PHILIPS

September 6, 2016

BY ELECTRONIC DELIVERY

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue S.W.
Room 445-G
Washington, DC 20201

Re: Comments on CMS-1656-P: Medicare Program; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Administrator Slavitt:

On behalf of Philips Healthcare (Philips), I am pleased to have the opportunity to comment on the 2017 Hospital Outpatient Prospective Payment System (the "Proposed Rule"). Philips provides solutions that span the health continuum, including imaging, patient monitoring, and cardiac care systems; medical alert systems; sleep management and respiratory solutions; healthcare informatics solutions and services; and a complete range of comprehensive telehealth programs.

For the reasons set forth below, we believe that:

- CMS should refrain from implementing the proposed restructuring of the Ambulatory Payment Classifications (APCs) for imaging procedures in 2017 and, to the extent that further consolidation of imaging APCs is sought, should work closely with the affected community to devise an APC structure that groups clinically comparable procedures together.

- CMS should delay implementing the provisions of Section 603 of the Balanced Budget Act of 2017 (Section 603) with respect to payment for new off-campus provider based departments (PBDs) until an appropriate facility enrollment and payment mechanism can be established and should refrain from implementing the proposed restrictions on off-campus PBDs that billed Medicare prior to Section 603's effective date.

- CMS is proposing to align packaging logic for all of the conditional packaging status indicators such that packaging would occur at the claim level and not based on the date of service (DOS). Since it is anticipated that adoption of this proposal would significantly expand packaging of imaging services and since there is evidence that many hospitals are not continuing to submit claims for packaged imaging procedures, we urge CMS to work closely

with the affected community to ensure that all imaging services—regardless of whether or not they are packaged—continue to be reported on hospital claims.

- Because the Proposed Rule does not set forth with specificity the film x-ray procedures subject to the discounts mandated by Section 502 of the Consolidated Appropriations Act of 2016, the agency should limit application of these reductions to the extent practicable. CMS should publish a list of the computed radiography services subject to future reductions in next year's HOPPS and PFS Proposed Rules.

- We urge CMS to ensure that the Appropriate Use Criteria (AUC) Program is implemented in a manner that will not place excessive administrative burdens on ordering and performing physicians, and to consider piloting Clinical Decision Support Mechanisms (CDSMs) prior to full implementation.

- We concur with the ACR's comments on C-APCs and packaging, and incorporate those comments by reference.

I. APC Restructuring

For CY 2017, CMS is proposing to restructure the Ambulatory Payment Classifications (APCs) for diagnostic imaging procedures, reducing the total number of non- nuclear medicine APCs from 17 to 8. Currently, the imaging procedure APCs are grouped based on the imaging technology used as well as whether or not contrast media are used. By contrast, the Proposed Rule would establish APCs that intermingle procedures performed using CT, MRI, X-Ray and ultrasound technologies in the same APC. While the Proposed Rule does not appear to provide any rationale for the proposed consolidated APC groupings, it appears that CMS' proposal classifies procedures based on whether or not contrast is used, but otherwise classifies procedures solely on the basis of their estimated geometric mean costs.

The proposed restructuring would result in massive payment shifts for individual modalities. While we have not had the opportunity to conduct a full analysis, it appears that, assuming the most recent available utilization data, Medicare payment for MRI procedures would be reduced by around -$85 million and Medicare payment for general ultrasound services would be reduced by an estimated -$60 million, while Medicare payment for x-ray procedures and CT procedures in the aggregate would increase. See Attachment A. In addition, due to the restrictions imposed by the DRA, the significant reductions in HOPPS payment for MRI procedures would result in a reduction in payment for certain MRI services in non-hospital settings of almost 20%.

We find it highly disturbing the CMS provides essentially no explanation of the methodology employed for the massive reconfiguration of the imaging procedure APCs, especially since CMS just undertook a wholescale restructuring of these same APCs last year. The 2016 restructuring reduced the number of non-nuclear imaging APCs from over 50 APCs to 17. At the time, Philips requested a delay in implementation of the proposal in light of the substantial swings in payment that it entailed, especially for CT and ultrasound, noting, for example, that CTA (chest (71275), CT of the abdomen and pelvis (74176-74178) were all reduced by 13-15%. This year's Proposed Rule would reduce Medicare payment for many of the same codes by an additional 20%. Annual reshuffling of APC assignments undermines the stability that providers need in order to plan for the major capital expenditures necessary to ensure that diagnostic imaging equipment is replaced when necessary and maintained in a manner that facilitates the provision of high quality care. We believe that it would be prudent for CMS to delay any further restructuring of these APCs until the implications of last year's significant consolidation can be analyzed.

While we are aware of CMS' strong interest in consolidating APCs, we believe that this particular proposal is inconsistent with the governing statute, which explicitly requires that the procedures assigned to APCs be "comparable clinically and with respect to the use of resources" (Social Security Act, Section 1833(t)(2)(B)). By contrast, the APC assignments set forth in the Proposed Rule are clinically random, grouping together procedures performed with different equipment, using different clinical personnel, requiring different supplies, and associated with highly variable overhead. The services are provided by different physicians, for different clinical conditions, and in different hospital departments. For example, proposed APC 5524 includes 35 procedures, including:

- eight codes involving lumbar, spinal and neck injections for myelography,
- eight echocardiography codes,
- over ten x-ray codes,
- a barium enema for colon cancer screening, and
- an MRI code.

For CMS to group these procedures together and assert that they are "clinically comparable" suggests that the agency believes all imaging to be fungible, an assumption that, in our, is clearly inconsistent with sound clinical practice.

We are also concerned that, because procedures appear to be grouped solely on the basis of their geometric mean costs, the proposed APCs are inherently unstable and may need to be reconfigured again next year as the result of anticipated drops in the geometric mean costs of CT and MRI due to the incorporation of cost and charge data from hospitals that have historically allocated equipment costs on a square footage basis. Specifically, it is anticipated that the geometric mean costs of MRI and CT procedures will be reduced substantially in 2018, when the data from all hospitals is used, rather than excluding the data from hospitals that allocate equipment costs on a square footage basis. We do not understand the logic of restructuring imaging APCs based solely on geometric mean costs when the geometric mean costs of many of the most complex procedures (MRI and CT, as well as cardiac catheterization) are still in the midst of a transition. [1] An added concern is that, if the proposed diagnostic APCs are finalized without change, the 2018 declines in the geometric mean costs of CT and MRI will adversely impact payment for non-advanced imaging services with which they are grouped (such as x-ray and ultrasound), whose allowances should not be impacted by hospitals' failure to adhere to proper cost reporting principles for the equipment associated with MRI and CT.

In addition, we believe that the proposed restructuring will have significant unanticipated consequences. The restricting results in a significant difference in the payment rates between APCs:

[1] CY 2018 will bring not only substantial changes in rates for the most complex imaging procedures but also may bring significant changes in the volume of radiological procedures that are separately paid: It is anticipated that, if implemented, the move to "package" services on a claim basis rather than on the basis of the date of service, will significantly change the volume and mix of imaging procedures that are separately paid, thereby further destabilizing the rates.

APC	Group Title	Payment Rate
5521	Level 1 Diagnostic Radiology without Contrast	$63.33
5522	Level 2 Diagnostic Radiology without Contrast	$117.40
5523	Level 3 Diagnostic Radiology without Contrast	$218.74
5524	Level 4 Diagnostic Radiology without Contrast	$440.92
5525	Level 5 Diagnostic Radiology without Contrast	$687.34
5571	Level 1 Diagnostic Radiology with Contrast	$278.87
5572	Level 2 Diagnostic Radiology with Contrast	$467.39
5573	Level 3 Diagnostic Radiology with Contrast	$777.31

Such significant a differentials between APCs can be expected to incentivize substantial "gaming," especially since, in some cases, the procedures involving the same modality and the same anatomical region are in different APCs (e.g. (CPT 76705) (limited abdominal ultrasound CPT 76705)($117.40) vs. (CPT 76700)(complete abdominal ultrasound ($218.74). In addition, the proposal includes glaring rank order anomalies (CPT (e.g. CPT 73120) (Radiological examination hand (two views) ($117.40) vs. (CPT 73130)(radiological examination hand (minimum of three views) ($63.33)). We are confident that a close analysis would reveal additional inconsistencies.

In light of the potential for rank order anomalies and gaming that naturally result from placing CPT codes that use identical technologies in different APCs, it is unclear what objective CMS is seeking to achieve in following this course of action. So long as diagnostic imaging procedures are not packaged—and by definition the procedures payable under the restructured APCs are not—the HOPPS essentially functions as a fee schedule, and rank order anomalies and opportunities for gaming through upcoding should be minimized. Those objectives are best achieved by grouping procedures that use the same equipment for the same anatomical region together, except as required by the "two times" rule. By intermingling the modalities and anatomical regions imaging indiscriminately, the proposed restructuring proposal is inimical to CMS' interests in increasing incentives to the delivery of cost effective care.

We believe that the proposal is also inimical to a number of the agency's broader policy objectives. It appears that CMS is moving rapidly toward episode based payment, along the lines of the Bundled Payment for Care Improvement models, and, to this end, has already instituted a joint replacement bundle which is proposed to be expanded along with institution of new Myocardial Infarction/CABG bundle. For the purposes of determining whether demonstration participants are entitled to shared savings (or responsible for shared losses), these demonstration programs compare Medicare revenues for the selected episodes during the performance period to those in a historical base period. By drastically modifying the allowances for numerous imaging services at this time, CMS would be complicating the integrity of these cost comparisons. For example, if a physician ordered an MRI of the chest and spine with contrast (CPT 72147) during the base period, the allowance built into the benchmark in 2017 performance period might be in the range of range of $454 (2016 rate), but if she ordered the same test in a 2017, the amount credited for the test would be $278. Thus it appears that instituting so drastic an APC restructuring at this time has the potential to distort cost saving calculations with regard to episodes of care that use imaging (in this case, by attributing $176 in savings to a physician who did not change her practice pattern).

Finally, the proposed restructuring will result in draconian reductions for important screening procedures, such as lung cancer and osteoporosis screening. Under the proposal, Medicare payment for Low-dose CT lung cancer screening (LDCT-LCS) –which only gained coverage in 2015—would be slashed by 44%. This extraordinary payment reduction is highly likely to preclude this critical screening service to gain sufficient traction to be readily accessible to Medicare patients. Many providers are just beginning their Lung Cancer screening programs and such a reduction in payment will undoubtedly hamper their ability to continue this vital community service, and providers who have not yet begun to offer LDCT-LCS screening will be dissuaded from doing so if the inadequate Medicare payment rate set forth in the Proposed Rule is finalized.

We believe that the consolidation of imaging APCs from over 50 APCs to 17 APCs, which was effectuated this year, goes a long way toward the kind of APC consolidation that CMS has announced as its objective. Of the over 270 current procedure/service APCs, only 17 are for non-nuclear diagnostic imaging. But to the extent that CMS seeks further APC consolidation, we are confident that the number of APCs can be reduced further without completely sacrificing clinical homogeneity. Such an approach would accomplish CMS' objective of reducing the number of APCs while limiting the opportunity for gaming, test substitution, and rank order anomalies. We urge CMS to refrain from implement the proposed restructuring and rather to work with the entire affected community to design imaging APCs that meet CMS' objectives while preserving clinical homogeneity.

II. Implementation of Section 603 of the Bipartisan Budget Act of 2015.

Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74) ("Section 603"), mandates payment of the services provided by certain off-campus PBDs (Non-Grandfathered PBDs) that first bill Medicare on or after November 2, 2015 on the basis of an "applicable payment system" other than HOPPS, and the Proposed Rule indicates that the "applicable payment system" for Non-Grandfathered PBDs will be the Physician Fee Schedule (PFS).

Preliminarily, we note that limiting Medicare payment rates for diagnostic imaging procedures provided by Non-Grandfathered PBDs to those paid under the PFS is likely to substantially constrain the provision of these vital services in remote locations Medicare payment for diagnostic imaging under the PFS are extremely low as the result of eleven separate payment reductions to PFS payments for imaging services over the last decade that resulted in precipitous payment drops in the range of -60 percent on average between 2006 and 2014 for MRI and 42 percent on average for CT. Applying these rates to Non-Grandfathered PBDs is likely to further impede access to these and other imaging services in locations remote from main hospital campuses. While we understand that CMS is obligated to implement Section 603, we urge the agency to closely monitor access to diagnostic imaging in remote areas that may be adversely impact by the extension of PFS rates to Non-Grandfathered PBDs.

Because CMS believes that it does not have time to implement information systems necessary to enable Non-Grandfathered PBDs to be paid for their services under the PFS by January 1, 2017 (the effective date of Section 603), it is proposing an interim solution, which would be in effect for one year only. Under the interim solution, a Non-Grandfathered PBD would be required to either: (1) enroll in Medicare Part B as a "physician group practice", or (2) require the physicians who provide services at the Non-Grandfathered PBD to bill for facility as well as professional services under the PFS (by claiming that they are provided in a "non-facility" site of service) and then compensate the hospital for the facility services provided by the Non-Grandfathered Facility.

We believe that implementation of the proposed interim solution places both hospitals and the physicians who practice at Non-Grandfathered PBDs at legal risk and, in any event, the proposed approach is not

practicable. Specifically, a Non-Grandfathered PBD that enrolls in the Medicare Program as a physician group practice when it is not, in fact, a group practice, may incur legal risk, since the applicable enrollment forms universally require the entity enrolling to attest to the truth of all statements made in the application. Moreover, since the HOPPS Final Rule likely will not be issued prior to early November, we believe it highly unlikely that Medicare Administrative Contractors (MACs) will process the required paperwork in time for hospitals to receive their new supplier numbers, program their systems and train billing personnel by January 1.

Nor is requiring physicians who provide services at a Non-Grandfathered PBDs to file claims for facility services and then pay hospitals a workable solution. An arrangement along these lines between a physician practicing a Non-Grandfathered PBD and the hospital would likely constitute a financial relationship within the meaning of the physician self-referral provisions set forth in Section 1877 of the Social Security Act, and it is unclear whether any exception would be available. Moreover, a physician who submits a claim indicating that a service was provided in a non-facility setting when it was in fact provided in a facility setting has the potential to trigger false claims liability. Finally, it is unclear how the hospital and the physician are to determine the amount to be paid by the physician to the hospital, without triggering anti-kickback concerns: If the physician retains too much, it could be argued that the hospital is incentivizing referrals, and if the hospital demands too much, it could be argued that the physician is paying the hospital for its referrals.

Thus the stop-gap approach outlined in the Proposed Rule –a solution that, in any event, is only anticipated to last for one year--is likely to raise significant legal concerns and require the expenditure of considerable time and effort by both providers and physicians. We believe that, rather than requiring providers to bear the brunt of this "work around" , CMS should work assiduously to establish the provider enrollment and billing mechanisms necessary to facility PFS payment for Non-Grandfathered PBDs and implement the new program once and done. While we recognize that Section 603's statutory effective date is January 1, 2017, the burden of compensating for the agency's inability to implement the provision properly by that date should not be shifted to providers.

> *<u>Recommendation:</u> Philips urges CMS to delay implementation of Section 603 with respect to Non-Grandfathered PBDs until appropriate enrollment and payment mechanisms can be implemented.*

We are also concerned about the restrictions that the Proposed Rule would place on off-campus PBDs that were billing for items and services under the HOPPS on and before Nov. 2, 2015 ("Grandfathered PBDs"). Under the Proposed Rule, Grandfathered PBDs could not relocate or change ownership without losing grandfather status, and the scope of their services that are reimbursable under HOPPS would be restricted to the "Clinical Families" provided prior to Section 603's effective date. We believe that these restrictions have the potential to substantially impede access to imaging services in outlying areas, or at the very least to significantly inconvenience patients.

Section 603itself does not suggest or imply any restriction on the operations of Grandfathered PBDs, and we do not believe that the scope of the statute should be extended beyond its terms. Grandfathered PBDs should be accorded the flexibility to relocate as necessary –whether as a result of natural disasters or for any other reason. Such facilities may be part of a larger hospital system that may wish to reorganize for any number of legitimate reasons. Yet, under the Proposed Rule, a change of ownership of a Grandfathered PBD in conjunction with a larger reorganization may jeopardize the PBD's grandfather status. And we see nothing in the statute that authorizes CMS to limit the availability of HOPPS payments to only certain services provided by a Grandfathered PBD.

We are also concerned that such restrictions have the potential to substantially impede the type of operational efficiencies that are increasingly necessary in an era of rapid transition to alternative payment models. In light of the rapidity of the changes impacting all providers, it is extremely important that they be provided the flexibility to adopt, as necessary to achieve the cost reduction and quality improvement goals increasingly required by payers and patients. By placing Grandfathered PBDs in any operational "straightjacket", the Proposed Rule would impede their ability to relocate and add services (including preventive services) as necessary to meet community needs.

Recommendation: Philips urges CMS to refrain from finalizing the limits on Grandfathered PBDs related to relocations, changes of ownership, and the scope of services eligible for HOPPS payment.

III. Hospital Reporting of Packaged Procedures

It is our understanding from discussions with the American College of Radiology that there is substantial evidence that imaging services performed in conjunction with C-APCs are not being reported by hospitals, and we believe that the same is likely true with respect to other packaged imaging services. We anticipate that adoption of the proposal to align packaging logic for all of the conditional packaging status indicators such that packaging would occur at the claim level and not based on the DOS will substantially increase packaging of imaging and many other services. As packaging continues to expand, hospitals' failure to accurately report packaged services will result in inaccurate—and inadequate—payment rates for many procedures that involve significant imaging and other ancillary services.

Recommendation: Philips recommends that CMS work with the affected community to put in place processes to ensure that hospitals continue to report packaged imaging and other packaged ancillary services.

IV. Implementation of Payment Reductions for Film X-ray and Computed Radiography

Under Section 502 of the Consolidated Appropriations Act of 2016, Medicare payment for the technical component (TC) of film X-Ray services is to be reduced by 20% beginning on January 1, 2017. Unfortunately, CMS has failed to publish the list of services to which this reduction will apply, making it difficult to comment implementation of this provision. Under these circumstances, we urge CMS to apply the reduction only to those procedures that are clearly straightforward film X-ray services.

We note that the Proposed Rule does not address implementation of Section 1848(b)(9)(B) of the Act, which provides for a 7 percent reduction in payments during CY 2018-2022 and a 10% reduction in CY 2023 and subsequent years for imaging services made under the PFS that are X-rays (including the X-ray component of a packaged service) taken using computed radiology. We strongly urge CMS to publish a list of the services to which these reductions apply in the HOPPS and PFS Proposed Rules for 2018. Without such a list, it will be extremely difficult for Philips and others to submit meaningful comments next year. Specifically, for the reasons set forth in the comments submitted by MITA, we believe that neither the reductions applicable to film X-ray to be instituted in 2017 nor the reductions to be instituted in 2018 and thereafter with regard to computed radiography should impact mammography.

V. Appropriate Use Criteria (AUC) Program Implementation

Philips has been, and continues to be, a strong supporter of the appropriate use criteria (AUC) policy, a policy that has the potential to improve quality and reduce medically unnecessary testing. It is because

we are strong supporters of this policy that we raise our concerns about CMS' Proposed Rules for implementing the policy.

Over the next several years, physicians will be facing increasingly complex administrative burdens as MACRA is implemented, including new rules for reporting of patient relationship and patient condition codes, new requirements pertaining to electronic health records and data submission, new requirements with regard to quality reporting and assessment, and new requirements to engage in clinical practice improvement activities. It is an unfortunate circumstance of timing that the new AUC program for advanced imaging services will be rolled out during the same period, and this coincidence of timing makes it extremely important that the requirements imposed on both physicians who order advanced imaging and those that perform these services be easy to use and straightforward, lest access to potentially critical advanced imaging services be deterred or denied.

Philips is extremely concerned that the manner in which CMS is proposing to implement this program is administratively burdensome and overly complex. While we understand CMS' interest in ensuring an open process for approving Provider- Led Entities (PLEs) whose AUC are to be used in the program, the multiplicity of PLEs that have been approved by CMS is likely to complicate the decision-making process for referring physicians, make it more difficult for performing physicians to ensure that an approved AUC was consulted, and make it more difficult for CMS to reliably identify "outliers."

CMS' proposed rules for Clinical Support Decision Mechanisms (CSDMs) are likely to further complicate all of these tasks. Unfortunately, the Proposed Rule has already created significant confusion regarding which procedures will be subject to the AUC consultation requirements. In particular, the Proposed Rule specifically states that CDSMs need only include AUC for the "focus areas" specified in the Proposed Rule, leading many readers to conclude that ordering physicians' AUC consultation requirements will be limited to these areas. Discussions with CMS suggest that, in fact, the AUC consultation requirements will apply to all advanced imaging services, and that if the CDSMs do not include AUC for an imaging study because, for example, the study is not ordered for a "focus area" indication, the AUC will be considered "inapplicable". We believe that such a process is likely to result in considerable frustration for ordering and performing physicians who will be required to document compliance with a process that is likely to be "inapplicable" in many situations. In addition, such a process is likely to yield incomplete and unreliable information when it comes time for CMS to identify "outliers", as required by the statute. We note that the fact that there were no applicable AUC was one of a number of factors that hampered the effectiveness of the AUC demonstration program for advanced imaging services that was previously conducted by CMS.

We are also concerned that the Proposed Rule fails to address the statutory provisions requiring that there be a free CDSM for any "applicable imaging service" that is subject to the AUC consultation requirements.

Recommendation: In light of these considerations, we urge CMS to refrain from implementing the program as proposed but, rather to scale it back to include only selected "applicable imaging services" and selected indications. CDSMs should be piloted for the first year, and the program should not be launched unless and until there is a simple, straightforward, and free way for all ordering physicians to implement the program and for performing physicians to check to ensure that the studies they perform have been entered into an approved CDSM.

We are pleased to have this opportunity to comment on the Proposed Rule. If you have any questions regarding these comments, please do not hesitate to contact me at lucy.mcdonough@philips.com>

Sincerely yours,

/s/

Lucy McDonough
Director Market Access North America
Philips

(978) 764-8889