



American Association of Physicists in Medicine

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August 25, 2009

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

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

Dear Ms. Frizzera:

The American Association of Physicists in Medicine¹ (AAPM) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the 2010 Medicare Physician Fee Schedule (MPFS) proposed rule published in the July 13, 2009 *Federal Register*.

AAPM will provide comments on the 2010 practice expense proposals and high dose rate (HDR) brachytherapy, technical component malpractice relative value units (RVUs), accreditation standards for suppliers furnishing the technical component (TC) of advanced diagnostic imaging, and 2010 physician fee schedule update.

The total impact of the 2010 practice expense proposals to radiation oncology is -17%. CPT 77336 *Continuing medical physics consultation* has significant practice expense RVU reductions under the current "bottom-up" practice expense methodology and the 2010 proposals further reduce reimbursement by 43% from 2009 payment. CPT 77336 is one of only two codes directly attributable to medical physicists and is the major procedure code in terms of reimbursement for medical physicist services. Other innovative technologies like IMRT and stereotactic radiosurgery will realize cuts in excess of 40% for 2010. Cuts of this magnitude would harm cancer care, limit access to HDR brachytherapy, IMRT and stereotactic radiosurgery procedures to Medicare beneficiaries especially in rural areas, and may lead to the elimination of freestanding and community-based cancer centers.

¹ The American Association of Physicists in Medicine's (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,700 medical physicists.

Resource-Based Practice Expense RVUs

A. Equipment Utilization Rate

For 2010, CMS proposes to change the equipment usage assumption from the current 50% usage rate to a 90% usage rate for equipment priced over \$1 million. This proposal stems from concerns raised by the Medicare Payment Advisory Commission (MedPAC) and others regarding the volume growth of diagnostic imaging services over the past several years.

In the proposed rule, CMS cites the MedPAC March 2009 Report to Congress, which details a 2006 survey of imaging providers in six (6) markets. The survey found that computed tomography (CT) and magnetic resonance imaging (MRI) machines were used much more than the 25 hours per week assumed by CMS under the current 50% utilization rate. In its Report to Congress, MedPAC also analyzed data from a 2007 survey of CT providers by IMV, a market research firm, which calculated the average provider use of a CT scanner at more than 50 hours per week, which is twice the number CMS assumes.

CMS states, " we believe that studies cited by MedPAC strongly suggest that our current usage rate assumption is significantly understated, especially with respect to the types of high cost equipment that were the subject of the studies."

It is not clear how or why CMS used the limited research data for CT and MRI equipment and extrapolated their 2010 proposal to all medical equipment priced over \$1 million, including linear accelerators, stereotactic radiosurgery systems, stereotactic body radiation therapy equipment and the Gammaknife units used in therapeutic radiation to treat cancer.

Radiation therapy is not diagnostic imaging. The therapeutic use of radiation to treat cancer should not be the focus of those concerned with volume growth in advanced diagnostic imaging. The CMS proposal regarding equipment utilization accounts for a 5% reduction to radiation oncology and is contributing to payment reductions of more than 40% for several specialized cancer treatments.

AAPM strongly objects to the extrapolation of the equipment utilization proposal to radiation therapy. CMS should not apply the 90% utilization rate to medical equipment priced over \$1 million and used for therapeutic radiation oncology (CPT codes 77261-77799).

B. AMA Physician Practice Information Survey

For 2010, CMS proposes to use new practice expense per hour (PE/HR) values from the AMA Physician Practice Information Survey (PPIS) for all Medicare recognized specialties that participated in the PPIS for payments effective January 1, 2010.

CMS estimates that this proposal will negatively impact radiation oncology by 12%, with payments for cancer treatments reduced by up to 53% (i.e. 77401). Given the magnitude of the resulting payment changes, AAPM is disappointed that CMS did not propose to phase-in the changes over a period of years, especially since practice expense RVUs based on the new "bottom-up" methodology are still being phased-in through 2010.

Under this proposal, the PE/HR for radiation oncology increases slightly, demonstrating that the costs for radiation therapy have increased since the last supplemental survey was conducted. Due to the complicated practice expense methodology, the current proposal changes the proportion of direct and indirect practice expenses, which has a significant negative impact on

technical component codes that are capital intensive. While this proposal does not decrease professional component payments to radiation oncologists in 2010, it will have a deleterious effect on freestanding and community-based cancer centers.

The AAPM has concerns regarding the weighting of the freestanding center data and the current blend of hospital and freestanding PE/HR. In addition, we are apprehensive regarding CMS' willingness to accept the new AMA PPIS survey data without the precision requirement that applied to the supplemental survey data.

Therefore, AAPM recommends that CMS delay use of the AMA Physician Practice Information Survey (PPIS) data because it does not provide an accurate reflection of practice expenses incurred by radiation oncologists. If CMS implements the AMA PPIS data effective January 1st, we implore the Agency to transition the proposal over several years and blend the AMA PPIS data with the current radiation oncology supplemental survey data.

C. High Dose Rate Brachytherapy

In the 2009 MPFS final rule, CMS established three (3) new procedure codes for HDR brachytherapy, CPT 77785, 77786 and 77787, effective January 1, 2009 with interim RVUs of 5.16, 15.47 and 22.99 respectively. The HDR brachytherapy interim RVUs yield payment decreases of 46% to 67% in 2009.

In the 2010 MPFS proposed rule, CMS states that they received comments regarding the practice expense direct cost inputs related to several high dose radiation therapy and placement CPT codes. Based on the CMS review of these codes and public comments received, CMS requested that the AMA RUC consider these CPT codes for additional review.

AAPM has serious concerns regarding the substantial reductions to the 2009 interim relative value units (RVUs) for new high dose rate (HDR) brachytherapy codes 77785, 77786 and 77787, which would be further reduced in 2010 due to pending CMS practice expense proposals. The extreme reductions in RVUs and 2009 payments have caused some freestanding cancer centers to abandon this cancer treatment entirely, redirect patients to more costly or invasive alternative treatments, or refer patients to the hospital setting for HDR brachytherapy treatment, which has already resulted in constricted access to this lifesaving cancer treatment for Medicare beneficiaries.

AAPM did not participate or have the opportunity to review the recommended nonphysician clinical staff types and times submitted to the AMA's RUC when the HDR brachytherapy codes were first valued. Medical physicists play a key role in the delivery of cancer care and are an important provider of healthcare to Medicare beneficiaries. We disagree with several of the clinical staff times and types in the current CMS database for CPT codes 77785, 77786 and 77787.

For example, the 2009 interim RVUs for 77785-77787 include a mix of a medical physicist and medical dosimetrist for intraservice time. Only a qualified medical physicist would provide these services for the typical patient receiving HDR brachytherapy treatment. The medical physicist actively participates for the entire duration of the treatment delivery process. The participation of the "authorized medical physicist" is required by the Nuclear Regulatory Commission (NRC) and Agreement State regulations and is clearly specified in professional practice recommendations.

In addition, the interim RVUs do not include any preservice time to prepare the HDR afterloading equipment for treatment as required by the NRC. Depending on the size and staffing of a center, either a medical dosimetrist or a medical physicist might provide this service.

In response to the 2009 MPFS final rule, AAPM submitted detailed comments and recommendations regarding the direct practice expense inputs used to determine the 2009 interim RVUs for HDR brachytherapy. We identified several errors and omissions regarding medical equipment and nonphysician clinical personnel. Upon further review and research, we have modified our recommendations.

AAPM recommends that CMS ensure that the revised HDR brachytherapy direct practice expense inputs include:

- **a correct useful life for the HDR Iridium-192 renewable brachytherapy source (ER060) by changing the useful life to one (1) year with an annual cost of \$45,326. Alternatively if CMS is not able to establish a useful life of one year, CMS should consider separate payment for the HDR Iridium-192 source under the Medicare Physician Fee Schedule utilizing HCPCS code Q3001;**
- **omitted medical equipment costs for HDR brachytherapy procedure codes 77785-77787, including but not limited to a 1) Well Chamber with Iridium-192 Calibration Capability, 2) Area Radiation Monitor, 3) HDR Afterloader Guide Tube Connector Set, 4) Pulse Oximeter (CPT 77786 and 77787 only), 5) Cardio-Respiratory Monitor (CPT 77786 and 77787 only), and 6) Prostate Brachytherapy Mattress (CPT 77787 only);**
- **new preservice time for each of the HDR brachytherapy codes (77785, 77786 and 77787) to prepare the HDR afterloading equipment for treatment; and**
- **corrected and revised intraservice nonphysician clinical staff types and times to reflect the Nuclear Regulatory Commission regulations.**

Representatives of the American Association of Physicists in Medicine have been invited to participate in the physician consensus panel for the revaluation of the HDR brachytherapy procedure codes and will be present at the October RUC meeting to present our recommendations. While we applaud your decision to have the AMA RUC reconsider the practice expense inputs, we do not think this effort will avert the significant reductions to the interim RVUs for the new HDR brachytherapy procedure codes, which will result in decreased patient access to this cost-effective cancer treatment.

Resource-Based Technical Component Malpractice RVUs

For 2010, CMS proposes to use the medical physicists' premium data as a proxy for the malpractice premiums paid by entities providing technical component (TC) services. CMS believes that the use of this data will better reflect the level of malpractice premiums paid by entities providing technical component services than the current charge-based malpractice RVUs or crosswalks to the malpractice premium data of physician specialties.

For the 2010 MPFS proposed rule, CMS's contractor (Acumen LLC) obtained medical physicist malpractice premium data from one of the largest association program insurance brokers and administrators in the United States. CMS notes that the premium data indicate that medical physicists have very low malpractice premiums relative to physicians. According to Acumen LLC, the non-surgical normalized premium rate for medical physicists is \$1,134.97, which appears reasonable.

Medical physicists, due to their key role in the design and quality assurance of high-risk radiation therapy procedures, have a significant liability exposure, and so liability insurance is normally carried by the medical physicist's employer or by the medical physicist if self-employed.

Further, CMS states 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 the current approach for these entities. Moreover, CMS believes that it is unlikely that actual malpractice premium rates for these entities would exceed those for medical physicists.

Freestanding and community-based cancer centers typically purchase an umbrella liability policy, which includes malpractice coverage of nonphysician clinical personnel, including radiation therapists and nurses. These centers also carry other forms of insurance, including but not limited to errors and omissions policies, property liability policies, and general liability policies.

The freestanding center's malpractice coverage is separate and distinct from a radiation oncologist's professional liability insurance, represented by the professional component (PC) malpractice RVUs. In general, radiation therapists and nurses employed by a freestanding cancer center do not purchase their own liability insurance and would be covered under the umbrella liability policy. On the other hand, medical physicists, whose work is reimbursed as part of the TC codes, frequently have individual policies.

AAPM opposes any policy that would make the technical component malpractice value zero. The current CMS proposal virtually eliminates existing TC malpractice RVUs. It is important that the cost of medical physicist's professional liability insurance be captured in the resource-based malpractice RVUs for technical services, however, this should be in addition to other malpractice costs incurred by freestanding and community-based cancer centers.

AAPM recommends that CMS consider actual malpractice premium data purchased by freestanding centers, in addition to medical physicists premium liability insurance, when calculating resource-based malpractice RVUs for technical component services.

We understand that the Radiology Business Management Association (RBMA) has collected preliminary data that reflects the true costs of nonphysician liability premiums paid by freestanding centers. AAPM supports the use of this data, in addition to the medical physicists premium liability insurance, when developing resource-based malpractice RVUs for technical component services.

Accreditation Standards for Suppliers Furnishing the Technical Component of Advanced Diagnostic Imaging Services

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires that beginning January 1, 2012, Medicare payment may only be made for the technical component (TC) of advanced diagnostic imaging services for which payment is made under the fee schedule to a supplier who is accredited by an accreditation organization designated by the Secretary.

The 2010 MPFS proposed rule sets forth criteria for designating organizations to accredit suppliers furnishing the technical component of advanced diagnostic imaging services. The

CMS-designated accreditation organization would apply standards that set qualifications for medical personnel who are not physicians but who furnish the TC service. In addition, the standards would require suppliers to: (1) establish and maintain a quality control program to ensure the technical quality of diagnostic images produced by the supplier; (2) ensure the equipment used meets performance specifications; and (3) ensure safety of personnel.

The American Association of Physicists in Medicine strongly supports the role of CMS when developing criteria for designation of accreditation organizations as described in MIPPA.

Specifically, we offer the following recommendations regarding the CMS responsibility described in the amendment to Section 1834 of the Social Security Act, (e) (2) (A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS. It is essential that factors determined by CMS pursuant to subsection (vi) require that the Accreditation Organizations include performance metrics related to image quality and (for ionizing radiation) dose measurement. These requirements should include measurement of image quality parameters for both clinical and phantom images as well as comparison of the resulting site-specific data to commonly accepted benchmarks.

In the criteria established for designation of an Accreditation Organization the standards for equipment performance should include both measurement and evaluation requirements for radiation dose and image quality by a qualified medical physicist (QMP). AAPM is the premier national organization providing the scientific and technical basis for evaluating image quality and dose in advanced imaging procedures.

Further we respectfully request that CMS, when promulgating the criteria for Accreditation Organizations for qualifications of medical personnel who are not physicians, require the use of nationally recognized certification standards. Medical Physics is one of only two non-physician medical specialties to participate in the certification process under the American Board of Medical Specialties. Clinical medical physicists are certified by the American Board of Radiology. It is essential for the effective implementation of an accreditation process for advanced diagnostic imaging services that Accreditation Organizations include the qualifications and responsibilities of properly credentialed medical physicists.

AAPM recommends that CMS ensure that qualified medical physicists (QMPs) are recognized and required to support accreditation programs mandated under the new Medicare legislation for advanced diagnostic imaging services. Accreditation criteria should require that a QMP supervise the process that determines image quality and patient dose / exposure. It is imperative that any accreditation criteria reflect the role of medical physicists in facility and program accreditation.

AAPM welcomes the opportunity to work with CMS to establish criteria for the designation of Accreditation Organizations that include the requirement for evaluation of dose, image quality and related processes, as well as the qualifications and responsibilities of medical physicists.

Physician Fee Schedule Update for 2010

In the 2010 MPFS proposed rule, CMS estimates that the annual update would be -21.5% for 2010. In addition, CMS estimates further reductions of between 5.0% and 6.5% for the next several years.

While we understand that CMS is required by law to update the conversion factor on an annual basis according to the sustainable growth rate (SGR) formula, we do not support reductions under the SGR system forecasted for 2010 and subsequent years. AAPM supports the CMS

proposal to remove physician-administered drugs from the definition of "physician services" for purposes of computing the physician update formula. However, the SGR formula is unreasonable and does not accurately reflect the health care costs of treating Medicare patients. Further, the current formula does not account for the costs and savings associated with new technologies. The current SGR formula must be replaced with one where payment updates keep pace with practice cost increases.

AAPM supports implementation of the 2010 CMS proposal to remove physician-administered drugs from the sustainable growth rate formula used to calculate the annual update factor.

AAPM continues to recommend that CMS replace the sustainable growth rate with an annual update system like those of other provider groups so that payment rates will better reflect actual increases in physician practice and freestanding cancer center costs and take into account Medicare Part B savings associated with new technologies.

Conclusion

Appropriate payment for radiation oncology procedures and medical physics services is necessary to ensure that Medicare beneficiaries will continue to have full access to high quality cancer treatment in freestanding cancer centers. The continued effect of multiple proposals on the technical component and global payment for radiation oncology procedures (e.g. CPT 77336) could be devastating to freestanding radiation oncology centers that provide cancer care to Medicare beneficiaries.

We hope that CMS will take these issues under consideration for the 2010 Physician Fee Schedule Final Rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (561) 637-6060.

Sincerely,



Maryellen L. Giger, Ph.D., FAAPM, FAIMBE
President