PHILIPS

September 11, 2017

BY ELECTRONIC DELIVERY

The Honorable Seema Verma
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–1678–P Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2018 HOPPS Proposed Rule" or "Proposed Rule")

Dear Administrator Verma:

On behalf of Philips Healthcare (Philips), I am pleased to have this opportunity to comment on the 2018 HOPPS 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.

Our comments focus on the potential impact of the proposed rule on Medicare payment for diagnostic imaging services, coronary angiography; certain drug-coated balloon interventional cardiology procedures and related imaging guidance; application of site neutrality adjustments for new off-campus provider based facilities; and the potential impact of the proposed rule on payments made to cancer hospitals, academic medical centers, and other hospitals serving a disproportionate share of uninsured or underinsured patients.

I. Diagnostic Imaging

A. Ensuring Stability of Diagnostic Imaging APCs.

Once again, diagnostic imaging procedures would experience substantial payment fluctuations if the Proposed Rule were adopted without change, and, generally, Medicare payment for imaging APCs will be significantly lower in 2018 if the proposed rates are adopted without change:

APC	Group title	Published APC Rate 2017	Published APC Rate 2018	Change in published rate
5521	Level 1 Imaging without Contrast	$60	$59	-1%
5522	Level 2 Imaging without Contrast	$113	$97	-14%
5523	Level 3 Imaging without Contrast	$226	$150	-34%
5524	Level 4 Imaging without Contrast	$450	$264	-41%
5525	Level 5 Imaging without Contrast		$473	
	Imaging without contrast total			
5571	Level 1 Imaging with Contrast	$265	$227	-14%
5572	Level 2 Imaging with Contrast	$427	$339	-20%
5573	Level 3 Imaging with Contrast	$657	$488	-26%

On an individual CPT code, the proposed payment swings are likewise dramatic. Under the proposal, payment for many relatively high volume hospital outpatient CT procedures would decrease by 14%, while proposed payment for commonly performed MR procedures reflect payment decreases in the range of 20%.

We continue to be extremely concerned that the annual fluctuations in Medicare payment for capital intensive diagnostic imaging services inject considerable uncertainty into hospitals' planning processes for capital-intensive imaging equipment. The imaging APC reconfiguration that went into effect in CY 2017 significantly exacerbates the problem by intermingling very different imaging modalities into the same APCs. While we understand that Medicare payment for various imaging procedures may increase or decrease due to changes in resource utilization such as technological changes that substantially increase or decrease costs, we believe that the HOPPS methodology should be designed and implemented to minimize random payment changes resulting solely from annual APC reclassifications and other technical aspects of CMS payment formulas.

Significantly, however, significant reductions in the APC rates impacting non-enhanced diagnostic imaging procedures appear to be entirely the result of CMS's proposed APC reconfiguration and reclassifications. For 2018, CMS is proposing to increase the number of APCs for unenhanced imaging procedures from four to five APCs, and to reclassify many procedures within the APC family, resulting in significant payment reductions for these procedures as a whole. If the number of APCs for unenhanced procedures and the classification of procedures within APCs had remained unchanged, however, there would have been only minimal change in payment. The conclusion is that all the payment reductions seen in this APC range are due to the reconfiguration of the APCs. If CMS had left them alone, payments would have been virtually unchanged

Model 2018 payments if CMS had left these imaging APCs unchanged				
APC	Group Title	Actual 2017 payment rate	2018 rate if there had been no 5525 created	% change
5521	Level 1 Imaging without Contrast	$59.86	$60.25	0.7%
5522	Level 2 Imaging without Contrast	$112.73	$112.11	-0.5%
5523	Level 3 Imaging without Contrast	$225.91	$226.85	0.4%
5524	Level 4 Imaging without Contrast	$449.68	$471.66	4.9%
5525	Does not exist in this scenario			

Thus the conclusion is inevitable that the Proposed Rule would institute substantial payment reductions for unenhanced diagnostic imaging procedures based solely on APC reconfiguration, even though the costs and charges for these procedures remain unchanged. This is precisely the kind of result that should be avoided.

The proposed reductions in Medicare payment for contrast-enhanced imaging procedures result in large measure from reclassifications of procedures within the existing APCs and not in significant reduction in the costs of, or charges associated with, these procedures. We note that these reclassifications result in a two-time rule violation for Level 3 Imaging with Contrast procedures, and while the preamble of the Proposed Rule suggests that this two times rule violation meets CMS' exception requirements, no detail is provided and it is unclear to us which exception, if any, is applicable.

Recommendation: *Contrast-Enhanced Imaging APCs We request that either the 2017 APC classifications for contrast-enhanced imaging procedures be retained without change or a new Level 4 APC be created for Imaging with Contrast, to eliminate the two times rule violation.* In order to increase the stability of the system overall, we have the following recommendations:

> ***Recommendation**: **Stability of Annual Adjustments**. We request that CMS review the APC classification of each diagnostic imaging procedure and reclassify or otherwise significantly modify the APC rate for the procedure only if its geometric mean cost varies in a manner that is statistically significant from the average geometric mean cost of the procedure for the prior three years.*

> ***Recommendation**: **Stability and Accuracy in Reflecting Imaging Equipment Costs in APC Rates.** Philips supports CMS' proposal to continue to remove claims from providers that allocate MRI and CT equipment costs across all cost centers using a ''square feet'' allocation methodology. Moreover, until hospitals begin to properly allocate MRI and CT equipment costs appropriately, cost-to-charge ratios (CCRs) for the MRI and CT cost centers will continue to be distorted. For this reason, we urge CMS to continue to refrain from utilizing the cost and charge data from hospitals that utilize the square footage allocation methodology in determining CT and MRI APC rates in 2019*

and future years, until cost allocation methodologies used by hospitals reflect Medicare instructions.

Recommendation: ***Long Term Stability in the Face of Increased Packaging.*** *Philips is extremely concerned that a recent study by the American College of Radiology (ACR) suggests, under CMS' current and proposed packaging policies, imaging procedures are increasingly packaged, rather than being separately paid, and that, as a result, hospital often no longer report the performance of imaging procedures. We urge CMS to modify packaging policies to exempt multiple imaging procedures performed on the same date of service as a "significant procedure")(SI J-1), and to provide separate payment for these imaging procedures under the applicable composite APC (C-APC).*

B. Ensuring Diagnostic Imaging APC Rates that More Accurately Reflect Costs of Resource Intensive Imaging Procedures.

The Diagnostic Imaging APC configurations for both contrast-enhanced and unenhanced procedures is significantly "skewed" toward lower-paying APCs, and the dollar intervals between APCs increases as procedures get more costly. The following charts sets forth the number of procedures in each diagnostic imaging APC, and the geometric mean cost for procedures in each APC.

APC	Group title	Total Frequency After Screens	CMS geometric mean cost
5521	Level 1 Imaging without Contrast	13,425,754	$62
5522	Level 2 Imaging without Contrast	9,700,472	$100
5523	Level 3 Imaging without Contrast	6,885,953	$156
5524	Level 4 Imaging without Contrast	1,991,250	$275
5525	Level 5 Imaging without Contrast	2,180,057	$492
5571	Level 1 Imaging with Contrast	2,137,693	$236
5572	Level 2 Imaging with Contrast	2,044,173	$353
5573	Level 3 Imaging with Contrast	1,135,600	$507

As this chart illustrates, there is a $ 217 difference between the rate for Level 4 and Level 5 unenhanced diagnostic imaging procedures, and a $154 difference between the rates paid for Level 2 and Level 3 contrast-enhanced procedures. Such large dollar intervals between the APC rates for the most costly imaging procedures makes the APC classification system for imaging

services extremely unstable: Im the case of unenhanced procedures, for example, reclassification of a high volume procedure from Level 4 to Level 5 may result in a payment reduction of about 44%, which may destabilize the imaging department's financial projections and disrupt the capital planning process. In addition, such widely spaced APC rates necessarily result in Medicare greater variation within APCs. To the extent that CMS does consider future reconfigurations in this area, we urge the agency to establish APC rates that minimize the "stakes" involved in reclassification of the most capital intensive imaging services.

II. Coronary Angiography

An analysis conducted by Direct Research (Chris Hogan) indicates that CMS ignored a large set of potential complexity adjustments for coronary angiography. In this regard, it appears that CPT codes that count as add-ons for coronary *angioplasty* in determining complexity adjustments were not counted as add-ons for coronary *angiography*, affecting about 20,000 claims. The ignored add-on codes include: 0291T (intravascular optical coherence tomography), 92978 (intravascular ultrasound), 93571 (Heart flow reserve measure).

Recommendation: We urge CMS to review the complexity adjustment for coronary angioplasty and determine whether all add-on codes were properly included

III. Angioplasty using Drug-Coated Balloon Technology

Angioplasty using Drug-Coated Balloon Technology

Drug-coated balloons represent an important recent advancement in the treatment of peripheral artery disease (PAD). In April, 2015, CMS recognized the substantial improvement in care provided by drug coated balloon (DCB) technology (marketed by Medtronic and Bard) and issued a transitional pass-through payment for DCBs to support access to the technology among Medicare beneficiaries; this payment will expire at the end of 2017. Recently, the FDA approved the Stellarex™ drug-coated balloon, manufactured by Spectranetics, now a part of Philips Image Guided Therapy Devices. We are very concerned that finalizing this proposal without change, has the potential to limit patient access to DCB technology for Medicare beneficiaries, because the proposed CY2018 payment for DCB angioplasty procedures does not adequately reflect the additional costs of the more advanced DCB technology.

Symptomatic PAD of the lower extremity arteries is a chronic, progressive, atherosclerotic vascular disease that affects 15%-20% of those over age 70 in the United States. PAD is a major contributor to health care costs due to the high rates of morbidity, mortality, and debilitating impact on patient quality of life. Patients with lower extremity PAD generally need repeated invasive treatments to reduce incapacitating symptoms and disability, and to prevent or treat ischemic events due to the high rates of recurrence of the disease. Patients therefore need a safe and durable treatment option to relieve blockages effectively, improve symptoms, and avoid the morbidity and costs of repeated invasive treatments. DCB technology represents an important advancement in PAD

therapies, designed to overcome the limitations of previous endovascular treatments, and it has emerged as an ideal treatment option for lower extremity PAD.

CMS recognized that DCB offers superior clinical outcomes for patients and reduced hospitalizations and costs to health systems when it first approved add-on payments for DCB under both the inpatient and outpatient new technology add-on payment programs in 2015. More specifically, DCBs have demonstrated a significant reduction in loss of patency across diverse patient populations; lower rates of revascularization; and a reduction in follow-up costs. Additionally, several long term studies demonstrate that the clinical benefits of DCBs extend through 24-36 months.[1,2,3,4] Upon expiration of the add-on payments for DCB, it is important to ensure that there is an appropriate payment structure in place to ensure continued patient access.

In 2018, CMS proposes to pay the same for DCB and non-DCB balloon angioplasty procedures in the CY2018 OPPS proposed rule, at a rate that is 40% less than the estimated cost of DCB angioplasty procedures. Hospital claims data from 2016 is summarized in the table below. Specifically, the historical cost of angioplasty procedures with DCB, (CPT 37224 and C2623) of $8,483 significantly exceeds the mean cost for angioplasty cases without a DCB (CPT 37224 without C2623) by $2,087. And the difference between the mean cost of DCB cases and the overall mean cost of APC 5192 is even higher at $3,283. Based on the current assignment of DCB angioplasty cases (CPT 37224 with C2623) to Level 2 Endovascular Procedures (APC 5192 in the Hospital Outpatient Prospective Payment System), the costs of DCB cases ($8,483) will far exceed OPPS payment of $4,999 in CY2018.

CY 2018 OPPS Proposed Rule Data				
	Single Frequency	Geometric Mean Cost	Difference Relative to DCB Cases	
			$	%
37224 with C2623 (DCB)	4,575	$8,483	---	---
37224 without C2623 (non-DCB)	6,057	$6,396	-$2,087	-25%
37224 (all claims)	10,695*	$7,153	-$1,330	-16%
Overall APC 5192	92,029	$5,200	-$3,283	-39%

Sources: Analysis by Direct Research, CMS 2018 OPPS Proposed Rule CPT and APC Cost Statistics
* Does not equal the sum of prior two lines because derived from CMS' CPT Cost Statistics file rather than from modeled results.

<u>Recommendation</u>: In order to ensure patient access to DCB technology in 2018, we recommend CMS create a new procedural HCPCS code (C or G code) to differentiate DCB angioplasty procedures from non-DCB angioplasty procedures

[1] Jaff, M. Drug-Coated Balloon Treatment for Patients with Intermittent Claudication: Insights from the In.Pact Global Full Clinical Cohort ; Presented at VIVA 2016, Las Vegas, NV.
2. Schroeder H, Werner M, Meyer DR, et al. Low-Dose Paclitaxel-Coated Versus Uncoated Percutaneous Transluminal Balloon Angioplasty for Femoropopliteal Peripheral Artery Disease: One-Year Results of the ILLUMENATE European Randomized Clinical Trial (Randomized Trial of a Novel Paclitaxel-Coated Percutaneous Angioplasty Balloon). *Circulation.* 2017;135(23):2227-2236.
3. Krishnan P, Faries P, Niazi K, et al. Stellarex Drug-Coated Balloon for Treatment of Femoropopliteal Disease: 12-Month Outcomes from the Randomized ILLUMENATE Pivotal and Pharmacokinetic Studies. *Circulation.* 2017.
4. Benenati JF. A Prospective, Global, Multicenter, Single Arm Real-World Registry Investigating the Clinical Use and Safety of the Lutonix® Drug Coated PTA Dilation Catheter. Presented at: Vascular InterVentional Advances (VIVA); September 19, 2016; Las Vegas, NV.

. We recommend the following procedural HCPCS code be created for use in the OPPS setting:

> *CXXXX or GXXXX-Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral: with transluminal drug-coated balloon angioplasty*

Additionally, we recommend CMS create two more levels (levels 5 and 6) within the Endovascular APC family to provide more adequate payment for DCB angioplasty procedures. This is consistent with the recommendation by the August Medicare Advisory Panel on Hospital Outpatient Payment. Analysis of CY 2016 claims data suggests CMS could create two new APC's with associated payment levels as shown in the table below.

Create 2 New Endovascular APCs and Assign CPT 37224 with CXXXX/GXXXX to APC 519X	
APC	**Modeled Payment**
5191 Level 1	$2,845
5192 Level 2	$4,875
519X New Level 3	$8,042
5193 Existing Level 3/ New Level 4	$10,084
519Y New Level 5	$12,149
5194 Existing Level 4/ New Level 6	$15,713

The following table lists the appropriate CPT codes to include in the new APCs outlined above:

HCPCS Code	Short Descriptor
35472*	Transluminal balloon angioplasty, percutaneous; aortic
CXXXX/GXXX	Fem/popl revas w/tla dcb**
9345A	Right heart caths (Complexity adjustment for multiple procedures)
37228	Tib/per revasc w/tla
37241	Vasc embolize/occlude venous
0234T	Trluml perip athrc renal art
0236T	Trluml perip athrc abd aorta
0237T	Trluml perip athrc brchiocph
37225	Fem/popl revas w/ather
37226	Fem/popl revasc w/stent
37242	Vasc embolize/occlude artery
37244	Vasc embolize/occlude bleed
61626	Transcath occlusion non-cns
93581	Transcath closure of vsd
93582	Perq transcath closure pda
C9606	Perc d-e cor revasc w ami s

* Deleted 1/1/2017.
** Suggested short descriptor.

We believe this solution will ensure more adequate payment for DCB angioplasty procedures, thereby maintaining patient access, and improve resource homogeneity across this group of APCs. We also believe this solution will remove any incentive by the hospitals to constrain their losses by using less costly alternatives to DCB, specifically non-drug coated balloons, in order to maximize their profits.

If the above expansion of the APC levels outlined above is not acceptable to CMS, we cautiously recommend CMS consider a second approach. As outlined above, we recommend CMS create two new APC's, however, under this scenario, CMS would include all cases involving CPT 37224, with or without DCB (C2623) in the new Level 3 APC. We are cautious about offering this solution, as it may incentivize hospitals to treat patients with plain balloons rather than DCBs, and thereby restrict patient access to this important technology. However, if CMS is unable to accept our first recommendation, we believe this solution is better than what CMS proposed in the OPPS proposed rule. The table below summarizes this option:

Create 2 New Endovascular APCs and Assign all 37224 cases to APC 519X	
APC	**Modeled Payment**
5191 Level 1	$ 2,845
5192 Level 2	$ 4,792
519X New Level 3	$ 7,389
5193 Existing Level 3/ New Level 4	$ 10,084
519Y New Level 5	$ 12,149
5194 Existing Level 4/ New Level 6	$ 15,713

IV. Medicare Payment for Contrast Agents and Radiopharmaceuticals

1. Separate Payment for Contrast Agents and Radiopharmaceuticals

We note that Medicare payment for contrast-enhanced procedures appears to have been especially volatile. For example, last year CMS proposed Medicare payment reductions for contrast-enhanced echocardiography in the range of 24%, but refrained from adopting this reduction in the 2017 HOPPS Final Rule. This year, once again, CMS is proposing a 24% Medicare payment reductions for these same procedures: If the proposal is adopted without change in the final regulations, contrast-enhanced and unenhanced procedures would be paid at approximately the same rate. Similar issues arise with respect to the APC rates payable for procedures involving the administration of radiopharmaceuticals, including, for example nuclear cardiology myocardial perfusion studies.

It appears that the instability of the APC rates for contrast-enhanced procedures and those involving the administration of radiopharmaceuticals may arise to some extent from the failure of hospitals to accurately and consistently report the cost of these products. While we understand that CMS has no choice but to utilize hospital-reported costs and charges as the basis for rate-setting, we believe that, to the extent that an alternative source of information is available, it may be prudent to utilize it to the extent practicable.

The Proposed Rule solicits comments on whether contrast agents, radiopharmaceuticals, and other drugs furnished in conjunction with surgical and diagnostic procedures should be paid separately, rather than packaged into the underlying APC rates. For any agent for which Average Sales Price (ASP) data is available, separate payment should be made on the basis of ASP+6%, which is the formula generally used for other outpatient drugs.

We note that there does not appear to be any legal authority for treating contrast agents any differently from other drugs for HOPPS payment purposes. The Social Security Act, § 1861 (t)(1) specifically states:

> (t)(1) The term "drugs" and the term "biologicals",. . ., include only such drugs (**including contrast agents)** and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.

(Emphasis added.) Under these circumstances, we do not believe that there is a statutory basis for treating contrast agents less favorably than other drugs under HOPPS packaging policies.

> ***Recommendation****: We urge CMS to provide separate payment for contrast agents and radiopharmaceuticals and to utilize ASP +6% as the basis for payment for any product for which ASP data is available.*

2. *Add-On Payment for non-HEU Technetium*

Some of the Technetium (Tc-99m) radioisotope used in diagnostic imaging services is produced in legacy reactors outside of the United States using highly enriched uranium (HEU). The United States would like to eliminate domestic reliance on these reactors, and is promoting the conversion of all medical radioisotope production to non-HEU sources.

Alternative methods for producing Tc-99m without HEU are technologically and economically viable, and conversion to such production has begun. CMS expects that this change in the supply source for the radioisotope used for modern medical imaging will introduce new costs into the payment system that are not accounted for in the historical claims data.

For this reason, CMS provides an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources. CMS reassesses this policy on an annual basis and is proposing to continue this supplemental payment in CY 2018.

3. *Payment for Radiopharmaceuticals and Other Products used in conjunction with Clinical Trials*

We note that CMS is proposing to cease providing pass-through payment for a number of drugs on December 31, 2017, including florbetapir, a radiopharmaceutical used in imaging the brain as

a diagnostic tool for Alzheimer's disease. This radiopharmaceutical is currently paid for under a Medicare National Coverage Determination (NCD) issued on September 27, 2013, which allows conditional coverage of amyloid PET under Coverage with Evidence Development (CED).

> ***Recommendation****: In order to ensure the stability of the CED and the ultimate reliability of the results, we urge CMS to extend pass-through status for all drugs and radiopharmaceuticals associated with the trial until it is completed and also to refrain from implementing substantial Medicare payment changes for procedures subject to an ongoing CED.*

V. New Off-Campus Provider-Based Facilities

In the 2018 Physician Fee Schedule Proposed Rule, CMS is proposing to slash Medicare payment rates for services provided at new off-campus hospital outpatient facilities[2] As set forth in our comments on the 2018 Physician Fee Schedule Proposed Rule, Philips strongly opposes CMS' proposal to pay for services provided in these facilities at 25% of the otherwise applicable HOPPS rates.

Section 603 of the Bipartisan Budget Act of 2015 states that certain "applicable items and services" furnished in certain off-campus provider-based departments (PBDs) will not be considered covered hospital outpatient department (HOPD) services for purposes of the HOPPS and will instead be paid under the "applicable payment system" under Medicare Part B. We understand that this legislation was motivated in large part due to concerns that physician practice acquisitions were being fueled by the reimbursement differential between the amounts paid to provider-based facilities under HOPPS and amounts paid to physicians' offices under the Physician Fee Schedule: Congress presumably intended to "level the playing field" between hospitals and physicians' offices with respect to the provision of off-campus outpatient services while protecting those outpatient facilities that had been established under prior law.

The proposed implementation of these provisions by CMS, however, will go considerably further—strongly dissuading hospitals from establishing outreach clinics in medically underserved areas and making it financially impracticable for any outreach facilities that are established to provide needed diagnostic imaging services in those facilities. In short, paying new off-campus hospital facilities at 25% of HOPPS rates will not result in a payment-neutral system, but rather will result in payment for many hospital clinic services at rates that are considerably lower than those paid for comparable services in non-hospital settings. This is especially true for diagnostic imaging procedures and many other procedures paid on the basis of separate technical component (TC) allowances under the PFS. We strongly believe that if this proposal is implemented without change, medically underserved areas—including many rural areas—will continue to be underserved, and that any new outreach clinics that are established will need to run on a "bare bones" budget that will not facilitate access to diagnostic imaging or other needed diagnostic and therapeutic health care services that have non-physician clinical

[2] The proposal impacts off-site provider-based facilities that were not mid-build as of November 2, 2015.

staff, equipment, supply and overhead costs that are sufficient to warrant separate TC payment under the PFS.

By way of illustration, the following chart sets forth the amounts that would be paid for a number of common diagnostic imaging procedures in new hospital outreach clinics if the proposed payment reduction is adopted and if 2018 HOPPS rates are adopted without change:

CPT	**Procedure**	**2018 Proposed HOPPS Rate**	**25%*HOPPS Rate**	**2018 Proposed PFS TC**
74176	CT Abd+Pelv	$149.67	$37.41	$ 113.73
93971	Extremity Study	$149.67	$37.41	$ 98.97
93880	Extracranial Bilateral Study	$149.67	$37.41	$ 165.20
72148	MR Lumbar Spine w/o contrast	$264.07	$66.02	$ 151.16
70450	CT head, brain w/o dye	$96.54	$24.14	$ 73.42
72125	CT Neck, spine	$149.67	$37.41	$ 131.72

We do not believe that CMS' rationale for these major payment reductions is justified by the data cited in the Proposed Rule. This proposal is based solely on a comparison between the amounts paid for physicians' office visit practice expenses and hospital clinic services. However, as CMS has indicated in the past, hospital outpatient clinic services are not comparable to physicians' office services. In particular, hospital outpatient clinic services include a broad array of "packaged" items and services that are separately paid under the Physician Fee Schedule and are generally more intensive and complex than physicians' office visits.

Moreover, CMS' own data suggests that the proposed cut would substantially underpay hospitals for the non-clinic procedures and services provided in new off-campus facilities. According to CMS' own analysis, the amounts paid for the TC or practice expenses associated with most common non-clinic services provided in off campus facilities approximates 40% of HOPPS rates—not 25%. If CMS finalizes the proposal without change, hospitals will be disincentivized to offer diagnostic imaging in any new outreach clinics that they may establish, including clinics established to provide medically necessary services to underserved populations. Finalizing these payment reductions without change will incentivize hospitals to provide diagnostic imaging only on the main hospital campus, potentially resulting in increased waiting times in these settings and significant inconvenience for Medicare beneficiaries whose transportation options are often limited. We would anticipate that access problems may be especially severe in rural areas, which often include a disproportionate number of elderly residents.

***Recommendation**: We recommend that CMS refrain from adopting the proposed reduction in Medicare payment for new off-site clinics. If CMS decides to proceed with a cut of this magnitude, the agency should institute a reconciliation process under at the end of each year, under which payments are adjusted to ensure that the amounts paid to hospitals for diagnostic imaging services provided in new hospital outpatient clinics are at least equal to the technical component payment amounts that would have been paid if these diagnostic imaging services had been provided in non-hospitals settings.*

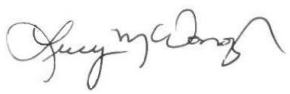
VI. Overall Impact of Proposed Rule on Cancer Centers, Teaching and Other Disproportionate Share Hospitals.

We urge CMS to consider the potential impact of some of the changes that are proposed on hospitals that provide care to a relatively large percentage of uninsured and underinsured patients, including many large teaching hospitals. In the Proposed Rule, CMS is proposing to reduce Medicare payment to hospitals participating in the 340B Program for outpatient drugs that are separately payable, such that these hospitals would be paid 22.5 percent below the applicable Average Sales Price (ASP), rather than 6% over the ASP. By definition, this payment reduction will disproportionately impact those hospitals that provide care to a disproportionate share of Medicaid, uninsured, and underinsured patients. We also note that Medicare payment reductions impacting new off-campus hospital outpatient clinics also have the potential to disproportionately impact larger urban and academic institutions which may be more likely to run off campus clinics in underserved areas. We urge CMS to consider the combined impact of all of the changes proposed in both the 2018 HOPPS and the 2018 PFS proposals on hospitals that serve our most vulnerable and clinically complex patient populations, and those specialized hospitals that provide care to complex cancer patients.

***Recommendation**: If CMS finalizes the 340B payment reductions outlined in the Proposed Rule, we urge the agency to design a methodology that redistributes at least some portion of the revenues raised through this reduction to large teaching and other disproportionate share hospitals, and that special efforts should be made to ensure that specialized PPS-exempt cancer hospitals are not adversely impacted.*

Philips appreciates the opportunity to submit these comments on the Proposed Rule. If you have any questions or if we can provide any additional information about Philips' positions on the Proposed Rule, please do not hesitate to contact me at lucy.mcdonough@philips.com.

Sincerely yours,



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