PHILIPS

Philips Medical Systems

August 30, 2007

Herb Kuhn, Acting Administrator
Centers for Medicare and Medicaid Administration
Department of Health and Human Services
CMS 1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1385-P; Proposed Physician Fee Schedule and other Part B Payment Policies for CY 2008. **CODING – ADDITIONAL CODES FROM 5-YEAR REVIEW**

Dear Mr. Kuhn:

On behalf of Philips Medical System ("Philips"), I am delighted to have this opportunity to comment on the proposed modifications of the Physician Fee Schedule for CY 2008 published in the July 12, 2007 Federal Register (the "PFS Proposed Rule"). Philips operates in four main business areas: Diagnostic Imaging Systems, Clinical Solutions, Healthcare Information and Customer Services. 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 and resuscitation products.

In general, we are extremely concerned about the impact of recent Medicare payment reductions for medical imaging services provided in non-hospital settings. These changes have resulted in substantial financial instability for many health care providers, major consolidations in the diagnostic imaging industry, and significant uncertainty about the future viability of promising technological innovations. We find it very disturbing that a number of aspects of the Proposed Rule, if implemented as proposed, have the potential to deepen the crisis in the diagnostic imaging industry.

As CMS has recognized in a number of the quality measures included in the PFS Proposed Rule, medical imaging plays a crucial and growing role in the diagnosis of many major illnesses affecting Medicare and other patients in this country. Yet, a number of the proposals included in the PFS Proposed Rule would deepen the already draconian payment reductions that have been implemented over the past year, while substantially increasing regulatory restrictions.
We urge CMS to:

- Refrain from implementing any modifications in the equipment utilization assumptions used to calculate practice expense relative value units unless and until the current

formula for determining Medicare payment for facilities' overhead and other indirect costs is modified to more accurately reflect overhead associated with technical component services.

- Refrain from implementing the proposed "bundling" of color Doppler into echocardiography "base" codes.

- Refrain from further decreasing Medicare payment for remote cardiac monitoring services.

- Reconsider the application of the multi-procedure discount to medical imaging services that are subject to the "cap" on technical component payments set forth in the Deficit Reduction Act.

- Confirm that the Deficit Reduction Act will not be applied to services, such as MRI, CT, PET (and PET/CT), echocardiography, and myocardial perfusion (SPECT) imaging, that are subject to "bundling" under the Hospital Outpatient Prospective Payment System (HOPPS).

We are also concerned about the tone of CMS's discussion of medical imaging utilization in those sections of the PFS Proposed Notice that address changes to the rules governing assignment, self-referral, and IDTF requirements. In particular, the PFS Proposed Rule appears to assume that the increased utilization of medical imaging services is primarily attributable to physician ownership of the facilities that provide these services and that much of this utilization is inappropriate. We respectfully disagree, and request that CMS reconsider its proposed changes to anti-assignment, physician self-referral, IDTF, and related rules in light of new information regarding the limited role played by physician self-referral in the increased utilization of medical imaging services.

Equipment Utilization Assumption

We appreciate CMS's interest in ensuring that all of the assumptions that are used in formulating the Physician Fee Schedule are accurate. In that regard, we understand the need for data to confirm the most appropriate equipment utilization rate for medical equipment reimbursed through the Practice Expense Relative Value Units (PE RVUs). We concur with CMS's judgment that reliable equipment utilization data is not available at this time and with the agency's decision to defer making any modification in the PFS equipment utilization assumption until reliable data is collected by an unbiased source.

In addition, prior to making any change in the equipment utilization assumption that may have the effect of further reducing Medicare payment for medical imaging technical component services, we urge CMS to re-evaluate its methodology for allocating indirect practice expenses among various PFS services. Approximately 67% of the total amount paid under the PFS for

practice expenses is allocated on the basis of physician work RVUs. Since TC services do not have any physician work RVUs, these services – which generally involve significant overhead expenses – are automatically ineligible for about two-thirds of the amounts available for practice expense reimbursement. In the past, CMS concluded that this allocation formula does not unfairly discriminate against TC services, because substantial indirect practice expenses are allocated to TC services on the basis of TC services' relative high direct expenses (including most especially equipment costs). If use of a different equipment utilization assumption substantially alters the direct practice expenses accorded to medical imaging services and other equipment-intensive TC services, as we would expect, it is crucial for CMS to re-evaluate whether the current indirect practice expense allocation formula accords these services an appropriate amount for their indirect costs.

Color Doppler

Philips strenuously opposes the proposed "bundling" of color Doppler into the allowance for other echocardiography "base" codes, and incorporates by reference the comments filed by the American Society of Echocardiography and the American College of Cardiology on this issue. CMS is proposing to eliminate Medicare payment for color Doppler on the grounds that this service is "intrinsic" to the performance of other echocardiography services. In fact, however, it is our understanding that color Doppler is not performed with many echocardiographic studies; therefore, it does not appear that the assumption underlying CMS's proposal is factually accurate. And even if color Doppler were intrinsic to the performance of all echocardiography studies, the Medicare payment for these services do not incorporate the direct or indirect costs of providing color Doppler, and for this reason it would be inappropriate to eliminate all Medicare payment for these important studies without increasing the Medicare payment for the echo "base" services with which color Doppler is provided.

Also, we understand that the CPT Editorial Panel has recently approved a new CPT code that includes color Doppler (CPT 93325), spectral Doppler (CPT 93320), and transthoracic echocardiograms (CPT 93307), and that the AMA Relative Value Update Committee is planning to value this new code using established valuation procedures. It is unclear to us why CMS is proposing an approach that appears to be inconsistent with that chosen by the RUC, especially in light of CMS's integral role in RUC deliberations.

For these reasons, we urge CMS to refrain from finalizing its proposal to "bundle" color Doppler into all "base" echocardiography codes in 2008, but rather to address this issue through recognition of the new "bundled" spectral Doppler-color Doppler- transthoracic echo code in CY 2009.

Cardiac Monitoring Services

Philips is extremely concerned about the continued reduction in Medicare payment for remote cardiac monitoring services. We are in agreement with comments filed by the Remote Cardiac

Services Provider Group regarding the current undervaluation of the direct costs involved in the provision of these services, including, for example, telephone transmission or line costs; web access fees; and holter and event monitor usage times. We strenuously urge CMS to adopt the modifications supported by the Remote Cardiac Services Provider Group with respect to direct costs.

We also note that cardiac monitoring services, like medical imaging services, are disadvantaged by the current allocation formula for indirect practice expenses, since remote cardiac monitoring services are "TC" services that do not include any physician work RVUs, and since the physician time involved in interpreting the studies is relatively minimal. Again, we believe that a review of the impact of the indirect PE allocation methodology would go a long way toward alleviating the untenable reductions proposed for remote cardiac monitoring services over the next several years.

Multiple Procedure Reduction and the DRA

We understand that CMS is proposing to retain the current 25% multiple procedure reduction applicable to certain medical imaging services. We very much appreciate CMS's decision not to increase the reduction from 25% to 50%; however, we continue to believe that any procedures that are subject to the "cap" on technical component payment that is imposed by the Deficit Reduction Act (DRA) should be exempted from the multiple procedure reduction.

In enacting the DRA, Congress intended to begin to level the playing field among the various sites of service commonly used for the performance of medical imaging services. The multiple procedure reduction results in substantially lower Medicare payment for medical imaging services (especially CT services) provided in non-hospital settings than in hospital settings, which we believe is inconsistent with the intent of the "cap."

Moreover, CMS decided not to apply the multiple procedure reduction to hospital outpatient medical imaging services because the APC rates already may reflect any cost efficiencies derived by hospitals from the provision of multiple imaging services on adjacent body parts at the same time. Medical imaging services performed in non-hospital settings and subject to the "cap" are paid on the same basis (*i.e.*, the applicable APC) as those same services provided in hospital outpatient settings. If the APC rates already reflect economies attributable to the concurrent performance of multiple procedures, then the imposition of an additional multiple procedure reduction for services performed in non-hospital settings is duplicative. It is clearly inappropriate to apply the multiple procedure reduction to facilities that are paid the HOPPS APC rates, simply because they bill as freestanding, rather than hospital-based, imaging centers.

Application of the DRA to "Bundled" Imaging Services

We note that CMS's proposed rule to establish Medicare payment rates and policies for CY 2008 under HOPPS (the "HOPPS Proposed Rule") proposes "bundling" a number of ancillary medical

imaging studies into the "principal" procedures that are provided at the same time. In addition, the HOPPS Proposed Rule would "bundle" Medicare payment for most image guidance services and for radiopharmaceutical and contrast agents into the principal service(s). If the HOPPS Proposed Rule is finalized without change, the APC payment for the principal procedure(s) will include Medicare payment for the "bundled" image guidance, radiopharmaceuticals, contrast agents, and other image-related services and separate payment for the bundled items and services will be disallowed.

Thus, for example, if the HOPPS Proposed Rule is finalized in its present form, the APC rate for PET (and PET/CT), CT/CTA, and MRI/MRA services will include Medicare payment for the applicable radiopharmaceutical(s) (in the case of PET and PET/CT) and for the applicable contrast agent(s) (in the case of MRI/MRA and CT/CTA). Likewise, the APC rate for myocardial perfusion (SPECT) imaging will include payment for the applicable radiopharmaceutical(s), stress agent, and the two principal "add-on" services generally performed with SPECT imaging.

Under the DRA, Medicare payment for the technical component of medical imaging studies is "capped" at the rate applicable to comparable procedures performed in a hospital outpatient setting and reimbursed under HOPPS. However, the applicable APC rate(s) for many of the procedures otherwise subject to the DRA will be either eliminated (in the case of certain imaging guidance services) or modified to include payment for add-on services, contrast agents, or radiopharmaceutical(s) – items and services that are paid separately under the Physician Fee Schedule. Thus, for many of the procedures otherwise subject to the DRA "cap" there will be no APC rate that is the direct analogue of the TC payment under the PFS.

We believe that it would be inappropriate to apply the DRA "cap" to any medical imaging procedure which, when performed in a hospital setting, is either "bundled" into the APC rate(s) of other procedure(s) (such as the image guidance codes) or is only one component of an APC that includes items or services that are separately payable under the PFS (such as CT/CTA; MRI/MRA; PET/PET-CT and myocardial perfusion (SPECT) studies). We request that, in the preamble to the final PFS rule, CMS clarify that the DRA is inapplicable to these services.

Proposed Physician Self-Referral, IDTF, and Assignment Changes

Many of the technical changes to the physician self-referral, assignment and IDTF rules set forth in the PFS Proposed Rule best addressed by the providers involved. However, we are troubled by the tone of CMS's discussion of these issues.

It appears that CMS is under the impression that the growing utilization of medical imaging services is driven in great measure by physician ownership of imaging facilities and that many of the medical imaging services provided by physician-owned entities, such as group practices, are inappropriate. We respectfully suggest that such a view is not supported by Medicare's own data on medical imaging utilization. To the contrary, "self-referral" is extremely uncommon for most

of the Diagnostic Imaging studies whose utilization has been growing more quickly than other physicians' services, according to an analysis of 2005 Medicare claims conducted by an independent consulting firm, Direct Research. The modalities included in the analysis include CT/CTA, MRI/MRA, PET and SPECT myocardial imaging studies. That study found:

- In 2005, the proportion of ADIS that are ordered and performed by the same physician is inconsequential for CT (2.8%), MRI (3.9%), and PET (5%). Approximately 22.8% of SPECT myocardial perfusion procedures are ordered and performed by physicians for their own patients.

- Approximately **90%** of all CT, MRI, and PET services are performed by radiologists or independent diagnostic testing facilities (IDTFs) (which, under current law, cannot be owned in whole or in part by referring physicians.)

- Hospitals are the dominant providers of some of the fastest-growing diagnostic imaging services. For example, in 2005, hospitals performed 81.3% of CTs and 52.6% of MRIs.

- Imaging is used for diagnosing and treating common medical conditions, such as stomach pain, back problems, cancer, and heart disease. Since these conditions are commonly managed by primary care physicians, it is not surprising that internists, family practitioners, and emergency room physicians are the primary referral sources for these studies.

- Thus, the fastest-growing imaging services are referred most often by family physicians or internists whose practices do not perform the tests and performed most often either by independent radiologists, IDTFs, or nuclear medicine physicians (in the case of PET).

Under these circumstances, it is clear that the charge that the rising utilization of medical imaging is attributable to physician "self-referral" is a red herring.

We are also struck by the extent to which the proposed changes to the physician self-referral regulations appear to be directed at business models that are already outlawed with respect to Medicare patients under the current self-referral regulations. For example, we believe that current Medicare regulations and instructions are already reasonably clear that mark-up of technical component services is prohibited for Medicare patients. It likewise appears that part-time block lease arrangements between IDTFs and physicians whose practices are located elsewhere generally cannot be structured to meet the "in office ancillary services" exception. Thus, the primary impact of the proposed changes in these areas appear to be aimed in large measure at precluding business arrangements that have been used to enable physicians to profit from referrals of non-Medicare patients. While this may or may not be an appropriate role for CMS, we believe that it would be useful to explicitly identify any proposed changes that are undertaken primarily to address business arrangements due to their potential impact on non-Medicare patients and payers.

We are also concerned about the apparent "micro-management" of physician groups' internal compensation arrangements and the implication that physician practices that are not in a position to engage a full time medical imaging specialist may be precluded from providing these services to their patients. We do not believe that such restrictions are authorized by the self-referral prohibition in the Medicare Act or any other provision of law, and strongly urge CMS to reconsider the extent to which it is appropriate to intervene in physicians' provision of imaging services in convenient office-based settings.

In this regard, it is troubling that the Proposed PFS Rule goes so far as to suggest that there are some services that may not be appropriate for the "in office ancillary services" exception. While CMS does not elaborate on the types of services that it believes may be ineligible for this exception, we strongly oppose limiting the applicability of this exception in any way that is not explicitly authorized by statute. As detailed above, an extremely small proportion of the most rapidly growing imaging studies are performed by physicians for their own patients, and precluding physician practices from providing medical imaging services in their own offices simply is not in the interests of the Medicare program or Medicare patients. We respectfully suggest that CMS's time and effort would be better spent in finding ways to assure that medical imaging – and all physicians' services – are provided only when appropriate, regardless of the setting in which they are offered and regardless of who provides them.

Finally, we would hope that CMS will clarify in the final PFS Rule that mobile IDTFs are not precluded from sharing space and facilities with physicians' offices or other providers. Clearly use of other facilities' space and facilities is integral to the operation of mobile facilities, many of which provided needed imaging and other services to patients in outlying areas.

We appreciate the opportunity to comment on the Proposed PFS Rule, and look forward to working with CMS on these and other issues in the future.

Sincerely yours,

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