concerning in the face of a recently released draft report from AHRQ entitled "Comparative Effectiveness and Safety of Radiotherapy Treatments for Head and Neck Cancer," which concludes, in part, that the evidence is consistent enough to suggest that IMRT is a better treatment choice for head and neck cancer than is three-dimensional convention conformal therapy or other radiation therapy alternatives.

<sup>6</sup> See 74 *Fed. Reg.* 35231, "Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates" (July 20, 2009).

certain RT services next year if the staggering proposed cuts facing freestanding community centers – centers that currently furnish about 40% of the RT services received by Medicare patients – cause a major shift in patients back to the hospital. Such a shift also could reduce beneficiary satisfaction with cancer care given that many patients report a preference for not having to make repeated visits to a hospital for treatment.

Assuming a facility's 2008 case mix is representative of its patient population today, a survey conducted by the American Society for Radiation Oncology (ASTRO) immediately after the PFS proposed rule was released suggests that many cancer centers will experience overall payment cuts between 18% and 31% because of their particular patient mix.<sup>7</sup> Such deep payment cuts are difficult to reconcile with PPI survey data showing that the cost per hour for providing radiation oncology services has increased from \$114 to \$126.66 since 2006. In many instances, they also are difficult to reconcile with the proposed payment rates for the same services under the 2010 HOPPS proposed rule. More importantly, they carry significant implications for patient access to care, particularly in rural areas. A study designed to assess rural access to cancer care commissioned by NPAF and The Global Access Project and conducted in 2005 find that there were no medical or radiation oncology practices in 45% of rural counties, representing 25% of the rural study population.<sup>8</sup> Three-quarters of the rural hospitals that reported providing oncology services did *not* offer radiation therapy. The ASTRO studies suggest that the proposed cuts would serve to significantly worsen an already difficult rural access problem facing patients in need of radiation therapy. At a minimum, center closures would add higher travel expenses to the already significant financial burden facing Medicare beneficiaries receiving radiation therapy.

Respondents to the ASTRO survey were asked how their practices would deal with overall cuts in Medicare payments for 2010 of 20% or 30%. The results raise significant concerns about the adverse access implications of the PFS proposed rule. The ASTRO survey showed that if case-mix adjusted cuts were at the 20% level:

- 18% of centers surveyed would close
- 39% of centers would consolidate locations
- 27% of rural centers v. 15% of urban/suburban centers would close

For facilities anticipating case-mix adjusted payment reductions reaching 30%:

- 39% of centers would close
- 60% of centers would consolidate locations
- 47% of rural centers v. 37% of urban/suburban centers would close.

If closures of freestanding community cancer centers occur at anywhere near the levels predicted by the ASTRO survey, NPAF has grave concerns about the ability of the

---

<sup>7</sup> ASTRO, "Proposed 20 to 30 Percent Medicare Cuts Would Devastate Cancer Care," available at <http://www.astro.org/MedicareCuts/documents/CMSfactsheetsGR.pdf>. The report is based on survey responses from 515 community-based or community- and hospital-outpatient-based practices.

<sup>8</sup> NPAF and The Global Access Project, Kathleen Dalton, University of North Carolina Chapel Hill, principal investigator, "Geographic Access to Care Study (Jan. 2005), available at [http://www.npaf.org/images/pdf/gap/unc\\_study.pdf](http://www.npaf.org/images/pdf/gap/unc_study.pdf).

surviving community and hospital-based facilities to handle the surge in cancer patients needing radiation treatment.

Radiation therapy typically requires 20-40 treatment sessions occurring daily five days a week over a period of 4-8 weeks. If existing cancer centers offering RT close or consolidate, patients will be forced to drive longer distances each day for weeks to receive treatment. Such a change has clinical implications. Patients receiving intense radiation therapy regimens are often quite nauseous after therapy and cannot tolerate long car rides. Moreover, a number of journal articles establish that there is an inverse relationship between distance to a radiation treatment facility and selection of radiation therapy as a treatment option.<sup>9</sup> One article<sup>10</sup> of which we are aware involves a study of women old enough to be eligible for Medicare. It shows that increasing distance to the nearest radiation treatment facility is associated with a decreased likelihood of receiving post-mastectomy RT despite the evidence from randomized trials showing a statistically significant survival benefit from radiation use after mastectomy in specific patient subgroups.<sup>11</sup>

As the following two case studies drawn from PAF's case management files show, the cost and logistics of transportation do, in the real world, pose a barrier to cancer care.

<b>City/State:</b>	Eagle Pass, TX
<b>Diagnosis:</b>	Thyroid Cancer
<b>Issue:</b>	Transportation
<b>Problem:</b>	Patient is an uninsured Spanish-speaking female diagnosed with thyroid cancer. She is required to travel 2½ hours one way to obtain necessary radiation therapy and surgeries under a charity care program in San Antonio
<b>Resolution:</b>	Patient Advocate Foundation coordinated transportation assistance to ensure access to care at the facility where she was able to obtain necessary treatment. She lived in a remote area with no services available.

In the preamble to the proposed rule, CMS argues that access limitations would not result from the proposed change in the utilization rate assumption and pointed to data from the American Hospital Association (AHA) showing that 95% of rural hospitals provide

---

<sup>9</sup> See e.g., van Dis, J., "Where We Live: Health Care in Rural vs Urban America," *Medical Student JAMA*, vol. 287, pp 108-113 (Jan. 2002); Nattinger, A.B., Kneusel, R.T., et al., "Brief Communication: Relationship of Distance from a Radiotherapy Facility and Initial Breast Cancer Treatment," *J. Nat'l Cancer Inst.*, vol. 93, pp 1344-1346 (Sept. 5, 2001)/

<sup>10</sup> Punglia, R.S., Weeks, J.C., et al., "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, pp 56-63 (2006).

<sup>11</sup> Overgaard, M., Hansen, P.S., Overgaard, J., et al., "Postoperative Radiotherapy in High-Risk Premenopausal Women with Breast Cancer who Receive Adjuvant Chemotherapy," *N. Engl. J. Med.*, vol. 337, pp 949-955 (1997); Overgaard, M., Jensen, M.B., Overgaard, J., et al., "Postoperative Radiotherapy in High-Risk Postmenopausal Breast-Cancer Patients Given Adjuvant Tamoxifen," *Lancet*, vol. 353, pp 1641-1648 (1999); Ragaz, J., Jackson, S.M., Le, N., et al., "Adjuvant Radiotherapy and Chemotherapy in Node-Positive Premenopausal Women with Breast Cancer," *N. Engl. J. Med.*, vol 337, pp 956-962 (1997).

computed tomography (CT) services in their community.<sup>12</sup> We note that CMS neglected to mention that the same AHA survey showed that only 79% of rural hospitals provide magnetic resonance imaging (MRI) services, illustrating that, even in the context of advanced diagnostic imaging, the closure of freestanding cancer and radiology centers could lead to access problems in certain areas.

Aside from increased travel costs and time, the proposed cuts in Medicare reimbursement for radiation oncology could affect patient access to quality care in other significant ways. The ASTRO survey suggests that many practices would respond to the proposed cuts by reducing both physician and non-physician staff at their cancer centers, cutting staff salaries and benefits (including health insurance), or both. They also likely would ratchet back the proportion of Medicare patients in their censuses. If case-mix adjusted cuts are at the 20% level:

- 40% of centers would lay-off physicians
- 78% of centers would lay-off non-physician staff
- 75% of centers would reduce salaries and/or benefits
- 30% of centers would stop accepting Medicare patients
- 55% of centers would limit their Medicare patient load

Assuming case-mix adjusted cuts were to reach 30%:

- 62% of centers would lay-off physicians
- 90% of centers would lay-off non-physician staff
- 90% of centers would reduce salaries and/or benefits
- 54% of centers would stop accepting Medicare patients
- 68 of centers would limit their Medicare patient load

If CMS finalizes the proposed rule without change, we fear that critical supportive services such as nutritional counseling and patient navigator services would become luxuries that many freestanding cancer centers would no longer be able to afford. Moreover, we suspect that strapped radiation oncology practices likely would cut back on charity care and reduce the proportion of Medicaid patients in their censuses as well. We are particularly troubled by the ASTRO finding that many practices foresee delaying scheduled equipment upgrades if the proposed Medicare reimbursement cuts go through because we know that newer radiation therapy equipment holds the potential for improved tumor targeting with reduced damage to surrounding healthy tissue. If nothing else, this improvement reduces long-term health issues stemming from radiation treatment in cancer survivors.

#### Impact of Proposed PE Changes on Medical Oncology

The overall payment reduction of 6% for medical oncology<sup>13</sup> pales in comparison with the 19% drop projected for radiation therapy. That said, the negative impact projected for medical oncology is limited to this level – a level that is not inconsequential – because of

---

<sup>12</sup> 74 *Fed. Reg.* at 33532.

<sup>13</sup> 74 *Fed. Reg.* at 33661.

the increase in payments for evaluation and management services that all physicians, including medical oncologists, will experience under the new PE methodology CMS contemplates employing in 2010.

A more detailed review of the proposed rule's effects on specific services critical to the provision of chemotherapy to patients reveals that, disregarding the SGR cuts, drug administration reimbursement rates will fall precipitously again in 2010. Medicare payments for CPT 96413 (Chemo, iv infusion, 1 hr) and CPT 96415 (chemo, iv infusion, adl hr) – the two most significant chemotherapy administration codes – will each drop more than 18%. Such decreases in payments for drug administration services are contrary to the promise of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).<sup>14</sup>

Prior to the MMA, oncologists used profits from Medicare drug payments to cover losses from inadequate payments for chemotherapy administration. MMA §303 mandated *simultaneous implementation* of the ASP methodology and revisions to the physician fee schedule methodology specific to the drug administration codes billed by medical oncologists with the intent of matching reimbursement for both drugs and drug administration to the actual costs incurred for each service component by physicians who furnish chemotherapy in their offices. NPAF was actively involved in the debate over MMA because we wanted to ensure the payment changes being contemplated would not adversely impact patients. We are quite familiar with the colloquies in both the House<sup>15</sup> and the Senate<sup>16</sup> during the MMA debate speaking to Congress' intent to establish a reimbursement system for Part B drugs and drug administration services that would provide payments to oncology practices at levels sufficient to support continued access to high-quality community-based chemotherapy services throughout the United States, in urban, suburban and rural areas and in communities both large and small.

We are growing increasingly troubled by the fact that CMS' revisions to the PFS PE methodology over the years since the initial implementation of the MMA have not been true to Congressional intent. Rather, they have consistently reduced drug administration payment rates to the point where we understand from oncologists active on the PAF Scientific Advisory Board and on the Board of NPAF that reimbursement does not come close to covering physicians' costs. The proposed changes for 2010 will make an already bad situation worse. As we understand it, for most medical oncology practices today, the negative margins on Medicare chemotherapy services are subsidized by slightly positive margins for non-Medicare patients. We fear that implementation of the proposed changes to the PE methodology in 2010, coupled with the growing bad debt problem that all health care providers are experiencing because of the downturn in the economy and the accompanying job losses, would make it financially impossible for many practices to continue underwriting the losses they incur whenever they administer chemotherapy to a Medicare beneficiary. Such an outcome could deprive many Medicare beneficiaries of the option of receiving community-based cancer care and push them instead to less patient friendly, and often more expensive, hospital outpatient departments for the chemotherapy

---

<sup>14</sup> Pub. L. 108-173.

<sup>15</sup> 144 Cong. Rec. H-12265-6 (Nov. 21, 2003).

<sup>16</sup> 144 Cong. Rec. S15887 (Nov. 25, 2003).

services they need. We are mindful that MedPAC recently reported that beneficiary cost-sharing under the HOOPS is generally higher than for other sectors, about 27% in 2007, versus the standard 20% in the office setting.<sup>17</sup>

Impact of Proposed PE Changes on Oncology Practices Offering Therapeutic Imaging Services

NPAF's mission is to give voice to patients who have two primary concerns which often are at odds with each other in the real world. Cancer patients all want convenient access to high-quality care that will offer them the best chance of beating their disease. At the same time, they want their care to be affordable.

As a result, NPAF fights for more liberal coverage decisions when we think a technology or therapeutic option holds promise. NPAF wants to commend CMS for the series of recent National Coverage Decisions recognizing the importance of Position Emission Tomography (PET) (FDG) in staging and treatment planning for a significant number of different cancer types. Providing coverage for these imaging services will undoubtedly improve the prognosis of many Medicare beneficiaries fighting a battle with this potentially life-threatening disease. The case managers at PAF also spend a significant amount of time working with commercial carriers to obtain prior authorizations or appeal coverage denials for imaging services needed by cancer patients.

At the same time, NPAF supports efforts to ratchet back costs whenever we think those efforts will not adversely affect patient care. We know from the experiences of PAF that many patients, including those insured by Medicare, have difficulty meeting their cost-sharing obligations. We will, however, argue against reimbursement cuts when data suggest the cuts are unsustainable and will have the effect of reducing access or quality. We would prefer to control the costs associated with diagnostic imaging by paying properly for the right amount and the right kind of services. We support the American College of Radiology's (ACR) efforts to develop appropriateness criteria for diagnostic imaging and we would not object to the enactment of a statutory requirement tying reimbursement to compliance with well-designed and well-vetted appropriateness standards. We also agree with the Medicare Improvement for Patients and Provider Act of 2008<sup>18</sup> requirement that calls for all providers of advanced diagnostic imaging services to be accredited by January 2012 to receive payments for the TC of CT, PET, MRI, and nuclear medicine. These steps are consistent with ensuring that patients receive quality care. They mesh with the movement towards value-based purchasing and they work with the evolving concept of Accountable Care Organizations, which we hope will be used to further the delivery of integrated cancer care to Medicare beneficiaries.

Radiology is facing an 11% cut in reimbursement under the 2010 PFS. This cut will also impact payments to medial and radiation oncology practices providing imaging services to their patients. NPAF is concerned about the magnitude of this proposed reduction in the face of the significant roll backs in payments for imaging services under the PFS that have already been implemented. We believe the aggressive push to reduce imaging payments

---

<sup>17</sup> MedPAC, "A Data Book: Healthcare Spending and the Medicare Program," p106 (June 2009).

<sup>18</sup> Pub. L. 110-275.

to control perceived over-utilization of diagnostic imaging may have gone too far. When imaging is used by oncologists taking care of cancer patients, NPAF would characterize the imaging services as therapeutic or prognosticative, not diagnostic and we do not believe the degree of over-utilization concerns that attaches to truly diagnostic imaging is merited in this context. CT scans and PET or PET/CT scans are frequently used to stage cancers and they play an integral role in the planning and management of cancer therapy. We must be careful not to adopt reimbursement policies – particularly not payment rates that are based on flawed data – if those rates have the potential to lead to such inadequate reimbursement for services as to jeopardize the quality of cancer care.

#### Issues Surrounding the Proposed Change in the Utilization Rate Assumption

A limited 2006 Medicare Payment Advisory Committee (MedPAC) study that looked at CT and MRI services in six urban areas and MedPAC's subsequent recommendations, based largely on the findings from this study, in its March 2009 Report to Congress<sup>19</sup> from the stated basis for CMS' planned increase in the equipment utilization rate assumption. The study found that CT providers used their scanners a mean of 42 and a median of 40 hours per week and that MRI providers' utilization was even more intense, at a mean of 52 and a median of 46 hours per week. These findings contrast with the utilization rate assumption for PE purposes of 25 hours per 50 hour week that CMS has used consistently since the implementation of the PE methodology.

MedPAC itself acknowledged that the results of its study “are not nationally representative.”<sup>20</sup> Even so, because the Commission is disturbed by the proliferation of costly imaging machines and what it views as an associated and, in some cases, unwarranted, increase in overall imaging volume, it recommended that Medicare set a normative standard for *costly imaging equipment* based on the level of use that Medicare wants to encourage. MedPAC suggested that a standard of 45 hours per 50 hour week (*i.e.*, a utilization rate of 90%) would be appropriate. It also indicated that it viewed imaging equipment costing \$1 million or more as “costly.”

The MedPAC study does not mention radiation therapy. Neither do the Commission's recommendations on utilization rate in the March 2009 Report to Congress. Rather, MedPAC is consistently focused only on advanced imaging. We note too that a search of the PFS proposed and final rules published since 2000 failed to reveal any request by CMS for utilization data for RT equipment. All such requests also were limited to advanced diagnostic imaging equipment. Despite the lack of supporting RT data, CMS has concluded that it would be appropriate to extrapolate from the MedPAC study and recommendations focused exclusively on diagnostic imaging to RT and other services involving non-imaging expensive equipment. CMS acknowledges it is doing so based on what it describes as its long-held suspicion that physicians and suppliers would not make huge capital investments in equipment that would only be utilized 50% of the time.<sup>21</sup>

---

<sup>19</sup> MedPAC March 2009 Report to Congress, Section 2B, “Physician Services and Ambulatory Surgical Centers,” pp 105-110 (March 17, 2009).

<sup>20</sup> *Id.* at p 108.

<sup>21</sup> 74 *Fed. Reg.* at 33532.

NPAF has not been able to identify any statutory provision that would give CMS the authority to set an aspirational utilization rate for RT equipment in the absence of empirical data to support its “suspicion” that providers do not buy expensive equipment and only use it only half of the time. In fact, the Balanced Budget Act of 1997 (BBA)<sup>22</sup> § 4505(d) requires CMS to use “actual data on equipment utilization” to the “maximum extent practicable.” It also directs CMS to consult with physician organizations about the PE methodology and about the data it intends to use to implement that methodology. NPAF thinks the proposed rule fails on both counts in the context of RT and, to a somewhat lesser degree, in the context of imaging.

Radiation therapy is *not* diagnostic imaging. The incentives for over-utilization of a therapeutic modality are not the same as those that concern CMS and MedPAC in the context of diagnostic imaging. Moreover, RT typically involves 20-40 treatments over a period of weeks whereas diagnostic imaging requires only one visit. As we understand it, cancer centers often need to buy a second RT machine before utilization of the first has reached capacity. Reasons for such a purchase include but are not necessarily limited to accommodating the need to initiate therapy rapidly for patients with certain types of cancer even in the face of temporarily high patient loads, avoiding treatment disruptions when machine maintenance is required or case loads periodically surge, and minimizing appointment delays and controlling patient total “treatment” times (travel + wait time + therapy). The application of a 90% utilization rate assumption to RT also ignores that some RT equipment (*e.g.*, CyberKnife, Gamma Knife) is designed only for the treatment of certain rare but hard to treat cancers and is not suitable for use more generally. One would expect such specialized equipment to be used only sporadically as the need arises and certainly not 50% of the time. Moreover, any methodology developed to measure the utilization rate for RT equipment needs to take into account the reality that patient set-up and positioning for RT typically require far more time than is the case for diagnostic imaging.

After the 2010 PFS proposed rule was published, ASTRO retained dmrkynetec – a well-respected research organization also used by the AMA to conduct the PPI survey – to create a database detailing the 2008 equipment utilization rates at freestanding cancer centers offering the six most common modalities of RT services (3D conformal, IMRT, IGRT, SRT, brachytherapy, and hyperthermia).<sup>23</sup> Questionnaires were completed by freestanding centers in 29 states, covering all major geographic areas of the country. Responses were received from 102 facilities including both community and hospital-based centers. Respondents were located in urban (34%), suburban (51%) and rural (15%) areas. Facilities surveyed varied in size, with 17% serving fewer than 50 patients per week, 52% treating 51-199 patients a week, and 31% with case volumes of 200 or more a week.

This new ASTRO survey is consistent with the discussion above about the utilization rate implications of the differences between radiation therapy and diagnostic imaging. When dmrkynetec collapsed the equipment utilization reported across the number of

---

<sup>22</sup> Pub. L. 105-33 (codified at Social Security Act § 1848(c)(2)(C)(ii).

<sup>23</sup> Dmrkynetec, “Equipment Utilization Study Report,” (August 2009), available at <http://www.astro.org/medicarecuts/documents/EURfinal.pdf>.

machines and across the six treatment modalities and prorated the data to a standard 10 hour day, it found that RT equipment utilization rates vary from a low of 18% to a high of 63%, with most being below or well-below 50%. The findings are summarized in the table below:

<u>Machine Type</u>	<u>Equipment Usage</u>
SRS System, Linac	42.0%
SRS System, SBRT, Six Systems Avg.	33.0%
Gamma Knife	18.0%
Accelerator, 6-18 MV	51.0%
Accelerator, 4-6 MV	63.0%
Room, CT	43.0%
IMRT, CT-Based Simulator	35.0%

Unlike the MedPAC study, which provides only limited data about CT and MRI utilization, the ASTRO study presents current, empirical data about RT equipment utilization. Furthermore, the BBA requires CMS use “actual data on equipment utilization” to the “maximum extent practicable” when it builds the PE RVUs. Given this statutory directive, NPAF would argue that CMS legally cannot justify, in the face of the independent ASTRO study and the dearth of imaging data from representative studies, the adoption of a 90% utilization rate assumption based purely on the agency’s suppositions about the business rationale underlying physicians’ investments in RT and other expensive equipment, including imaging equipment. NPAF, therefore, would like to add its voice and the voice of the patients for whom it speaks – patients who have a critical, sometimes, life-sustaining need for access to adequate RT and “therapeutic” imaging services – to that of ASTRO and strongly encouraging CMS to maintain the current utilization rate assumption of 50% for expensive equipment in 2010.

#### Issues Surrounding the Proposed Adoption of the AMA PPI Survey

CMS’ planned adoption of the recently completed AMA PPI survey underlies approximately 12% of the projected reduction in overall reimbursement to radiation oncology, essentially all of the projected reduction in payments to medical oncologists for drug administration services and much of the cut back for diagnostic imaging services. NPAF appreciates CMS’ and Congress’ desire to improve reimbursement for primary care services. We also recognize that, given the statutory requirement imposing budget neutrality constraints on the construction of the PFS, that doing so will, of necessity, result in a redistribution of payments away from specialties. That said, if Medicare patients in need of specialty services are to get the quality of care they need and deserve, it is essential that any redistribution of payments be fair, based on sound defensible data, and allow adequate payments to specialists, such as oncologists, who treat diseases common among the elderly and not amendable to management by primary care physicians. The AMA PPI survey does not appear to us to be up to the task.

The supplemental surveys from the specialty societies accepted by CMS pursuant to BBRA for use in building PE RUVs were required to meet pre-established precision levels to ensure their validity. This requirement was reflective of the BBRA directive to

use supplemental data “consistent with sound data practices.” Supplemental data applicable to payments for medical and radiation oncology services and for the imaging services they frequently provide was collected in adherence with CMS’ strict precision requirements. The American Society of Clinical Oncology (ASCO) survey used to set medical oncology PE/hour had to qualify under a precision standard of + or –10% or less<sup>24</sup> and the ASTRO/Association of Freestanding Radiation Oncology Centers (AFROC) combined survey and the American College of Radiology (ACR) survey were collected under a regulation requiring a precision of + or –15% or less.<sup>25</sup>

Without offering a statistically meaningful explanation, CMS has concluded that “[b]ecause the PPIS is a contemporaneous, consistently collected, and comprehensive multispecialty survey, we do not believe similar precision requirements are necessary and are not proposing to establish them for the use of the PPIS data.”<sup>26</sup> The explanation for not requiring precision standards in the Lewin survey is similar, saying the “goal of using consistently collected and the most recent information available for as many specialties as possible outweighs the use of precision criteria that would not allow use to [sic] all of the PPIS data.”<sup>27</sup>

NPAF finds CMS’ reject of a precision requirement troubling, particularly given the central role that the new survey data will play in the determination of indirect PE and the allocation of PE between direct and indirect costs for each specialty. NPAF is sympathetic to the equity argument for using financial data collected during the same time period for all of the specialties when PE RVUs are determined. We do not, however, view that consideration as sufficient justification for using data that is too variable to be consistent with the “sound data practices” that Congress recognized as being essential to the PE methodology when it permitted the collection of supplemental survey data to support the original conversion to a RVU-based approach to the determination of PE.

The reported precision of the PE/hour calculated for medical oncology in the PPI survey is 14%<sup>28</sup> compared with a precision standard of 10% or less for the ASCO survey. The situation is even worse in the context of radiation oncology and radiology, where the reported precision of the PE/hour calculated from the PPI survey data is 21% and 22%, respectively.<sup>29</sup> The use of less precise survey data is all the more troubling from our perspective because the new survey underlines reimbursement cuts for drug administration services, radiation oncology and critical imaging services that likely are deep enough to jeopardize patient access to care. We favor instead the continued use of the more precise supplemental survey data collected from much larger groups of specialists by ASCO, ASTRO, AFROC, ACR and others.

---

<sup>24</sup> 65 *Fed. Reg.* 25668 (May 3, 2000).

<sup>25</sup> 67 *Fed. Reg.* 43558 (June 28, 2002).

<sup>26</sup> 74 *Fed. Reg.* at 33531.

<sup>27</sup> The Lewin Group, “Physician Practice information Survey (PPIS) Data submitted for 2010 Non-MD/DO and Health Professionals Practice Information, p 5 (June 18, 2009), available at <http://www.cms.hhs.gov/PhysicianFeeSched/PFSFRN/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=4&sortOrder=descending&itemID=CMS1223902&intNumPerPage=10>.

<sup>28</sup> AMA PPIS Wkst #3, available at

<http://www.cms.hhs.gov/PhysicianFeeSched/PFSFRN/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=4&sortOrder=descending&itemID=CMS1223902&intNumPerPage=10>.

<sup>29</sup> *Id.*

NPAF is concerned about whether the PPI survey is representative for other reasons as well. In the name of consistency, the survey asked the same questions of physicians in all specialties. To us, such an approach seems fundamentally biased toward primary care. We simply do not see how a survey can capture all the relevant expenses incurred by some specialties without the inclusion of some specialty-specific questions.

We also question whether enough individuals in each specialty were surveyed to produce statistically defensible data. On the medical oncology side, the PPI survey represents data drawn from only 50 useable *individual* physician surveys against a target set forth in the survey design of 100. The ASCO survey included data from 245 medical oncology *practices*. More radiologists and radiation oncologists responded, but even here, there were only 56 and 71 useable surveys, respectively, against the same target of 100. We have been unable to find information about what proportion of the surveys used in the AMA and Lewin analyses were actually submitted by physicians or non-physician professionals in private practice as opposed to hospital-based practitioners or academics. Therefore, we are left to wonder whether private-practice professionals are adequately represented in the limited PPI survey pools for medical oncology, radiation oncology, and radiology even though it is these private-practice professionals who are reimbursed under the PFS.

In NPAF's view, CMS does not have the statutory authority to adopt the AMA PPI survey when it comes to developing PE RVUs for the drug administration codes relevant to medical oncology. Social Security Act § 1848(c)(2)(H)(i), which was added by the MMA, stipulates that CMS "*shall, in determining practice expense relative value units [for those drug administration services typically billed by medical oncologists] utilize a survey submitted to the Secretary as of January 1, 2003, by a physician specialty organization pursuant to section 212 of [BBRA] if the survey . . . covers practice expenses for oncology drug administration services; and . . . meets criteria established by the Secretary for acceptance of such surveys (emphasis added).*" The ASCO supplemental survey qualifies under this statutory directive. The AMA PPI survey does not. It was submitted too late, it does not meet the BBRA precision requirement, it was not developed by a specialty society and it did not include specific questions directed toward the cost of drug administration services.

NPAF also must question CMS' statutory authority to implement the PPI survey for any other purpose in 2010 because it has not satisfied the requirement to consult with MedPAC first. Social Security Act § 1848(c)(2)(B) directs CMS to make adjustments to PE RVUs, not less often than every 5 years, to take into account, among other things, new data on relative value components. The same statutory provision also stipulates that CMS must consult first with MedPAC and organizations representing physicians when it makes such changes. We know that numerous specialty societies, including ASCO, ASTRO, and ACR encouraged their members to participate in the AMA survey. We appreciate that the AMA itself endorses the findings of its work. We suspect that CMS would argue specialty society involvement is sufficient to satisfy the second prong of the consultation requirement in the statute even though a number of the same specialty societies are challenging the reliability and appropriateness of the PPI survey results. We have, however, found no evidence showing that MedPAC has weighed in on the reliability or

appropriateness of the PPI survey or the reasonableness of adopting it for payment purposes. We view MedPAC's silence to date as leaving the first prong of the statutory consultation requirement unsatisfied.

NPAF encourages CMS to reject the PPI survey. Because it is statistically inadequate, the PPI survey should not be used to determine PE RVUs until the AMA takes steps to increase the survey's statistical power and precision. Alternatively, CMS could again solicit supplemental survey data based on equivalent 2006 financial information from the specialties that appear to be underrepresented in the PPI survey or, for that matter, from all specialties to make the survey in its entirety more robust. CMS also must obtain permission from Congress in the form of a statutory amendment to replace the ASCO supplemental survey data before it resorts to other data sources for the determination of payment amounts for chemotherapy drug administration services. Finally, CMS needs to consult with MedPAC about the *bona fides* of the AMA survey or any other data source(s) it proposed to use in a revamped PE methodology.

CMS, not the AMA, holds the statutory authority to select defensible data sources for developing the PE RVUs used to build the annual PFS. Given the PPI surveys shortcomings, CMS does not have an obligation to use the flawed PPI survey just because the AMA undertook the initiative to collect the information. Rather, CMS has a responsibility exercise independent judgment and to reject the AMA PPI survey until more data can be collected to improve the survey's accuracy, completeness and precision. NPAF strongly urges it to exercise that responsibility.

Given the magnitude of some of the payment shifts resulting from the PE methodology changes, NPAF was surprised the PFS proposed rule did not include a transition period. Adopting a new data source for the determination of PE RVUs represents a significant methodological shift with the potential to cause a major redistribution of payments among specialties. Both Congress and CMS have recognized the need for a transition period when such changes occur. Congress provided for a four-year transition period for those services that would otherwise have experienced payment changes of more than 15% when it first moved physician reimbursement from a charge-based system to a fee schedule in 1992.<sup>30</sup> At CMS' urging,<sup>31</sup> Congress also added, through BBRA, a four-year transition period to the statutory provisions mandating the use PE RVUs beginning in 1999.<sup>32</sup> Finally, when CMS implemented the bottom-up approach to the calculation of direct PE RVUs, it again provided for a transition period, saying "the shifts in some of the PE RVUs resulting from the immediate implementation of our proposals could potentially cause some disruption for medical practices. Therefore, we are proposing to transition the

---

<sup>30</sup> Social Security Act § 1848(a)(2).

<sup>31</sup> See 62 *Fed. Reg.* 33157, 33172 (June 18, 1997) (In the proposed PFS rule for 2008, CMS states "The practice expense legislation requires the Secretary to develop and implement a resource-based system for practice expenses under the physician fee schedule, effective January 1, 1998. . . We are issuing this proposed rule to fulfill the statutory requirement. *However, we believe the magnitude of the redistributions are [sic] of such consequence that legislation should be enacted to provide for a transition period. This phased-in implementation schedule will allow us to refine the application of our methodology to ensure that the inequities this legislation was intended to address are eased. We will work with Congress to change the law so that resource-based practice expense payments would be phased in gradually* (emphasis added).

<sup>32</sup> Social Security Act § 1848(c)(2)(C).

proposed PE changes over a 4-year period.”<sup>33</sup> For the same reasons, NPAF recommends providing for a four-year phase-in period if or when CMS decides to update the survey data underlying the PE methodology.

### **Malpractice Expense Methodology**

CMS has proposed changes to the malpractice RVU methodology that involve using the premiums paid by medical physicists as a proxy for insurance costs to entities furnishing technical component (TC) services. This revision to the current malpractice expense methodology will add 1% to the unsustainable Medicare reimbursement cuts facing radiation oncology because of the proposed change in the equipment utilization rate assumption and the adoption of the AMA PPI survey. It has a similar impact on payments to medical oncology and radiology. NPAF would like to suggest that CMS consider looking to survey data the Radiology Business Management Association is collecting on malpractice premiums pay by freestanding cancer centers and diagnostic testing centers as a more appropriate measure of the true cost of non-physician liability premiums paid by freestanding facilities offering TC services.

### **Specific Coding Changes: HDR Brachytherapy**

HDR is a well-established form of radiation therapy that offers excellent outcomes for patients. Traditionally, HDR brachytherapy has been used to treat cancers of the cervix and endometrium, bronchus, esophagus, head and neck, and soft tissue sarcomas. More recently, the technology has been successfully applied to prostate and breast cancers. Patients report HDR brachytherapy is a convenient treatment alternative because it typically requires fewer treatments over a shorter time than other radiation therapy options. In our experience, this consideration is particularly important to patients living in more rural areas where travel times and distances to medical appointments can be an issue. HDR brachytherapy also is appropriate for use more patient-friendly community or hospital outpatient settings and it frequently costs less than other forms of radiation therapy. Just as importantly, HDR brachytherapy reportedly results in fewer negative side effects than other radiation treatment options.

We support CMS’ decision to request review by the American Medical Association’s (AMA) Relative Value Update Committee (RUC) of the PE direct cost inputs associated with HDR brachytherapy (CPT 77785-77787). We understand the RUC undervalued the RVUs assigned to the new HDR brachytherapy CPT codes that were adopted in 2009. CMS then incorporated the flawed PE RVUs into the 2009 Physician Fee Schedule Final Rule, resulting in payments for CPT 77785-77787 that reportedly severely understate the actual costs associated with the procedures. The PE RVU for the code describing the single catheter or channel procedure (CPT 77785) typically used to treat breast cancer dropped 72% from 2008 to 2009, going from 12.62 to 3.54. Similarly, the PE RVU for the 12 or more catheter or channel codes describing the procedure (CPT 77787) typically used to treat prostate cancer dropped 49%, going from 33.92 to 17.41. Absent appropriate adjustments by the RUC, HDR brachytherapy will face additional cuts in 2010 that will reduce the non-facility PE RVUs even further. CPT 77785 would face an additional 7%

---

<sup>33</sup> 71 *Fed. Reg.* 37170, 37252 (June 29, 2006).

reduction in its PE RVU to 3.29 and the cut to 14.57 for CPT 77787 would be more than twice that magnitude, at almost 16.5%. These cuts flow from CMS' proposed adoption of the new AMA Physician Practice Information Survey (PPIS) in the calculation of indirect practice expenses despite the survey's failure to adequately sample radiation oncologists and other smaller specialties. Consequently, it appears to us that the PPIS is weighted inappropriately in favor of the primary care specialties.

Because NPAF speaks on behalf of patients, we appreciate CMS' efforts to improve the RUC review process and to ensure that appropriate relative values are established for PFS services. When CPT codes are overvalued, beneficiaries face excessive cost-sharing obligations. We cannot support apparent mistakes in PE RVU assignments of the magnitude of those associated with the HDR brachytherapy codes because, in our experience, many physicians will stop offering beneficiaries access to services that are severely under-reimbursed.

To ensure continued beneficiary access to DHR brachytherapy, we encourage CMS to correct the errors that underlie the inappropriate PE RVUs assigned to CPT 77785-77787 for 2009 before it finalizes the CY 2010 Physician Fee Schedule. It is our understanding that the most egregious error involves coupling the annual cost of the Iridium-192 source with a 5-year useful life assumption, even though Iridium-192 typically must be replaced every 90 days. CMS could correct this error in one of two ways. It could couple the annual cost of Iridium-192 with the assumption of a one-year useful life when it re-sets the DHR brachytherapy PE RVUs. Alternatively, CMS could take the approach it already has adopted in hospital outpatient departments and ambulatory surgery centers and pay separately for Iridium-92 used in HDR brachytherapy procedures performed in freestanding clinics. This approach would put HDR brachytherapy on a par with low dose rate brachytherapy where the renewable sources are currently paid separately from the procedure under the Physician Fee Schedule based on invoice cost and using HCPCS code Q3001. CMS should also look carefully at the non-physician staff types and times used in the calculation of PE RVUs to ensure that it has accounted appropriately for medical physicist and medical dosimetrist staffing conventions and work requirements.

In addition to correcting the errors associated with the PE RVUs currently assigned to CPT 77785-77787, CMS should refrain from using the AMA PPIS in 2010 to allow sufficient time for the specialty societies to provide supplemental survey data or for the AMA itself to take steps to improve the survey's assessment of costs incurred by the specialty groups. Regardless of when CMS decides to change the base survey data it uses to build the Physician Fee Schedule, we are of the view that it should phase in the change over four years to mitigate the dramatic impact the change will inevitably have on many procedures, likely including HDR brachytherapy and other services provided primarily by radiation oncologists.

### **Consultation Codes**

CMS currently only reimburses consultation services if the consultation request is documented in the medical record of the requestor and the consultation findings and recommendations are documented in a written report prepared by the consulting physician and provided to the requesting physician. As we understand it, the AMA CPT coding

manual does not set forth the Medicare documentation requirements nor does it unambiguously distinguish between consultations and “transfers of care.” CMS contends that because of the tension between its policies and the AMA guidance, physicians have had difficulty adhering to Medicare standards for reimbursement of consultation services. It also argues that the historical rationale for higher payments for consultations no longer exists. The incremental changes over the years in CMS’ documentation requirements made to address the conflict with the AMA have lead to documentation requirements that, in CMS’ view are now substantially similar among consultation services, office visits and hospital and facility visits.

For these reasons, CMS is proposing to eliminate, in a budget neutral fashion, reimbursement for all outpatient (CPT 99241-99245) and inpatient (CPT 99251-99255) consultation codes in 2010. The work RVUs assigned to these codes would be redistributed to the evaluation and management (E/M) services for new and established office visits and initial hospital and nursing facility visits, respectively. If the proposal is finalized, the change would reduce reimbursement to physician specialists who provide consultation services, which historically have been paid at a higher rate than the E/M codes that would have to be used next year. CMS estimates the increase in payments for new and established office visits because of the redistribution of the consultation RVUs will be approximately 6% and the increase for initial hospital and facility visits about 2%.

NPAF recognizes that the overall impact of the proposed change will vary from physician to physician and practice to practice, depending on the mix of consultation and other E/M services currently being billed to Medicare. The difference could potentially be positive, as with a primary care physician who infrequently bills consultation codes, and would therefore experience a windfall when the work RVUs for office visits increase. Conversely, specialists who routinely collaborate with primary care providers or even other specialists stand to lose.

We believe that many oncologists will suffer a reimbursement cut as a result of the proposed elimination of the consultation codes because they frequently provide consults to physicians outside their own practice who are less expert in treating a particular cancer or to physicians within their own practice when a patient present with a tumor(s) that potentially could benefit from some combination of chemotherapy and radiation therapy. The Proposed Rule’s projection of a 6% overall reduction in reimbursement to the specialties of hematology and oncology indicates that the depth of the cuts to drug administration that will result from the implementation of the PPIS will not be offset by the increase in E/M payments even when those payments are enhanced by the redistribution of the PE RVUs currently assigned to the consult codes.

Before moving forward to finalize the proposed elimination of consultation codes, NPAF strongly encourages CMS to carefully weigh the input we expect it will receive from the specialty societies and the specialists they represent to assess the barriers to treatment plan development, care coordination and care quality that might arise because of the proposed elimination of consultation codes. Many cancer patients who, for various reasons, including cost, travel distances and shortages of specialists in their communities, must receive ongoing care from requesting physicians who need and willingly ask for guidance from more experienced or more highly trained consulting oncologists. We particularly

worry about the impact of the proposed elimination of consultation codes on patients residing in rural areas who may need to receive ongoing care from physicians who have had limited experience treating less common or more complex cancers. We also know that there is an impending workforce shortage in oncology which likely will necessitate more consultations if Medicare beneficiaries with cancer are to continue receiving the quality of care they need and deserve. A study commissioned by the American Society of Clinical Oncology<sup>34</sup> concludes an aging and growing population, increasing numbers of cancer survivors, and slower growth in the supply of oncologists will result in a shortage of 2,550 to 4,080 oncologists by 2020. At that time, the total supply of oncologists is projected to be roughly 12,500. If this projection is correct, the need for oncology consults will be more pressing than ever. In our view, now is not the time for CMS to create a reimbursement barrier to such consults.

NPAF disagrees with CMS' assertion that an OIG study<sup>35</sup> supports its concerns about confusion over consultation documentation requirements. The cited OIG study found that only 9% of the reviewed consult claims were inappropriate because of lack of adequate documentation. The majority of the questionable claims – 47% of those reviewed – related to the level of complexity at which the consult was coded. We suspect that the OIG would have documented similar concerns if it had reviewed outpatient or inpatient E/M codes for regular patient visits. The coding of all type of E/M visits is complex and it is not unusual for auditors to disagree about the appropriate level. The OIG found that another 19% of the services allowed as consultations did not meet the definition of a consult but observed that most of these miscoded claims were for services billed as follow-up inpatient consultations. This coding problem was resolved even before the OIG report was published when the AMA CPT panel eliminated the CPT codes for follow-up inpatient consults effective January 1, 2006. Further, in its reply to the OIG report, dated February 7, 2006, CMS indicates that the error rate for consultations in 2005, measured as part of CERT, was only half that found by the OIG's review of claims from 2001. CMS also noted that the majority of errors in 2005 were attributable to incorrect coding, not documentation deficiencies.

We also question CMS's conclusion that the extra documentation originally required to support consultation claims constitutes the only, or even the primary, difference in work between a consult and a regular patient visit. Specialists who consult with physicians with less training, experience and expertise to facilitate appropriate ongoing treatment of a patient by the requesting physician are often asked about complex cases that require significant cognitive work to develop and clearly lay out appropriate treatment plans for execution by another physician. In addition, they often must engage in more than the usual amount of pre-visit record review and study in preparation for the consult E/M encounter because they have not been involved over time in the patient's work up or care. CMS' relaxation of its documentation requirements does not impact this aspect of the work that a consulting physician agrees to undertake when he or she accepts a colleague's request for assistance. We hope CMS will factor this fact into its thinking about the appropriateness of collapsing consultation codes into standard E/M visits.

---

<sup>34</sup> ASCO Workforce Advisory Group, *Future Demand for Oncologists*, Journal of Clinical Oncology, p. 300 (Nov. 2008).

<sup>35</sup> HHS Office of Inspector General, *Consultations in Medicare: Coding and Reimbursement*, OEI-09-02-00030 (March 2006).

### **AMA RUC Review of Potentially Misvalued Services**

NPAF endorses the establishment of an expert panel separate from the AMA RUC to review RVUs in an effort to better ensure that appropriate RVUs are established for all procedures on the Physician Fee Schedule. The Agency notes that MedPAC first made this recommendation in 2006 and again in its March 2008 Report to Congress. The concern underlying the MedPAC recommendation and CMS' request for input seems to tie to the belief that the consensus-based RUC process does not adequately address codes that are overvalued. NPAF has this same concern. MedPAC envisions the expert panel being composed of "members who do not directly benefit from changes in Medicare's payment rates, such as experts in medical economics and technology diffusion and physicians who are employed by managed care organizations and academic medical centers."<sup>36</sup> NPAF agrees that the integration of such a panel into the RUC review process holds promise for allowing practitioners to be paid enough to ensure access without be paid too much at the expense of excessive beneficiary deductible and co-payment costs.

NPAF also would like to encourage CMS to support a more transparent RUC process – one that allows public scrutiny of and comment on the appropriateness of the PE inputs prior to CMS' inclusion of PE RVUs recommended by the RUC in the Physician Fee Schedule Final Rule. It would be an improvement if RUC meetings, like AMA CPT Editorial Panel meetings, APC Panel meetings, and HCPCS Code Workgroup meetings, were open to the public. Such openness might allow informed stakeholders to identify the types of errors and omissions that have inappropriately limited payments for – and possibly beneficiary access to – HDR brachytherapy for the last year. We also would favor adjusting the timing of RUC deliberations and reports to permit public review of the PE data inputs adopted by the Committee during the Proposed Rule phase of the annual Physician Fee Schedule rule-making cycle.

### **Physician Quality Reporting Initiative and Transition to Value-Based Purchasing**

NPAF has been an active proponent of the movement towards both electronic health records (EHRs) and personal health records. In fact, in my role as President of NPAF and PAF, I served as the Chair of the American Health Information Community (AHIC) Consumer Empowerment Workgroup.

NPAF believes that achieving comprehensive national uptake of health information technology (IT) is a monumental issue for the United States, in terms of improving patient safety, lowering patient and taxpayer costs, and making health care portable in our increasingly portable society. By incorporating advanced IT into our health care delivery system, we will be able to transform our current system into one that better meets patients' needs consistently through timely, affordable, transparent, interoperable processes that assure instant access to complete medical information — anytime, anywhere — that is transmitted seamlessly and securely from provider to provider. EHRs can facilitate e-prescribing, reduce medical errors, eliminate duplicative testing and

---

<sup>36</sup> MedPAC, March 2008 Report to Congress, p 97.

accelerate the information transfers that are needed to effectively diagnose, define therapeutic interventions, manage and coordinate care, and measure outcomes and provider performance. Consumers who must struggle with access to health care stand to benefit immensely from putting EHRs and other health IT technologies in place. The U.S. Department of Health and Human Services estimates that health spending could be reduced by as much as 30% annually with the adoption of health IT. A significant portion of the cost saving will flow to patients, including those covered by Medicare. So too with the value of improved safety and outcomes that will come as payers begin to utilize quality and outcomes data that can be extracted from EHRs to pay providers to performance, not just for the quantity of services – needed or not – delivered.

Because of NPAF's belief in the value of health IT and the use of EHRs, we are pleased CMS is again proposing to accept PQRI quality measure data extracted from qualified electronic health records (EHRs) in 2010. We regret the decision to limit EHR-based reporting initially to a narrow subset of the universe of approved quality measures. We recognize the EHR PQRI reporting proposal has been made contingent upon a finding, when the results of the 2009 EHR data submission testing process are analyzed, that such reporting is practical and feasible. Because we have little doubt the 2009 test will be a success, we strongly encourage CMS to move forward with EHR-based PQRI reporting proposal in 2010. Doing so will provide participating practices and CMS with experience sending and receiving quality data electronically – experience that should prove helpful as physicians and the Agency move forward with the broader implementation and adoption of EHRs expected to begin in 2011 in response to the health information technology (HIT) incentives and penalties included in the HITECH Act.

We applaud the inclusion of Measure Number 124 – Health Information Technology (HIT): Adoption/Use of Electronic Health Records in the handful of measures being considered for EHR-based reporting next year. To us, inclusion of this measure signals CMS' concurrence with our belief that the adoption of EHRs is critical to the implementation of a national health IT infrastructure and a successful transition to value-based purchasing. The complexity of quality and outcomes data that will be needed to make the value-based purchasing approach to payment for professional services viable is inconsistent with manual data extraction and with reporting protocols based solely on the limited amount of data that can be submitted on claims for payment. We also appreciate the value of including prevention and screening measures and, given our commitment to cancer care, are extremely pleased to see mammograms and colorectal cancer screening on the list.

NPAF also is supportive of CMS' plans to expand PQRI reporting through qualified registries in 2010. We endorse CMS' goal of approving a sufficient number of qualified PQRI registries by 2011 to permit the reduction or discontinuation of the claims-based reporting mechanism for most PQRI measures after next year. We recognize the registry approach to PQRI reporting offers several advantages. Registries can collect more detailed, sophisticated clinical data without the limitations of a single data submission that must be made at the time claims are filed. Equally important, registries can be populated with data received from EHRs. They also permit feedback of quality improvement and resource utilization data that will be essential to achieving patient care improvements, efficiencies, and program savings.

NPAF is excited about the promise the incentives built into the HITECH Act hold for speeding the adoption of EHRs and health IT generally. That said, as advocates for individuals fighting cancer, we urge CMS to work with the HIT Policy Committee and the Office of the National Coordinator for Health Information Technology (ONCHIT) to ensure that the definition and phased in measurements of “meaningful use” and the certification criteria that will be an integral part of the “meaningful use” that physicians and providers must achieve to qualify for financial assistance with EHR implementation are broad enough to encompass specialty-specific EHRs geared towards oncology, not just records designed for primary care.

In our view, it would be particularly shortsighted for ONCHIT and HHS to create unnecessary qualification hurdles for oncology-specific EHRs. Cancer is a disease of old age. It is becoming, because of improvements in treatments, a chronic disease that requires often expensive clinical interventions over many years. More than 11 million Americans now live with a previous cancer diagnosis and many face medical issues associated with the treatment(s) they received to save their lives. According to an article published in the *Journal of the National Cancer Institute*<sup>37</sup> in July 2009, data drawn from the 2003 Medicare Current Beneficiary Survey showed that 18.8% of the respondents had been diagnosed with a non-skin cancer. Moreover, the article concluded that Medicare beneficiaries with a diagnosis of a non-skin cancer had increased levels of disability and geriatric syndromes and were more likely to meet criteria for vulnerability and frailty – all conditions that add to the cost of cancer care, which is staggering. In the United States, cancer treatment expenditures alone are expected to exceed \$100 billion in 2010. Absenteeism, lost productivity and other costs will bring the total cost of cancer to almost \$300 billion next year alone.

Several organizations have put forth recommendations to the federal government for implementation of HIT certification. US Oncology believes the recommendations received to date from the Institute of Medicine, the National Research Council and others point to the need for a specialty-focused certification for oncology. While the overarching goals of both a general ambulatory and specialty certification can remain the same, we hope CMS and the advisory organizations support it will recognize that the criteria for implementation likely should be different.

While all EHRs should meet the goal of containing comprehensive information relevant to each patient’s condition, their treatment plan and outcomes, oncology requires specific terminology and data collection to support physicians in the selection, planning, and management of chemotherapy and radiation therapy for their patients, including those who have elected to enroll in clinical trials. Certification test cases for oncology EHRs therefore need to include oncology-specific elements.

All EHRs also should have the capability to integrate evidence-based practice guidelines and research results into information systems. EHRs used by oncologists must include

---

<sup>37</sup> Mohile, S.G. et al. *Association of a Cancer Diagnosis with Vulnerability and Frailty in Older Medicare Beneficiaries*, *Journal of the National Cancer Institute Advance Access* published online, July 28, 2009, available at <http://jnci.oxfordjournals.org/cgi/content/full/djp239v1>.

complex information to guide the treatment of cancer, not information needed to treat other ailments typically handled, even for cancer patients under active oncology care, by primary care physicians or other specialists. We do not want vendors of oncology-specific EHRs to have to adjust their software to comply with certification procedures designed for a general ambulatory system. Having to do so would slow the certification process but likely offer little, if any, value to oncologists or their patients.

NPAF is convinced it is essential to establish separate, stand-alone certification criteria for oncology EHRs. Simply put, some ambulatory criteria do not apply to oncology. Moreover, oncology EHRs must accommodate oncology-specific terminology and criteria if they are to be used effectively to: (1) assist with the disease management, care coordination and survivorship monitoring needs of individuals fighting cancer and (2) facilitate the workflow efficiency, safety and quality improvement, and outcome reporting objectives of the oncologists who care for cancer patients. Absent stand-alone oncology certification criteria, it is hard for us to imagine how an EHR could be designed to support adequately the types of pay-for-performance objectives that we hope will flow from health reform and the comprehensive uptake of health IT.

We encourage the HIT Policy Committee, ONCHIT and CMS to engage in an open dialogue with oncology professional organizations such as the American Society for Clinical Oncology and the American Society for Therapeutic Radiology and Oncology, with vendors of oncology-specific EHRs, and with patient groups such as NPAF to develop appropriate certification criteria for oncology in time for incorporation into the meaningful use regulations to be finalized by CMS to implement the HITECH Act provisions included in the American Recovery and Reinvestment Act of 2009.

### **Coverage of Kidney Disease Patient Education Services**

NPAF would like to commend CMS for acting expeditiously to implement Section 152(b) of the Medicare Improvements for Patients and Providers Act of 2008<sup>38</sup> (MIPPA) allowing Medicare coverage of patient education services for individuals suffering from chronic kidney disease (CKD). Even though the proportion of CKD patients served by PAF is small, the statistics developed annually to track the Foundation's activities and inform stakeholders and decision-makers about patient access concerns indicate that CKD is a fast growing disease category among individuals seeking assistance. Between 2004 and 2008, PAF experiences a 75% increase in calls from individuals with CKD. Given this, the need for this new service could not be clearer.

### **Compendia Transparency**

NPAF heartedly endorsed CMS' decision to create a process for vetting and adding new compendia to the list of authoritative sources used by the Agency and its contractors to determine whether an off-label use of a drug or biological in an anticancer chemotherapeutic regimen should qualify as a "medically-accepted indication" eligible for coverage under Medicare Part B. Based on the battles that PAF case managers wage on a daily basis for commercially insured patients facing prior authorization requirements, we

---

<sup>38</sup> Pub. L. 110-275.

can say with confidence that much of cancer care, including many chemotherapy regimes viewed as the standard-of-care, involves off-label uses of drug products. A regulatory structure that allows physicians to use compendia to determine with reasonable certainty whether a particular off-label use will be covered by Medicare is essential in oncology. We were extremely pleased that CMS added four new compendia last year to the list of references available to its contractors. Absent compendia input, we expect many physicians would be unwilling to take on the financial risk that would come from buying and administering a very expensive medication to a Medicare patient in need of an off-label therapy.

NPAF also endorses the proposed revisions to the regulations at 42 C.F.R. § 414.930 defining a compendium and setting forth the vetting process used to identify those compendia to be listed pursuant to Social Security Act § 1861(t)(2). The addition of requirements for public transparency with respect to both the process for evaluating therapies and the identification of conflicts of interest that potentially color reviewers' assessments is an extremely helpful and necessary revision to the current process. The new information that will be available when the change is finalized will, in our view, prove key to effective compendium use in a world of value-based purchasing.

The proposed disclosures of compensation and ownership relationships between compendia reviewers, their immediate family members and the applicants supporting addition of a particular drug/indication pair to a compendium should allow pharmaceutical and therapeutics committees to better assess available clinical evidence in the context of potential financial conflicts. Such disclosures also are consistent with the aims of evolving federal legislation requiring "sunshine" on the myriad relationships that exist today between pharmaceutical manufacturers and physicians – legislation which NPAF supports. The proposed disclosures also might serve to dispel, at least in part, some of the growing concerns among patients, the general public, the Congress, and the enforcement community about the nature and appropriateness of relationships between industry and medicine, some of which are crucial to innovation and high-quality patient care.

### **Fee Schedule Update**

CMS is projecting an across-the-board 21.5% reduction in reimbursement under the 2010 Physician Fee Schedule. Such a deep cut would be unsustainable by the physician community and would put Medicare beneficiaries at significant risk of losing their access to primary care providers and specialists alike. Since 2004, Congress has repeatedly had to step in to address negative Fee Schedule update projections, even when the expected reductions were less than a quarter of this year's size. Given this history, NPAF does not expect Congress to permit such a steep across-the-board physician payment cut to go into effect in 2010 in the face of demonstrably increasing costs. Although we recognize Congress may choose to provide for another temporary "fix" for budgetary reasons, we urge CMS to support legislation in the context of broader healthcare reform that will, once and for all, either appropriately revise the flawed Sustainable Growth Rate (SGR) formula or eliminate the SGR cap altogether. Reimbursement methodologies applicable to other provider and supplier types typically do not include a cost cap provision. Rather, they permit annual market-basket updates in recognition of the fact that inflationary pressures cause the cost of providing patient care services to increase over time. Physicians operate

in the same economic environment. They too deserve to receive reasonable annual updates in their Medicare reimbursement rates. Failure to provide for such adjustments has the potential to disrupt physician-patient relationships and, ultimately, to cause the Medicare program to collapse on itself.

We applaud CMS' decision to remove, beginning in 2010, physician-administered drugs from the SGR formula retroactive to the Fee Schedule base year. The proposed change will reduce the Congressional Budget Office's projected cost to the government of a temporary fix or a permanent resolution to the SGR problem. We are appreciative of the budgetary assistance that CMS has provided to the 111<sup>th</sup> Congress and hopeful that health reform will improve the lives of all patients PAF and NPAF serve.

\* \* \* \* \*

NPAF appreciates the demanding requirements that burden CMS today. However, we must share that in 2008, 44% of Medicare beneficiaries served through PAF were disabled patients under the age of 65. Additionally, when we looked across our Medicare population in 2008, the largest percentage of Medicare beneficiaries at PAF had an average household income of \$23,000 a year. We would urge that each decision being made relative to the Physician Fee Schedule take into account the average household income of Medicare beneficiaries. We submit our comments and suggestions with a willingness to lend our support to you and your agency in any way moving forward.

Thank you for the opportunity to submit comments on CMS-1406-P. If we can be of assistance, please do not hesitate to contact me.

Sincerely,



Nancy Davenport-Ennis  
President and Chief Executive Officer

**EXHIBIT 1**