

Philips Healthcare

---

***BY ELECTRONIC DELIVERY***

August 31, 2009

Charlene Frizzera, Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

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

Dear Acting Administrator Frizzera:

Philips Healthcare (Philips) appreciates the opportunity to comment on the proposed CY 2010 Physician Fee Schedule policies and rates (the Proposed Rule). Philips' current activities are organized across five businesses: Imaging Systems (x-ray, computed tomography (CT), magnetic resonance (MR) imaging, and nuclear medicine imaging equipment); Clinical Care Systems (ultrasound imaging, hospital respiratory systems, cardiac care systems and children's medical ventures); Home Healthcare Solutions (sleep management and respiratory care, medical alert services, remote cardiac services, remote patient management); Healthcare Informatics and Patient Monitoring (patient monitoring systems, healthcare informatics and image management services); and Customer Services (consultancy, clinical services, education, equipment financing, asset management and equipment maintenance and repair).

If the Proposed Rule is adopted without change, Medicare payment for a broad range of non-hospital diagnostic imaging services will fall to levels that are almost certainly financially unsustainable for numerous physician practices and freestanding diagnostic imaging centers throughout the country. Our analysis suggests that, on average, Medicare payment for MRI technical component services would drop by up to 44%; for CT, by up to 39%, for echocardiography, by 50%; and for nuclear cardiology, by 41%. In addition, Medicare payment for remote cardiac monitoring services, such as holter monitoring and cardiac event monitoring, would fall by an average of 38%. These reductions would result in large measure from the incorporation of the Physician Practice Information Survey (PPIS) data into the CMS rate setting methodology, and (and, in the case of certain radiation oncology and imaging services), from CMS's proposal to modify the utilization rate used to calculate Medicare payment for medical equipment costing over \$1 million. For the reasons set forth below, we urge CMS not to finalize these changes as proposed.

In addition to the proposed use of PPIS data to calculate the practice expense RVUs and the proposed increase in the utilization rate assumption for equipment priced over \$1 million from 50 percent to 90 percent, our comments also address a number of the changes proposed to the process used to establish Physician Fee Schedule allowances: CMS's proposal to establish malpractice





# PHILIPS

RVUs based on physicists' malpractice costs and its proposals with respect to potentially mispriced services. With respect to specific services, our comments address the direct cost data used for high dose brachytherapy and for echocardiography. In addition, we respond to CMS' request for comments on its policy that a written order for diagnostic tests must be signed by the ordering physician and we continue to object to CMS's refusal to include remote critical care services on the list of telehealth services that are eligible for Medicare payment. Finally, we address implementation of the Medicare Improvements for Patient and Providers Act (MIPPA) provisions regarding accreditation.

**I. There is no statutory or factual basis for increasing the equipment utilization assumption for equipment costing over \$1 million.**

CMS proposes to increase the equipment utilization assumption from 50 percent to 90 percent for equipment priced over \$1 million. We urge CMS not to implement this proposal because it is based on faulty data and analysis and, coming after significant cuts in reimbursement, could severely limit beneficiaries' access to appropriate imaging and radiation therapy services.

First, and most importantly, we do not believe that the proposed modification of the utilization rate is authorized by the governing statute. The Balanced Budget Act of 1997 directs CMS to "use actual data on equipment utilization and other key assumptions" to the extent practicable, in establishing resource-based practice expense relative value units (PE-RVUs). Yet, CMS' basis for changing the utilization assumption for diagnostic imaging equipment is MedPAC data that MedPAC itself acknowledges is not nationally representative, and that MedPAC staff acknowledges were not designed to determine equipment use rates. Under these circumstances, it is clear that the statutory authority to modify the equipment utilization rate for either radiation oncology or diagnostic imaging equipment is lacking.

In addition, survey data regarding equipment utilization submitted by the Radiology Business Management Association (RBMA) (for diagnostic imaging) and by the American Society of Therapeutic Radiology and Oncology (ASTRO) (for radiation oncology), indicate that the current 50% utilization rate for both types of equipment is reasonable and realistic. Data from the Radiology Business Management Association (RBMA) show urban provider utilization rates for imaging services at 56 percent and rural providers at 48 percent. <http://rightscanrighttime.org/wp-content/uploads/2009/06/sfc-rbma-utilization-rate-excerpt.pdf>. And ASTRO's survey of 103 free-standing radiation oncology centers located throughout the country found that, generally, radiation therapy equipment costing over \$1 million is used less than 51% of the time. DMRkynetec, Equipment Utilization Survey Prepared for ASTRO, August 2009, 5, available at <http://www.astro.org/MedicareCuts/documents/EURfinal.pdf>.

In addition, we urge CMS to reconsider the proposed modification of the equipment utilization rate in light of the other adjustments made to equipment costs under the Physician Fee Schedule methodology. In fact, because of the direct cost adjustment, which eliminates 50% of all direct costs (including 50% of all equipment costs) from being considered in establishing the Medicare rates, the actual amount paid to physicians and others paid under the Physician Fee Schedule for their equipment costs is the amount that would be paid if their equipment were used 100% of the time. While CMS does assume that medical equipment is used 50% of the time as an *initial step* in determining the amount of payment for medical equipment, medical equipment costs are actually



# PHILIPS

cut in half before they are factored into the rate setting methodology. Assuming a 50% utilization assumption and taking into account 50% of equipment costs (which is what the CMS PE methodology does) yields the same equipment allowance as considering all of the equipment costs and applying a 100% utilization rate. Thus, in effect, CMS is already paying for medical equipment as if a 100% utilization rate were being used. Mathematically, by increasing the assumed equipment utilization to 90%, CMS is proposing to pay an equipment allowance equivalent to the allowance that would apply if the equipment were used 180% of the time.

**II. CMS should not utilize the PPIS data in establishing Physician Fee Schedule allowances for CY 2010, or, if it does should continue to use the Supplemental Survey data for cardiology and radiology, and make certain changes in the PPIS data used for radiation oncology.**

CMS is proposing to replace the PPIS data in place of the American Medical Association's Socioeconomic Monitoring System (SMS) data and Supplemental Survey Data submitted by certain specialties (including cardiology, radiology, and radiation oncology), in calculating PE RVUs. The substitution of this data for the data currently used in establishing PE-RVUs would result in extraordinary reductions in Medicare payment for cardiology, radiology, and radiation therapy services in particular.

The negative impact on providers of remote cardiac services is of particular concern, threatening the financial viability of the cardiac monitoring companies that furnish these services. Philips estimates that the overall Medicare reimbursement to companies that furnish remote cardiac services is -38% based on a weighted average of total Medicare payments for the "bread and butter" cardiac monitoring services (CPT Codes 93226, 93232, 93012, 93271 and 93293). Unfortunately, too, cardiac monitoring companies, unlike physicians' practices generally do not perform a wide range of services, which would enable to offset these losses against payment increases for other services. Since these services are provided virtually exclusively through cardiac monitoring services companies, access to these vital services will be threatened not only for Medicare patients but for all patients. This result is particularly troublesome since these types of providers are quite different in structure and operations from physicians' practices, and no remote cardiac services companies were included, directly or indirectly in either the PPIS or the Lewin survey of non-physician providers, or the IDTF survey conducted several years ago.

In the Proposed Rule, CMS indicates that it believes "the PPIS is the most comprehensive source of PE survey information available to date." However, no information is provided to the public regarding the process used by the AMA in conducting the survey, the methodology used to verify that the survey respondents were representative, the way raw data was converted to specialty-based PE/hr data, or other critical aspects of the survey, it is fundamentally impossible for the public to determine the basis upon which CMS drew this conclusion. In fact, the Supplemental Survey data is uniformly of higher quality than the PPIS data: The Supplemental Data has met rigorous standards, which ensure that it is representative and meets precision requirements. By contrast, the PPIS data appears to be even less precise (when considered on a specialty level) than the SMS data. Philips is



# PHILIPS

extremely concerned that such large payment reductions (and increases) are proposed based on such sparse data—for some specialties, only a few dozen responses.<sup>1</sup>

We are particularly concerned that, in the case of cardiology and radiology, the PPIS data would take the place of Supplemental Survey data that appears to be far more representative and valid, from a statistical standpoint. We note that the Cardiology Supplemental Survey data is consistent with two independent data sources: While the Cardiology Supplemental Survey data suggests a cardiology PE/hr of \$ 235/hr, 2006 data collected by the Medical Group Management Association suggests a cardiology PE/hr of \$240.<sup>2</sup> Likewise, based on 2006 data collected by MedAxiom for over 100 cardiology practices throughout the country, it appears that the PE/hr for cardiology based on the MedAXiom data (which is collected solely for benchmarking and internal management purposes), is approximately \$247-\$256/hr. In light of the fact that the cardiology Supplemental Survey data is substantiated by two independent and reliable sources, we believe that it is likely far more reliable than the 55 responses received from cardiologists that were included in the cardiology PPIS data.

Likewise, it appears that the PPIS data for radiology also is highly suspect. We understand that, based on data that was released by the AMA to the American College of Radiology, out of 56 complete radiology surveys, at least 66.9 percent of the responses were from radiologists who work in the hospital setting, leaving only 18 from practices that provide technical component services. Further, for interventional radiology, 89.9% of the 33 survey respondents work in teaching hospital settings, leaving only three survey respondents that provide technical component services. For nuclear medicine, 77.7% of the 16 surveys were hospital-based, leaving no more than three that provide TC services. Since approximately 48% of radiology charges and procedures include TC services (either billed separately or billed globally), respondents providing TC services were substantially underrepresented among the PPIS survey respondents. The underrepresentation of TC survey respondents in the SMS survey was a primary factor contributing to CMS's decision to establish the non-physician work pool, rather than applying the SMS survey results to radiology TC services. Correcting this deficiency was a primary reason for ACR's decision to conduct the radiology Supplemental Survey, and the Lewin Group specifically determined that the radiology Supplemental Survey is representative in this regard. In our view, it hardly makes sense to now utilize, without substantial scrutiny, AMA-sponsored data that again appears to under-represent TC providers.

We urge CMS not to discard good data for bad, in an effort to ensure that the same survey is used for all specialties. In fact, it appears that the PPIS exhibits a number of the same deficiencies that led CMS to reject the use of the SMS to establish payment allowances for technical component services and to instead establish the non-physician work pool. It was the completion of Supplemental surveys for cardiology and radiology that were more representative and reliable than

---

<sup>1</sup> For example, the figure in the “number of completes” column for PE/hour for radiology is 56; for cardiology, 55; and for nuclear medicine, only 16.

<sup>2</sup> The MGMA data indicates that total operating costs of the \_\_cardiology practices participating in the 2006 MGMA survey was \$615,852\_\_\_\_, and, assuming \_2571\_\_\_\_\_ hours (average annual cardiology hours from the PPIS), the PE/hr for cardiology based on the MGMA data is approximately \_ per hour.



# PHILIPS

facilitated the elimination of the non-physician work pool. Philips urges CMS to retain the use of these Supplemental Surveys in establishing the Medicare payment rates for CY 2010, even if the agency does move forward to use the PPIS for other specialties.

By contrast, it appears that the PPIS radiation oncology data, by design, does include a representative number of technical component providers, and, in fact, the PPIS data on the whole is comparable to the radiation oncology Supplemental Survey data upon which the current radiation oncology physician fee schedule payments are based. If CMS moves ahead to incorporate the PPIS data into the PFS methodology, we urge the agency to modify the PPIS PE/hr for radiation oncology to eliminate the errors identified by the radiation oncology community and to update the “blend” of freestanding and hospital-based radiation oncologists, to ensure that the PE/hr for radiation oncology is accurate.

### **III. CMS Should Utilize the Data Submitted by RBMA to establish Malpractice Relative Value Units**

CMS proposes to value malpractice relative value units for TC services by using premium data for medical physicists instead of historical allowed charges. It is our understanding that this may not accurately reflect the true malpractice costs associated with the provision of TC services, including, for example, the cost of umbrella liability policies, which typically cover imaging centers and well as their non-physician clinical personnel, such as radiologic technologists, sonographers, and nurses. It is our understanding that RBMA has submitted data regarding malpractice costs associated with the provision of TC services, and we urge the agency to utilize this data in establishing appropriate malpractice RVUs. The information collected shows that the mean for the total annual liability premiums is \$31,526 with the minimum being \$3,401 to maximum being \$83,464.

### **IV. CMS should correct the direct cost data for particular services.**

#### **a. Brachytherapy Services.**

Philips urges CMS to review the direct cost data used to establish Medicare payment for high dose radiation therapy (HDRT) service, and to make the following corrections in the final rule:

- The life of the High Dose Radiation (HDR) Iridium-192 renewable source should be changed from 5 years to one year. Alternatively, CMS should consider paying separately for the HDR Iridium-192 source under the Medicare Physician Fee Schedule using HCPCS code Q3001 (*Radioelements for brachytherapy, any type, each*), which would make Medicare payment policy for HDR consistent with the payment policy for radiation sources for low dose brachytherapy treatment.
- The following equipment should be added to the equipment inputs for CPT codes 77785-77787 :
  - i. Well Chamber with Iridium-192 Calibration Capability;
  - ii. Radiation Wall Monitor;
  - iii. HDR Afterloader Guide Tube Connector Set (not associated with brachytherapy catheter or applicator codes); and



# PHILIPS

iv. Prostate Brachytherapy Mattress (CPT 77787 only).

**b. Echocardiography services.**

We request that CMS review the Direct Cost file with respect to the equipment time for echocardiography (CPT code 93306). We note that the intraservice cardiac sonographer time for this code is 63 minutes, but that the equipment time for the code is only 42 minutes. This is inconsistent with the direct cost data for all other ultrasound services, for which the equipment time is equal to the sonographer intraservice time. We believe that the likelihood of a clerical error is significant, since 42 minutes is the amount of cardiac sonographer time that was evidently approved for one of the three components of CPT code 93306—the imaging component formerly reported under CPT code 93307.

We also request that CMS consider establishing an “echocardiography room”, using an approach comparable to that used for general and vascular ultrasound services. In this regard, we incorporate by reference the cost data that was submitted by the American Society of Echocardiography, and urge that the direct cost revisions recommended by ASE be accepted.

**V. CMS should reconsider its refusal to add remote critical care services to the list of approved telehealth services.**

In the Proposed Rule, the Agency responds to Philips’ request to add remote critical care services to the list of telehealth services covered under the Medicare program, stating “Within the current standards of practice, we believe critical care services require the physical presence of the physician rendering the hands-on interventions.” The Agency also states that it does not believe that the clinical studies submitted with the request were persuasive that telehealth can be an adequate substitute for the face-to-face delivery of critical care services. We disagree with this conclusion for several reasons and ask that CMS re-consider this request.

First, the data submitted with the request strongly supported improvements in the outcomes of ICU patients. Using the Apache III critical care severity system, the data demonstrate reduced actual-to-predicted ICU length of stay (LOS), actual-to-predicted mortality rates, and actual-to-predicted hospital LOS, among other improvements. Furthermore, we submit a soon-to-be published peer-reviewed article by Dr. Craig Lilly of the University of Massachusetts that highlights these improvements across many tele-ICU sites (attached). In light of the Agency’s recent strong emphasis on outcomes improvement as opposed to process measures, we find it puzzling that CMS appears to discount the evidence of improved outcomes submitted in support of the request. At the very least, the fact that the outcomes of remote critical care services is equivalent to (or better than) the outcomes of critical care services that are provided in person suggest that the activities performed by remote and on-site intensivists are comparable. These outcomes data alone suggest that remote intensivists can and are providing the type of critical care services that are necessary for ICU patients to deliver improved outcomes, and that are otherwise billable under the critical care codes 99291 and 99292.

These services provide a means to improve and regionalize the delivery of care without regard to time of day or local availability of specialized practitioners. Approximately 40 percent of US hospitals are located in rural communities which do not have the means to recruit or support on-site



# PHILIPS

daytime intensivists, let alone a 24-hour on-site intensivist. Even larger urban hospitals with intensivists on staff generally do not retain intensivist staffing in the ICU 24 hours a day.

In our view, CMS' denial of the request to add remote critical care services to the list of approved telehealth services misunderstands the role of the intensivist within the ICU. Whether the intensivist is "on site" in person or remotely, he or she is part of the ICU team. Whether present in person or remotely, the intensivist provides the necessary expertise and ability to direct the on-site clinical staff to perform any necessary "hands-on" interventions that might otherwise have been missed or put on hold until an attending physician or onsite intensivist could be located. Whether the intensivist is on site in person or remotely, his or her role is to determine the appropriate adjustments that should be made in the patient's care, not necessarily to effectuate them. That task can and generally should be performed by the specially trained critical care nurses who are well qualified to perform the "hands on" functions necessary for critical care patients.

A recent survey of seven tele-ICU sites over a three-month period that was sponsored by the American College of Chest Physicians to submit to the CPT committee confirms that the role typically performed by the intensivist can be performed remotely, and that the same activities are involved regardless of whether the intensivist is "on site" in person or remotely (attached). The survey indicates that the types of activities performed remotely include, for example, evaluation of medical data, evaluation of pulse oximetry, ABGs and ventilator settings, review and interpretation of chest x-rays and hemodynamic data, review of ECGs and rhythm tracings, orders for placement of intravenous catheters, documentation of progress into medical records, discussions with bedside caregivers and attending physicians, and discussions with families regarding substantive issues. These remote services are all within the scope of an intensivist's role and are supported by the vignette for the critical care codes 99291 and 99292 (see Attachment A).

We believe that CMS' denial of the request to add these services to the list of approved telehealth services does not take into account the role telemedicine can play in the delivery of high quality ICU services, and, in effect, denies potentially lifesaving care to millions of Medicare patients who could otherwise benefit from these services. Intensive care admissions for Medicare patients continue to grow; the number of available intensivists does not. In light of this and the evidence presented, we ask that CMS reconsider its conclusions.

## **VI. Medicare Should Not Require that Written Orders for Diagnostic Tests be Signed by the Ordering Physician**

Philips agrees with the comments submitted by the Remote Cardiac Services Provider Group (RCSPG) that the current manual guidance (Medicare Benefits Policy Manual Pub. 100-2, Ch. 15, 80.6.1) is clear that a signature is not required. The policy specifically states that there are three ways that an order for a diagnostic test can be delivered: a written document signed by the treating physician/practitioner; a telephone call by the treating physician/practitioner or his/her office to the testing facility; or via electronic mail by the treating physician/practitioner or his/her office to the testing facility. We also agree that IDTFs and other providers should have written documentation supporting the fact that the test was ordered by the treating physician. These documentation requirements, however, should take a number of forms in order to not disrupt current established business practices, maintain efficiencies, and be consistent with the movement toward electronic



# PHILIPS

health records and electronic communications. Therefore, we ask that CMS not implement a physician signature requirement with respect to physician orders for diagnostic tests, but amend the current guidance to require written documentation by both the ordering physician and the testing facility in the patient medical record (paper or electronic).

## **VII. CMS should implement the accreditation standards for suppliers furnishing the technical component (TC) of Advanced Diagnostic Imaging Services, as proposed.**

Philips thanks CMS for working closely with us in implementing the accreditation standards for suppliers furnishing the TC of Advanced Diagnostic Imaging Services. Although Philips generally supports the process that CMS has developed for selecting accreditation organizations, we encourage CMS to work closely with the Intersocietal Accreditation Commission and the American College of Radiology and its accrediting arm to ensure that the IAC and the ACR accrediting bodies can meet the CMS criteria without substantially altering their current accreditation processes and criteria, to the extent practicable. In this regard, we note that the proposed criteria do require an on-site survey audit; yet, is our understanding that one or both of these groups currently do not require an on-site survey as a condition of accreditation. We urge CMS to work directly with both groups to minimize the burden both on accreditation organizations and on organizations seeking accreditation.

Lastly, CMS lists the requirements it proposes for entities applying for approval as accreditation organizations.<sup>3</sup> In addition to these requirements, we recommend that CMS also require these entities to have an open and transparent standards development process, particularly for equipment standards, and that accreditation organizations have an established mechanism for accepting input from outside organizations, including equipment manufacturers.

## **VIII. Conclusion**

In conclusion, Philips urges CMS to make the following changes to the physician fee schedule proposed rule for 2010:

- Do not increase the equipment utilization assumption from 50 percent to 90 percent for equipment priced over \$1 million;
- Do not implement the proposed changes to the PE RVUs based on the PPIS data, or, at a minimum, utilize the Supplemental Survey data for radiology and cardiology, and revised PPIS data for radiation oncology;
- Correct the data used to set reimbursement for brachytherapy and echocardiography services;
- Approve remote critical care services for inclusion on the telehealth list;
- Do not implement a physician signature requirement with respect to physician orders for diagnostic tests; and
- Implement the accreditation standards for suppliers furnishing the TC of advanced diagnostic imaging services as proposed.

---

<sup>3</sup> Id.



# PHILIPS

Philips appreciates this opportunity to comment on the physician fee schedule proposed rule for fiscal year 2010.

Respectfully submitted,

Laurel Sweeney  
Sr. Director, Reimbursement & Legislative Affairs  
Philips Healthcare



# PHILIPS

## Attachment A

### **CPT code 99291: Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes**

#### **Vignette**

A 65-year-old female who, following hysterectomy, suffers an onset of severe dyspnea. Time spent 30 to 74 minutes. Services included in 99291 are: interpretation of cardiac output measurements (93561, 93562), chest x-rays (71010, 71015, 71020), pulse oximetry (94760, 94761, 94762), blood gases, and information data stored in computers (eg, ECGs, blood pressure, hematologic data (99090); gastric intubation (43752, 91105); temporary transcutaneous pacing (92953); ventilatory management (94656, 94657, 94660, 94662); and vascular access procedures (36000, 36410, 36415, 36540, 36600). Any services not listed are reported separately.

#### **Pre-service**

Patient is critically ill. Review, assessment and integration of available data from multiple databases (eg, {not all inclusive} telemetry, central venous/intracardiac measurements of blood gases, as well as other diagnostic laboratory, radiological and nuclear medicine data in correlation with the patient's signs, symptoms and reactions to therapeutic interventions) and reading of films, rhythm strips, etc.

#### **Intra-service**

- \*Patient is examined assessing all body systems.
- \* Consultations with nurses, respiratory therapists, nutritionists, physical therapists, pharmacists and other physicians.
- \* Adjustments to ventilator settings; titration of fluid replacement; calculation of needed parenteral nutritional support; titration of amounts of vasoactives to maintain patient's blood pressure, and determining need for blood and volume expanders.
- \* Any necessary procedures are performed, and those not included in the list above, may be reported separately and the time to perform those procedures is NOT counted in critical care time.
- \* End-of-life discussions with surrogate decision-makers.

#### **Post Service**

A note is written describing the patient's critical illness, the critical care service provided including any procedures performed (bundled into critical care, and not separately billable), and the time (total time or start-stop time) spent.

- \* Notes may include explanations of interpretations of data and planned course of action.
- \* Discussions with nurses, respiratory therapists, nutritionists, physical therapists, pharmacists and other physicians are often noted.
- \* Detailed instructions and orders are written for staff.
- \* Consultations with family members or surrogate decision makers are more frequent and complex than in other E/M services because of the severity of the patient's condition.
- \* High probability of imminent or life threatening deterioration in the patient's condition.
- \* Medically significant decisions for next 24 hours on-call, or until next subsequent hospital visit.



**PHILIPS**