PHILIPS

September 27, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Re: Comments on CMS-1717-P Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals ("Proposed Rule")

Dear Administrator Verma:

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

I. COMMENTS RELATED TO PAYMENT FOR NEW TECHNOLOGY

A. Proposed Alternative Pathway to Establish "Substantial Clinical Improvement" for the Purposes of New Device Pass-Through Payment

CMS is proposing that, beginning with applications submitted on or after January 1, 2020, technologies that are classified by the FDA as "breakthrough" technologies and that have been cleared for marketing would automatically be considered to offer a "substantial clinical improvement," for the purposes of the HOPPS Pass Through Payment. Under the Proposed Rule, breakthrough technologies would be approved for device add-on payments once they demonstrate that they meet the program's cost and other criteria.

> ***Recommendation:*** *Philips strongly supports the alternative payment pathway for breakthrough technologies to be considered eligible for New Device Pass-Through Payment under the HOPPS. We also urge CMS to consider breakthrough status in determining whether a device or service performed using a new device should be eligible for classification into a New Technology APC.*

> ***Recommendation:*** *To minimize confusion and in order to align with the current process for review of applications that would have been eligible for pass-through payment on January 1,*

2020, Philips recommends that the new alternative pathway apply to any New Device Add-On applications submitted on or after September 1, 2019.

B. Packaging of New Technology APC Services into Comprehensive APC (C-APC) for Observation Care

Just last year, CMS clarified that services assigned to a New Technology APC are not generally packaged into a C-APC. This decision is consistent with the rationale for New Technology APCs, which are designed to pay hospitals for new procedures or services while CMS collects and reviews sufficient claims data to determine an appropriate clinical APC. In the Proposed Rule, however, CMS proposes to make an exception for those services that are classified into a New Technology APC but that appear on the same claim as a service that is packaged into the "Comprehensive Observation Services" C–APC (C–APC 8011).

Recommendation: *Because packaging a service that is assigned to a New Technology APC into C-APC 8011 would preclude accurately tracking of claims and would undermine the accurate assignment of the new service into a clinical APC, we urge CMS to continue to continue to provide separate payment for all New Technology APC services-- including those otherwise associated with C-APC 8011.*

II. IMAGING

A. Cost-to-Charge ratio (CCR) for Radiology Procedures.

A number of years ago, CMS established separate cost centers for MR and CT procedures, after concluding that the CCRs for these services were overstated. Since that time, CMS has used separate CCRs for these procedures, which has had the effect of reducing the estimated costs of CT and MR procedures performed in hospital outpatient settings, and increasing the estimated costs of other radiology services.

We urge CMS to reconsider this proposal for a number of reasons. First, it appears that the use of separate CCRs for MR and CT procedures is no longer necessary, in light of changes that have been made in the imaging APCs since these establishment of separate cost centers for these services. At the time separate cost centers for these services were established, the classification of imaging procedures into APCs was generally modality specific, except that separate APCs were established for contrast-enhanced and unenhanced procedures. In other words, all non-contrast-enhanced MRI procedures were classified into a single APC; all non-contrast enhanced CTs were classified into a single APC; etc. In light of this APC classification method, any overestimation of MR and CT costs would have a direct and potentially significant positive impact on payment for these procedures and an indirect and potentially negative significant impact on payment for other radiology procedures.

At this stage, however, MR and CT are "intermingled" with other imaging services, and for this reason, the potential overstatement of MR and CT costs does not directly impact MR and CT rates in the same manner. For this reason, any inaccuracy resulting from potential overstatement of the MR and CT CCRs should be weighed against the potential inaccuracy introduced into the system as the result of the establishment of non-standard MR and CT cost centers.

CCRs are allocated for each cost center "using hospital-specific data from [HCRIS]." In its proposed and final FY 2016 Inpatient Prospective Payment System (IPPS) rules, CMS described inconsistencies in the Healthcare Cost Report Information System (HCRIS) that may result in invalid Radiology and Other

Services CCRs. These inconsistences result from the way hospitals allocate costs to nonstandard cost centers and are compounded by the process CMS applies to map and "roll up" each nonstandard code to standard cost centers.

In light of these inaccuracies, it is not at all clear that the establishment of separate cost centers for MR and CT contribute to the accuracy of cost estimates of MR, CT, or other radiology services. In fact, we believe that it is possible, if not likely, that the cost estimates used for the purpose of determining Imaging APC classifications and rates would be more accurate if a single CCR for all radiology services were used.

Moreover, the CCRs for MR and CT cost centers have historically excluded claims from hospitals that use a "square foot" allocation method for CT and MR equipment. In the Proposed Rule, CMS is proposing to use all claims with CT and MRI cost centers, including those that use a "square foot" cost allocation method, to determine estimated costs for these procedures. Finalizing CMS' proposal to use claims from hospitals that utilize square footage to allocate equipment costs would exacerbate the problems resulting from the separation of CT and MR into separate cost centers, as described above.

> ***Recommendation:*** *Philips recommends that CMS revisit its decision to establish separate CCRs for MR and CT in light of the reconfiguration of the imaging APCs that took place since that decision was made. We also recommend that, if separate MR and CT cost centers are maintained, CMS should continue to exclude from the rate-setting methodology claims from hospitals that allocate capital costs on a square footage basis, and should issue instructions to hospitals that require them to allocate capital costs on a the basis of direct assignment or dollar value.*

B. Diagnostic Imaging Agents

CMS had previously solicited comments regarding whether the current contrast agent packaging policy under which both diagnostic contrast agents and contrast agents used in conjunction with the performance of surgical procedures are packaged, regardless of cost, should be continued. However, it does not appear that the agency has followed up on this issue, and, at this stage, all contrast agents are packaged, regardless of indication.

The Medicare Act specifically defines contrast agents as drugs[1], and contrast agents, unlike supplies, improve diagnostic accuracy and reduce unnecessary procedures and surgeries for patients. Unlike supplies, contrast agents required to be approved by the FDA and clear the same or similar regulatory hurdles as other drugs.

> ***Recommendation****: We recommend that both diagnostic and therapeutic contrast agents be subject to the same HOPPS packaging policies as other drugs.*

C. Radioisotopes from Non-Highly Enriched Uranium (non-HEU) Sources

As noted in prior rules, some of the Technetium (Tc-99m) radioisotope used in diagnostic imaging services is produced in legacy reactors outside of the United States using HEU sources, and the United States is promoting the conversion of all medical radioisotope production to non-HEU sources. For a number of years, CMS has provided an additional payment of $10 for the marginal cost for radioisotopes

[1] Social Security Act Section 1861(t)(1)

produced by non-HEU sources; however, the Proposed Rule does not specifically address whether or not this policy will be continued in 2020.

> ***Recommendation****: Philips proposes that the Final Rule specifically provide for the continuation of a $10 additional payment for TC-99m produced by non-HEU sources.*

D. Image-Guidance Performed in Conjunction with the Administration of Non-Opioid Drugs for the Treatment of Pain.

CMS has requested information on the types of incentives the health system creates that unfavorably impact utilization trends of non-opioid alternatives. Last year, Philips supported separate payment for non-opioid drugs, and we believe that this payment change has the potential to increase the utilization of non-opioid treatment alternatives. We also note that non-opioid prescription drugs are often furnished using image-guided procedures, and that separate Medicare payment for image guidance used for the administration of non-opioid drugs may encourage this treatment alternative.

> ***Recommendation:*** *Philips recommends that CMS provide separate Medicare payment for image guidance in conjunction with the administration of non-opioid drugs for the treatment of pain.*

III. ASC Payment and Policy Issues

Proposed Addition of Coronary Intervention Procedures to the List of ASC Covered Surgical Procedures for CY 2020

CMS proposes to add the following three coronary intervention procedures, as well as their respective add-on procedures, to the list of covered surgical procedures for CY 2020:

92920	*Percutaneous transluminal coronary angioplasty; single major coronary artery or branch*
92921	*--- each additional branch of a major coronary artery*
92928	*Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch*
92929	*--- each additional branch of a major coronary artery*
C9600	*Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch*
C9601	*--- each additional branch of a major coronary artery*

Philips supports the proposal and urges CMS to finalize the addition of these codes to the covered procedure list. We agree with CMS that these procedures meet the requisite inclusion criteria in that they are separately paid under OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require an overnight stay.

> *Recommendation:* Philips recommends that CMS finalize the proposal to include the three coronary intervention procedures, as well as their respective add-on procedures, to the list of ASC covered surgical procedures for CY 2020.

Bundled Payment for FFR/iFR Compromises the Appropriate Use Criteria for Cardiac Procedures

Philips is concerned with the current ASC payment policy that packages fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) (herein referred to as "FFR/iFR") with the "primary" procedure. FFR/iFR are important physiologic tools where clinical studies have demonstrated improved quality of care resulting in cost savings to Medicare and their beneficiaries. FFR/iFR is supported by appropriate use criteria guidelines issued by expert specialty societies in the United States and Europe. However, packaging these services with significantly lower payments in the ASC setting, compared to hospital outpatient departments, results in payment levels that will limit its use.

Background on FFR/iFR

FFR/iFR provide physicians with a physiologic tool to accurately assess blood flow and the severity of blockages in the coronary artery. Through a highly advanced, miniaturized pressure sensor, mounted on a guidewire into the coronary artery, FFR/iFR identifies areas where blood flow is reduced significantly enough to benefit from an interventional cardiac procedure. As a result, FFR/iFR has been revolutionary in helping physicians determine when to treat coronary lesions. iFR differs from FFR in that it is a next-generation physiologic measurement that uses the same pressure guide wires and equipment as FFR but instead measures blood flow without requiring a hyperemic drug. Thus, iFR further reduces procedural costs and improves patient outcomes.

The use of FFR/iFR to diagnose and document ischemia is supported by the 2017 Society of Cardiac Angiography and Interventions (SCAI)/American College of Cardiology (ACC) Appropriate Use Criteria.[2] Additionally, SCAI has designated FFR/iFR as "definitely beneficial" and in multivessel coronary disease "improves outcomes and saves resources when compared to angiography guided PCI."[3] Additionally, the European Society of Cardiology has incorporated iFR into its updated revascularization guidelines.[4] The guidelines provide the highest recommendation (class I A) for iFR alongside FFR for the objective assessment of the hemodynamic relevance of coronary lesions.

Clinical Studies Show that FFR/iFR Improves Patient Outcomes and Help Reduce Cost

The use of FFR/iFR, as compared to angiographic assessment, to guide revascularization has been found to improve patient outcomes and defer stenting of nonischemic lesions compared with angiographic assessment. A high-level summary of the findings are listed below:

[2] Patel M, et al., ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients with Stable Ischemic Heart Disease. J Am Coll Cardiol. 2017 May 2;69(17):2212-2241.

[3] Lofti A, et al. Focused update of expert consensus statement: Use of invasive assessments of coronary physiology and structure: A position statement of the society of cardiac angiography and interventions. Catheter Cardiovasc Interv. 2018;1–12.

[4] 2018 ESC/EACTS Guidelines on myocardial revascularization: The task force on myocardial revascularization of the European society of cardiology (ESC) and European association for cardio-thoracic surgery (EACTS). Eur Heart J. 2018;00:1-96.

- The DEFER (Percutaneous Coronary Intervention (PCI) of Functionally Nonsignificant Stenosis) study demonstrated that PCI can be safely deferred based on a nonsignificant FFR.[5] At 15-years follow-up, the rate of myocardial infarction was significantly lower in the defer group (2.2%) compared with patients who underwent revascularization (10%).[6]

- The FAME (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation) study demonstrated the importance of FFR in patients with multivessel coronary disease undergoing revascularization. FFR-guided PCI was associated with lower 1-year adverse events and reduced costs compared to using angiography alone.[7]

- The FAME economic evaluation showed that FFR guidance in multi-vessel disease reduced costs while improving patient outcomes. The overall cost in the FFR guided arm were significantly lower than in patients with angiography guided PCI ($14, 315 versus $16,700; P<0.001). Additionally Major Adverse Cardiac Events (MACE) were 39% lower in the FFR guided arm vs the angiographically guided arm (13.2% vs 18.3%, p=0.02).[8]

- In the FAME 2 study, FFR-guided PCI, compared with medical therapy alone, was found to improve outcomes; patients without evidence of ischemia had favorable outcomes without PCI. The reduction in adverse events seen with FFR in the PCI group was driven by a reduction in urgent revascularization.[9]

- Muller et al. demonstrated good prognostication by deferring revascularization with a negative FFR for the long-term clinical outcome of patients with an angiographically intermediate left anterior descending coronary artery (LAD). In this study, medical treatment of patients with a hemodynamically nonsignificant stenosis in the proximal LAD was associated with an excellent long-term clinical outcome, with survival at 5 years, which is similar to a control group without known coronary artery disease (92.9% survival).[10]

- Finally, the DEFINE-FLAIR and iFR-SWEDEHEART trials demonstrated that iFR was equivalent to FFR in terms of incidence of major adverse events in patients with intermediate

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[5] Bech GJ, De Bruyne B, Pijls NH, et al. Fractional flow reserve to determine the appropriateness of angioplasty in moderate coronary stenosis: a randomized trial. Circulation 2001;103:2928-34.

[6] Zimmermann FM, Ferrara A, Johnson NP, et al. Deferral vs. performance of percutaneous coronary intervention of functionally non-significant coronary stenosis: 15-year follow-up of the DEFER trial. Eur Heart J 2015;36:3182-8.

[7] *See* De Bruyne B, Pijls NH, Kalesan B, et al. Fractional flow reserve-guided PCI versus medical therapy in stable coronary disease. N Engl J Med 2012;367:991-1001; and De Bruyne B, Fearon WF, Pijls NH, et al. Fractional flow reserve-guided PCI for stable coronary artery disease. N Engl J Med 2014;371:1208-17.

[8] Fearon FW, Economic evaluation of fractional flow reserve-guided percutaneous coronary intervention in patients with multivessel disease. Circulation. 2010 Dec 14;122(24):2545-50.

[9] *See id.*

[10] Muller O, Mangiacapra F, Ntalianis A, et al. Long-term follow-up after fractional flow reserve-guided treatment strategy in patients with an isolated proximal left anterior descending coronary artery stenosis. JACC Cardiovasc Interv 2011;4:1175-82.

coronary artery disease. The studies also showed iFR resulted in markedly less patient discomfort and reduced procedure-related adverse events compared with FFR.[11]

Thus, FFR/iFR prevents, unnecessary treatments, which enhances patient care and helps reduce costs to the Medicare program and beneficiaries.

IV. Prostate High-Intensity Focused Ultrasound

The Proposed Rule would classify C9747 – Focused Ultrasound Ablation of Prostate Cancer to Urology APC Level 5 which will be paid at a rate of approximately ~$4,300. Under CMS' cost estimation methodology, the estimated cost of this procedure is approximately $5,600: If clearly erroneous claims were excluded, the hospital cost of this procedure would be in the range of $6,250.

> ***Recommendation****: Philips recommends that prostate high-intensity focused ultrasound be reclassified into Urology APC Level 6, since it is clinically comparable and comparable in terms of resources to CPT 55873: cryosurgery of prostate is classified into Urology APC Level 6*

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If you have any questions, please contact Lucy McDonough at Lucy.McDonough@philips.com.

Sincerely yours,

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Director, Market Access North America
Philips

[11] *See* Davies JE, et al., Use of the Instantaneous Wave-free Ratio or Fractional Flow Reserve in PCI. N Engl J Med. 2017 May 11;376(19):1824-1834; and Gotberg M, et al., iFR-SWEDEHEART Investigators.. Instantaneous Wave-free Ratio versus Fractional Flow Reserve to Guide PCI. N Engl J Med. 2017 May 11;376(19):1813-18233.