PHILIPS

September 6, 2016

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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-1654-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017

Dear Administrator Slavitt:

On behalf of Philips Healthcare (Philips), I am pleased to have the opportunity to comment on the 2017 Physician Fee Schedule Proposed Rule (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.

Our comments are divided into four parts, the first of which addresses diagnostic imaging issues, the second of which addresses CMS' proposal to provide coverage of critical care consultation under the telehealth benefit; the third of which addresses the new proposed diabetes prevention program benefit; and the fourth of which addresses CMS' proposals to provide payment for complex care management and prolonged Evaluation and Management services.

I. **Diagnostic Imaging**

A. Proposed Payment Rates

Our comments with respect to the proposed rates for diagnostic imaging procedures are as follows:

- We support CMS' proposed implementation of statutory provisions that reduce the impact of the multiple procedure payment reductions for the professional component of radiology services.

- We note that the Proposed Rule does not explicitly set forth the film-based x-ray procedures that would be subject to the 20% reduction mandated by law, effective January 1, 2017, thus making it impossible to submit meaningful comments on implementation of this provision. In the

absence of a meaningful opportunity to comment, we urge CMS to limit application of this provision to traditional diagnostic x-ray procedures only. We also note that the Proposed Rule does not set forth the specific procedures that will be subject to the reductions required by section 1848(b)(9)(B) of the Act, which provides for a 7 percent reduction in payments for X-rays (including the X-ray component of a packaged service) taken using computed radiology furnished during CY 2018-2022 and additional reductions thereafter. We urge CMS to interpret this provision narrowly and to exclude vascular and mammography services from the scope of these reductions, for the reasons set forth in the comments submitted by the Medical Imaging and Technology Alliance (MITA).

- We support CMS' proposal to essentially maintain current payment rates for digital mammography, pending collection of additional pricing information, and believe that the reduction of Medicare payment for these services of the magnitude described in the Proposed Rule has the potential to seriously and adversely impact access to these important services.

- We support CMS' proposal to take into consideration the cost of professional PAC workstations for the services set forth in Table 4 of the Proposed Rule, and suggest that similar costs be considered in determining the Medicare payment rates for imaging services outside of the 70000 series CPT codes (e.g. echocardiography (generally, CPT 93303-93352)).

- We support and incorporate by reference the comments made by the RUC with respect to interventional radiology CPT code revaluations set forth in the Proposed Rule.

- We do not agree with CMS' assumption that portable equipment is typically used to perform screening for abdominal aortic aneurisms (AAA) and urge CMS to adopt the direct cost inputs proposed by the RUC. We believe that the type of AAA screening services mandated for coverage as a preventive health service generally would be provided by a vascular specialist, and that the specialty distribution cited by CMS in the Proposed Rule, indicating a predominance of family practitioner and other primary care practitioners, may reflect some level of misunderstanding regarding the nature of the screening necessary for coverage.

B. Proposed Payment Policies

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 the scope of the AUC consultation requirements and the advanced diagnostic imaging procedures to which these requirements will apply. 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 the AUC consultation requirements are to 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 the test because, for example, the test 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 irrelevant in many situations. In addition, such a process is likely to yield incomplete and unreliable information when it comes time to identify "outliers", as required by the statute.

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.

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.

II. Telehealth

A. Inclusion of remote critical care consultations on the telehealth list

CMS is proposing to expand telehealth coverage to critical care consultations furnished via telehealth and has proposed two new HCPCS codes to report these services: (GTTT1) for the initial consultation and (GTTT2) for subsequent consultations. Philips strongly supports this proposal, as a step in the right direction in improving the care of Medicare patients in critical condition.

It is well established that there is a significant and increasing shortage of intensivists.[1] There are approximately 6500-7000 intensivists in active practice; however, only 15% of ICUs have dedicated intensivist care and only 35% of hospital ICU patients have an intensivist involved in their care. These statistics do not take into account the critically ill patients who do not have access to an ICU at all, which is extremely common in rural and medically underserved areas. An additional 25,000 intensivists would be necessary to cover all U.S. ICUs 24 hours per day/7 days per week, and the number of intensivists who will enter the workforce over the next 5-10 years is projected to be flat.[2]

[1] *COMPACCS Study, JAMA 2000;284:2762*

[2] New CCM.

Shortages of intensivists, lifestyle issues of nighttime coverage and cost concerns inhibit the adoption of 24 X7 intensivist staffing on a broader scale. It is estimated that four times as many full-time intensivists would be needed to provide around-the-clock staffing for the more than 7,000 ICUs in this country alone, again not counting critical care patients not treated in ICUs. Patients requiring the care of intensivists are predominantly elderly patients and experts project that as the U.S. population ages this shortage of intensivists will become increasingly acute. Angus and colleagues (2000) predicted that by 2020 the supply of intensivists will meet only 22 percent of the demand for their services; and The Department of Health and Human Services in a report to Congress in 2006 similarly projected this supply-demand imbalance and further stated that telemedicine offers a solution to this shortage. CMS' proposal to allow coverage under the telehealth benefit for critical care consultations provided remotely is an important step in the right direction in improving access to intensivists' expertise for Medicare patients in rural and medically underserved areas.

In addition, we urge CMS to consider further expanding coverage or the remote provision of critical care management services not only through the telehealth benefit, but also as a Medicare-covered benefit under the Physician Fee Schedule. CMS has recognized the importance of chronic care management services, has acknowledged that these services can be provided remotely; and is taking steps to ensure that payment rates for these services are sufficient to make them generally accessible. We believe that a similar approach should be taken to the remote management of the critically ill.

It is clear that intensivist led care substantially reduces hospital and ICU length of stay (LOS) and mortality and promotes better decision-making, thereby improving quality and reducing costs. The majority of the literature reports significant reductions in patient mortality when care is managed by board-certified intensivists.[3] Intensive care provided by critical care specialists results in more patients appropriately admitted to and discharged from the ICU to other hospital wards in fewer days.

The remote provision of critical care services restructures ICU care, standardizing on-site activities and adding an intensivist-led remote care team to assist the bedside nurses and to be available during hours when bedside intensivists are not on-site. Appropriate provision of remote critical care services by intensivists, using properly equipped technology, ensures that all tasks are performed in a consistent and timely manner, that care plans are executed around-the-clock and that new problems are identified and treated promptly, all of which results in substantially improved patient outcomes. Tele-ICUs are supported by the Leapfrog Group[4], which represents the largest consortium of Fortune 500 companies and the major private purchasers of health care who have established standards for improved care, including intensivist staffing.

We believe that the recognition of remote critical care management services is the logical next step following the agency's recognition of non-face-to-face chronic care management services, and that many of the lessons learned in addressing the challenges of non-face-to-face chronic care management are equally applicable to remote critical care management. We would be delighted to work with you to design appropriate coverage requirements, coding, and payment guidelines for remote critical care management, using CMS' experience with non-face-to-face chronic care management as a model.

B. Place of Service Indicator for Telehealth Services.

[3] Pronovost PJ, Angus DC, Dorman T, et al.: Physician staffing pattems and clinical outcomes in critically ill patients- A systematic review. JAMA, November 6,2002; 288(17):21sr-2162.onovost, 2001).

[4] www.leapfroggroup.com

The Proposed Rule proposes to use the "Facility" place of service code for all telehealth services, on the assumption that the facility where the remote services are provided generally will incur (and be reimbursed separately for) any overhead expenses associated with the provision of these services. We disagree.

For example, in the case of remote critical care consultation, the Tele-ICU, which may not be located at a hospital, provides the intensivist or other physician providing the critical care consultation with real-time access to the patient's medical record, including progress notes, nursing notes, current medications, vital signs, clinical laboratory test results, other diagnostic test results and radiographic images. In addition, the Tele-ICU provides real-time capability to:

- enter electronic orders into the patients chart;
- document into the medical record the remote care services that are provided;
- videoconference with the on-site health care team in the patient room;
- assess patients in their individual rooms, using high fidelity audio and video capabilities, including but not limited to clear observation of the patient, monitors, ventilators, and infusion pumps; and
- speak to patients and family members.

The substantial resources involved in providing these capabilities are not separately reimbursable to the hospital and are borne by the Tele-ICU provider.

Likewise, the technology necessary to provide remote access for other telehealth services are not reimbursable expenses to hospitals under Medicare payment systems, and should be paid as part of the remote professional services, under the telehealth benefit. For technology-related and the other overhead expenses associated with the provision of telehealth services to be paid, it is necessary for these services to be valued as "non-facility" services.

III. Diabetes Prevention Program

We are very pleased that the success of the Diabetes Prevention Programs (DPPs) demonstration projects instituted by the Centers for Medicare and Medicaid Innovation (CMMI) is now leading to the proposed expansion of Medicare coverage for such programs. There is strong evidence that intensive behavior change programs, such as DPPs, result in significant improvements in health outcomes and reduction in healthcare costs.

As outlined in the Proposed Rule, the Medicare population is affected by chronic diseases, such as diabetes, heart disease, as well as other chronic conditions, at epidemic levels. Beyond those who have been diagnosed with such chronic diseases, there is an even larger number that have elevated risk to develop chronic disease: Millions have been diagnosed as pre-diabetic or pre-hypertensive. We applaud the proposed expansion of coverage for DPPs, which we believe will be of considerable assistance to this large group of Medicare beneficiaries.

Recommendation: In light of the potential benefit of this program for Medicare beneficiaries, we urge CMS to make coverage effective on January 1, 2018, without a protracted phase-in.

To guarantee program effectiveness and thereby increase the likelihood of Medicare savings, we appreciate the focus on pay for performance in terms of engagement and outcomes. We believe that programs should align with performance standards that are established in the CDC DPRP Standards.

> *Recommendation: Where the CMS rules deviate from those established by the CDC, we urge CMS to provide clear guidance to providers. For that reason, we urge CMS to clarify what is meant by "Preliminary" CDC DPRP status, since this category is not currently defined in the CDC DPRP.*

We note that the potential beneficiaries who may become eligible for DPP coverage are a very diverse group with very diverse needs. We believe that a wide variety of DPPs may be needed, so that the patients can chose the program that will be most effective for them.

> *<u>Recommendation</u>: We strongly support the proposal to allow both in-person as well as virtual delivery of program services, since this will allow beneficiaries to choose the program best tailored to their needs and lifestyles.*

Philips urges CMS to ensure that the final rule allows for innovation; is sufficiently flexible to afford coverage for DPPs that are tailored to the varied needs of this population; and can accommodate new technology or new behavior modification methods as they are shown to be successful.

> *<u>Recommendation</u>: We look forward to working with CMS to obtain further guidance regarding Medicare payment for devices that may be strongly associated with, or integral to, the success of DPPs, including, for example, connected wearables and blood pressure devices. We believe that such wearables can be an effective addition to intensive behavior change programs.*

We are hopeful that recognition of coverage of DPP is just the first step: We encourage CMS to also consider coverage for programs that address not only diabetes prevention, but also include broader programs that could focus on prevention of cardio-metabolic disease in general.

IV. Primary Care, Care Management, and "Patient-Centered" Services

CMS is proposing to continue its efforts to shift payment under the PFS toward primary care by creating HCPCS codes and payment allowances for a number of new patient management and related services, including prolonged evaluation and management services before or after direct patient care (CPT codes 99358 and 99359) and a number of complex chronic care management and complex chronic care management follow-up codes. In addition, CMS is proposing to revalue non-complex chronic care management. Philips supports these proposed changes.

Philips has extensive experience in partnering with providers to manage patients with multiple chronic conditions. Specifically, as described at greater length in Attachment A, Philips' **Intensive Ambulatory Care (eIAC) Program** partners with providers to manage high-risk patients with multiple chronic conditions (MCCs) in the home using a telehealth-enabled program that combines "high tech" technology and "high touch" services to address the very special needs of those most severely impacted by multiple serious and complex chronic conditions (the "Severely Debilitated MCC population" or SD-MCC).[5] Data

[5] For the purposes of these comments, the SD-MCC patient population is defined as those with:

- Four or more chronic illnesses (including depression and anxiety);

from a pilot program involving Philips' partnership with Banner Health (Phoenix, AZ) indicate that the eIAC program has the potential to result in cost reductions in the range of 27%, reductions in acute and long-term care of 32%, and reductions in hospitalization in the range of 45%.

We support the proposed new coverage of prolonged evaluation and management services and the new proposed allowances for complex chronic care management (base and add-on codes) as well as revaluation of the current chronic management codes. We believe that the addition of coverage for these services will encourage providers to adopt more comprehensive programs (such as e-IAC) for the management of Medicare patients with multiple complex chronic conditions.

We appreciate the opportunity to comment on this rule. If you have any questions regarding these comments or if we can provide any additional information, 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

- Three or more hospital admissions in last 12 months;
- Living at home and/or recently discharged from long term care facility; and
- 10 or more prescription medications

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