

Philips Healthcare

August 25, 2008

Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1390-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted via the CMS public comment website: <http://www.regulations.gov>

Re: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; CMS-1403-P; IDTF, Anti-Mark-Up, Telehealth, and Application of Multiple-Procedure Discount to Diagnostic Imaging Procedures

Dear Mr. Weems:

Philips Healthcare (Philips) is pleased to have this opportunity to comment on the proposed physician fee schedule rule for 2009, as published in the July 7, 2008 Federal Register (the "Proposed Notice"). Philips operates in five main business areas: Diagnostic Imaging Systems, Clinical Solutions, Healthcare Information, Customer Services and Home Healthcare Solutions. Our product line includes best-in-class technologies in X-ray, ultrasound, magnetic resonance, computed tomography, nuclear medicine, PET, radiation oncology systems, patient monitoring, information management, personal emergency response systems, and resuscitation products.

Philips has a number of general concerns about various provisions of the Proposed Notice:

- Philips urges CMS to refrain from finalizing the proposal to apply the requirements that are currently applicable to Independent Diagnostic Testing Facilities (IDTFs) to physicians' practices that provide diagnostic services.
- Philips strongly opposes CMS's proposal to extend the anti-mark-up prohibition to services provided directly by physician practices, rather than through outside suppliers. At the very least, Philips urges CMS to determine that the anti-markup prohibition is inapplicable to group practices that already meet the requirements imposed by the Stark Law regulations.
- Philips requests clarification on how the Deficit Reduction Act (DRA) cap on diagnostic imaging services and the multiple procedure reduction will be applied to diagnostic imaging services reimbursed under the Physician Fee Schedule, if CMS finalizes the

proposal in proposed CY 2009 Hospital Outpatient Prospective Payment (HOPPS) rule to institute new composite Ambulatory Payment Classification (APC) rates for multiple diagnostic imaging services performed in hospital outpatient settings

Additionally, Philips has a number of concerns about coverage and payment for particular services under the proposed Physician Fee Schedule for CY 2009:

- While Philips understands that CMS is unable to propose adding remote critical care services to the list of telehealth services at this time since the agency was not provided with data supporting the request that it received last year, we want to make the agency aware that significant data supporting the remote provision of critical care services is available, and that such data will be submitted by no later than December 31, 2008, in time for the agency to reconsider the addition of remote critical care services to the list of approved telehealth services during the course of next year's rulemaking.
- Philips has several comments regarding payment for cardiac monitoring services. First, Philips wishes to once again call to CMS's attention the drastic reductions in Medicare payment for holter monitoring (CPT 93230, 93224, 93226, and 93232) as the result of the transition to resource-based practice expense relative value units. We strongly support the request made by the American College of Cardiology (ACC) and the Remote Services Provider Group (RSPG) to increase the RVUs for these service to more closely reflect the actual time of equipment usage by patients. Also, Philips supports the proposed change in the equipment utilization assumption for cardiac event monitoring.
- Philips urges CMS to authorize Medicare coverage for the four new cardiac MRI codes that involve blood flow/velocity measurement by determining that the current National Coverage Determination (NCD) that precludes coverage for flow measurement utilizing MRI is inapplicable to cardiac MRI. Alternatively, Philips urges CMS modify the current NCD applicable to MRI as soon as practicable to authorize coverage of these services.

I. General Comments on Proposed Revisions of Medicare Policy

A. The Extension of IDTF Requirements to Physicians' Offices

CMS is proposing to require any physician's office that provides diagnostic tests to enroll in the Medicare Program as an "Independent Diagnostic Testing Facility" (IDTF) and to meet all of the requirements generally imposed on IDTFs. These requirements were designed specifically to address particular concerns that had been raised about the quality of the diagnostic tests performed by IDTFs, their failure to comply with Medicare fraud and abuse restrictions, and other concerns unique to the types of diagnostic imaging facilities that constitute the great majority of IDTFs. Under these requirements, each IDTF must undergo an inspection by its Medicare carrier; must document the licensure and/or certification of non-physician personnel and report all changes in such personnel; and must contract with one or more physicians to supervise the diagnostic tests that are performed by the IDTF. These requirements are inappropriate when applied to physicians' offices where care is generally rendered by or under

the supervision of the patient's own physician or member of the physician group, and where diagnostic services are already required to be provided in compliance with supervision requirements specifically mandated by the Medicare Program.

The direction taken by CMS in this proposal is inconsistent with that taken by Congress in legislation that was just recently enacted, the Medicare Patients and Provider Improvement Act of 2008 (MPPIA). This legislation mandates that physicians' practices that provide "advanced diagnostic imaging services," such as MRI, CT, and nuclear medicine services (including PET), be accredited by private accreditation organizations approved by CMS. The legislation is aimed at precisely the types of diagnostic services that CMS targets in its IDTF proposal. However, MPPIA takes an entirely different approach: MPPIA relies on private accreditation organizations and reflects a preference for national standards. CMS's approach, unlike that mandated under the MPPIA, relies on under funded carriers to implement quality requirements, raising the potential for substantial local variation in enforcement and resulting in the unnecessary expenditure of increasingly scarce government funds.

Moreover, because IDTFs are owned and operated by business enterprises that have no relationship to patients' own physicians, they are subject to particularly strict physician supervision requirements, the purpose of which is to ensure that the diagnostic tests that they provide are appropriately supervised. These requirements, if applied to physicians' offices, would create a *de facto* privileging program under Medicare under which physicians could be precluded from supervising the tests performed on their own patients. In addition, under CMS's IDTF proposal, the authority to supervise or perform various diagnostic tests would be granted based on clinical specialty rather than training, experience and competence, in direct contradiction to MedPAC's recommendation on this subject and contrary to the intent of the MPPIA.

Finally, CMS's IDTF proposal would impose substantial and ongoing additional administrative costs both on providers and on the Medicare Program. In addition to the costs of preparing a cumbersome enrollment application, a physician practice offering diagnostic tests likely would be required to use a special IDTF supplier number when billing for diagnostic services, rather than using its regular billing number; would be required to update its enrollment form every time there is a change in clinical personnel; and would be required to meet other administrative requirements. Medicare carriers would be charged with inspecting an untold number of private physicians' offices and to ensure compliance with IDTF billing requirements for thousands of additional providers, resulting in substantial waste of Medicare resources.

B. The Extension of Anti-Mark-Up Provisions to Services Provided by *Bona Fide* Group Practices

CMS is also proposing to implement certain "anti-mark-up" prohibitions that were adopted last year but put on hold (except with respect to certain pathology services) as the result of strong opposition from the medical community. The anti-mark-up rule, which is based on Section 1842(n) of the Social Security Act, precludes physician practices from charging more than their costs for diagnostic tests covered under the Medicare Program under certain circumstances. However, Section 1842(n) specifically excludes from the anti-mark-up prohibition diagnostic

tests that are performed personally by, or supervised by, the billing physician or another physician “with whom [the billing physician or entity] shares a practice.”

Despite this statutory language, CMS is proposing to extend the anti-mark-up rule to diagnostic services performed **within** a physician group. In fact, under the CMS proposal, the anti-mark-up prohibition may apply to a physician practice that qualifies as a “group practice” under the federal self-referral law (the “Stark Law”). In the Stark Law, Congress thoroughly considered and set forth in statutory language the circumstances under which physicians who share a practice are authorized to bill the Medicare Program for diagnostic services. That statutory language has been implemented by CMS through regulations that have been developed over the course of almost 19 years, since the adoption of the first self-referral restrictions in 1989. The agency now seeks to overlay a new and inconsistent set of requirements for *bona fide* group practices meeting the Stark Law requirements in order for these practices to provide diagnostic testing, by relying on the “anti-mark-up” language of Section 1842(n), even though that language pre-dates the Stark Law and explicitly exempts testing performed by physicians who “share a practice.” This proposal, if adopted, would impose a new and untenable burden on physician’s practices that have already taken pains to comply with the complex and onerous strictures imposed by the Stark Law.

C. Application of Multiple Procedure Discount to Certain Diagnostic Imaging Procedures

It is our understanding that, in a separate rulemaking, CMS is proposing to establish new “composite rates” for certain multiple diagnostic imaging procedures performed at the same time in hospital outpatient settings. A multiple procedure reduction that serves much the same purpose is currently applied to multiple diagnostic imaging services that are performed on contiguous body parts and that are reimbursed under the Physician Fee Schedule.

We further understand that, under current Medicare payment policy, the diagnostic imaging service payment reductions authorized by the Deficit Reduction Act (DRA) are applied after the multiple procedure reductions applicable to multiple imaging services performed contemporaneously on contiguous body parts. It is unclear to us whether this policy will change if the new composite rates are adopted under the Hospital Outpatient Prospective Payment System (HOPPS). Nor is it clear to us whether the DRA will be applied to each procedure separately or to the sum of the allowances of both procedures, if a new Ambulatory Payment Classification (APC) composite rate is adopted for multiple imaging procedures under the HOPPS system. We would appreciate CMS’s clarifying these issues in the final Physician Fee Schedule or HOPPS rule.

II. **Comments on Specific Services Under the Physician Fee Schedule.**

A. The Inclusion of Remote Critical Care Services on the list of Approved Telehealth Services

It is our understanding that CMS received a request to add remote critical care services to the list of approved telehealth services last year; however, the requestor did not submit any data establishing that critical care services that are provided remotely are clinically equivalent to those provided on site or any other data regarding the clinical benefit of critical care services that are provided remotely. Under the circumstances, we certainly understand CMS's decision to refrain from proposing the inclusion of remote critical care services on the list of approved telehealth services.

We do want CMS to be aware, however, that there is substantial data supporting the clinical utility of remote critical care services. Remote critical care is the direct delivery by a physician(s) of medical care for a critically ill or critically injured patient from an off-site location. Remote critical care is intended to supplement on-site critical care services at times when a critically ill or injured patient requires additional critical care resources than are available on-site. Remote critical care is provided as the result of hospital policies and/or at the request of the patient's attending physician.

The current shortage of intensive care specialists (intensivists) will worsen over the next 20 years at the same time that the population of elderly patients in this country grows (1, 2). This impending imbalance is further exacerbated by the critical care nursing shortage. Remote critical care is a model that has been available for eight years and can effectively leverage a limited resource of caregivers across any geography or physician shortage region. The argument that remote ICU care is not comparable to on-site care has been suggested. A meta-analysis of studies performed over the past 15 years demonstrates that a high intensity intensivist staffing model improves mortality for ICU patients by 15-30% (3). If that is taken as the standard for on-site intensivist care then remote ICU care should be viewed as comparable. This is based on the fact that two published studies (4, 5) and numerous published data presented at scientific meetings (6-12) and submitted to medical journals demonstrate similar mortality improvement and suggest that remote critical care is equally efficacious to an on-site intensivist care model.

Furthermore, the impact of a remote critical care model has had a more demonstrable effect on ICU length of stay and the cost of care. Based upon these data, HRSA suggested in its report to Congress (*Critical Care Workforce*) in 2006 (2) that remote ICU care should be considered a solution to the looming intensivist shortage. A major healthcare quality organization (The Leapfrog Group) has created recommendations for the core functionalities of these systems and has found the remote critical care model to be in accordance with their standards (13). Additionally, the University Health Consortium in March 2006 stated that, "ICU telemedicine will likely be a standard of care within 10 years, so all hospitals should begin to evaluate budget, staffing and infrastructure needs." (14).

Remote critical care services not only results in outcomes similar to the outcomes resulting from the onsite provision of critical care services, remote critical care is also comparable in terms of the actual activities and services performed by the responsible physician. The cognitive and other services performed by an intensivist who provides his or her services remotely are functionally and clinically comparable to the on-site provision of these services, as described in the CPT. We anticipate submitting additional data supporting the functional and clinical equivalence of these services by December 31, 2008, the deadline for applications for additions to the list of covered

telehealth services for next year. We are hopeful that CMS will consider this request during the course of next year's rulemaking process for the 2010 Physician Fee Schedule.

B. Cardiac Monitoring Services

We urge CMS to adopt several modifications to the equipment time allocated to certain cardiac monitoring codes. Specifically, with respect to holter monitoring, it is our understanding that CMS assumes 1440 minutes or 24 hours of use of the holter monitor for each procedure performed. While this reflects the amount of time of each recording, Philips agrees with RSPG that patients typically do not return the device immediately, but rather keep the device longer than 24 hours. Increasing the equipment use time from 24 to 48 hours would provide a more reasonable estimate of equipment use time and a more reasonable allowance for the direct equipment costs for these procedures.

We also understand that CMS's current methodology assumes that cardiac event monitoring devices are utilized 100 percent of the time. CMS is proposing to change the 100 percent utilization assumption to an assumed 50 percent utilization rate, which is the utilization rate used for other equipment paid under the Physician Fee Schedule methodology. We believe that this modification is reasonable, and we support this change for all cardiac event-monitoring services.

C. Cardiac MRI Services

We understand that the four new (2008) cardiac MRI codes that include the language, "with flow/velocity quantification," (i.e. CPT codes 75558, 75560, 75562 and 75564) are not currently covered under the Medicare Physician Fee Schedule, because blood flow measurements performed utilizing MRI are subject to a 1995 National Coverage Determination (NCD) which generally precludes coverage for blood flow measurement applications of MRI. It is unclear to us whether the NCD should be considered to be applicable to these new cardiac MRI codes, since the use of cardiac MRI to measure blood flow is relatively recent, and the NCD was established in 1995. In any event, however, the current NCD is clearly outdated. If CMS continues to believe the current NCD precludes Medicare coverage of these new cardiac MRI codes, we urge CMS to modify the NCD as soon as possible. Flow quantification and velocity assessment are fundamental parts of cardiac MRI examinations, especially in cases involving potential aortic disease. The current NCD should be modified to clearly authorize Medicare coverage for flow measurement when utilized in cardiac MRI studies.

If you have any questions regarding Philips' comments on these issues, please do not hesitate to contact me.

Sincerely yours,

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