PHILIPS

June 27, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS–5517–P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-P)

Dear Acting Administrator Slavitt:

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

Philips supports efforts by CMS and private payers to transform the country's health care system. Our products span the health care continuum from diagnosis through treatment and patient monitoring, and we strongly believe that our products, especially in the field of telehealth, have the potential to add real value and facilitate the transition to value-based models of care. For this reason, we are disappointed by the relatively narrow definition of Advanced Alternative Payment Models (AAPMs) set forth in the Proposed Rule. We believe that a broader definition of AAPMs, combined with the financial incentives for practice transformation included in MACRA, would have the potential to accelerate needed change in our health care system, and that, conversely, the narrow definition of AAPMs in the MACRA Proposed Rule, if not modified in the final regulation, would represent a significant missed opportunity to speed needed changes. When MACRA was enacted, it was the expectation of Congress and the medical community that the new legislation would function as a harbinger of health system transformation by providing physicians with strong financial incentives to align themselves with new and emerging value-based care models qualified as AAPMS. However, under the MACRA Proposed Rule, virtually all physicians are likely to continue to be paid under fee-for-service models, with adjustments as mandated by the Merit-based Incentive Program (MIPS).

Because of the narrow AAPM definition, we agree with CMS projections indicating that few physicians are likely to meet the definition of qualified AAPM clinicians, and that virtually all of the providers who utilize our technology are likely to be paid under MIPS. For that reason, the comments below focus on MIPS; however, we urge CMS to reconsider its narrow definition of AAPMs and to make such changes

as may be necessary in the final regulation to facilitate the transformation of Medicare from a fee-for-service to a pay-for-value care model.

With regard to MIPS, our comments are divided into the following areas:

- Diagnostic Imaging; and
- Telehealth;

I. Diagnostic Imaging

With respect to diagnostic imaging, we generally agree with the comments filed by the American College of Radiology, and urge CMS to incorporate in the MACRA Final Rule the changes set forth in the ACR's comments.

First, we are particularly concerned with the extremely narrow definition of non-patient-facing physicians set forth in the Proposed Rule; We believe that many physicians whose practices primarily comprise the interpretation of diagnostic studies but who also provide clinic or other face to face services are unlikely to meet the definition of non-patient facing physicians. This is especially true in the area of cardiovascular imaging, since many physicians specializing in the interpretation of nuclear, echocardiographic, cardiac CT and cardiac MRI studies also perform face-to-face services exceeding the 25 claim threshold in the Proposed Rule.

Recommendation: We urge CMS to substantially broaden the definition of non-patient facing physician to include any physician whose non-patient facing claims constitute 80-90% of the physician's total claims.

Second, we believe that the quality requirements applicable to physicians whose practices are dedicated primarily to the interpretation of diagnostic studies are not realistic. In particular, the only difference between the quality requirements for patient-facing and non-patient facing physicians under the Proposed Rule is that non-patient-facing physicians need not report on a cross-cutting measure. Under the Proposed Rule, non-patient facing physicians are required to report an outcomes measure. We do not believe that it is appropriate for diagnostic technologies, including diagnostic imaging, to be measured on the basis of patient outcomes. The accepted approach in the evaluation of technologies includes sequential evaluation of the following six levels of efficacy: *(1)* technology, *(2)* diagnostic accuracy, *(3)* diagnostic thinking; *(4)* therapeutic planning; *(5)* patient outcomes, and (6) societal efficacy.[1] However, for most diagnostic technologies, assessments should be conducted at Levels 1, 2, and 3: The critical questions relating to a diagnostic technology are the technical capability of the test, its diagnostic accuracy, and its impact on physician decision making. Patient outcomes are often the result of the efficacy of treatment and a myriad of other intervening factors that are considerably beyond the scope of, and completely unrelated to, the diagnostic testing used to accurately diagnose the patient's condition.

On the other hand, we applaud CMS' inclusion of a number of quality measures that relate to radiation dose. We believe that it is critical that dose minimization is a significant public health objective and appreciate the inclusion of these measures in the Proposed Rule.

Recommendation: We urge CMS to remove the quality measure requirement related to patient outcomes for non-patient facing physicians and applaud the inclusion of radiation dose measure.

Third, we believe that while the proposed quality measures include a number of "efficiency" measures that will identify inappropriate overutilization of diagnostic imaging, they do not appear to include a single measure intended to identify underutilization of imaging. As Medicare shifts from pay-for-volume to pay-for value models, the primary concern shifts from overutilization to underutilization, and,

since the same quality measures will be used under (fee-for service) MIPS and (pay-for-value) Alternative Payment Models, we believe that quality measures should focus on both ends of the spectrum.

Recommendation: We urge CMS to include quality measures focused on the identification of underutilization of diagnostic imaging, and would be delighted to work with CMS to identify appropriate underutilization measures based on the available clinical literature.

Fourth, we note that the Proposed Rule significantly increases the quality data reporting requirement from the current 50% threshold required under PQRS to 80-90% under the new MIPS system. We concur with the ACR and others that it is inappropriate to so significantly increase the reporting burden for physicians in a single year, especially in the first year of the new program.

Recommendation: We urge CMS to maintain the current PQRS 50% quality reporting threshold and to increase that threshold only when participation in quality measurement has increased such that virtually all clinicians are participating in the program at some level.

Fifth, we urge CMS to retain specialty adjustments of the MSPB measure, retain recently adopted thresholds for scoring this measure; and reconsider the inclusion of the new episodes of care in the resource/cost component of MIPS. We are particularly concerned that 13 of the 40 episodes of care proposed are for cardiovascular conditions, and that a number of the proposed episodes are not included in the current QRUR reports and are otherwise untested. We believe that measuring resource use for these episodes of care—especially those episodes that are for chronic conditions and may be triggered by clinic visits rather than inpatient hospitalizations—may have substantial unanticipated consequences and may result in the underutilization of medically necessary imaging and other critical services. We also understand that these episode groups are currently subject to public comment, through August.

Recommendation: We urge CMS to refrain finalizing the episode group measures identified in the MACRA Proposed Rule as part of the resource/cost component of MIPS and to retain the current specialty adjustment and patient thresholds for the MSPB measure.

Sixth, we note that many physicians whose practices primarily focus on the interpretation of diagnostic studies but who provide more than 25 patient-facing services annually may have substantial difficulty getting full credit under the Clinical Practice Improvement Activity (CPIA) component of MIPS. Most of the heavily weighted CPIAs are geared toward primary care physicians and are inappropriate for those specializing in diagnostic imaging, and it may be difficult for physicians with say, 26 patient-facing services during the performance period to find six medium-weighted CPIAs to report. For these reasons, we believe that, unless the definition of non-patient-facing physician is expanded significantly, a number of CPIAs should be included on the list to enable those specializing in the interpretation of diagnostic studies to obtain full credit under this category.

Recommendation: We urge CMS to amend the list of CPIAs to include a highly weighted CPIA that would give physicians credit for providing imaging services in an accredited facility and another that would give such physicians credit for implementing a quality review system that incorporates appropriate use criteria. These CPIAs should be made available for attestation regardless of whether they are required by law. (In this regard, we note that providers of advanced diagnostic imaging services (ADIS) in non-hospital settings are required to provide services only in accredited facilities, but this requirement does not apply to hospital-based providers of ADIS or to any providers of other, non-ADIS studies.)

II. Telehealth

Philips believes that coordinated telehealth programs are among the most cost-effective solutions to systematically manage patient populations with ongoing needs, particularly those with medically complex and/or chronic conditions. Philips' telehealth programs are designed to enable providers to coordinate care across the continuum for patients ranging from those who require chronic management to patients with complex, high-risk conditions requiring acute intervention. [1] Philips telehealth programs include the Remote Intensive Care Program (eICU®), a comprehensive technology and clinical reengineering program that enables health care professionals from a centralized telehealth center to provide around-the-clock care for critically ill patients; eAcute Program, which is modeled after the eICU, and monitors high-risk hospitalized patients on medical-surgical floors to prevent avoidable complications, and eConsultant program, which provides remote management services to Skilled Nursing Facilities (SNFs) and emergency department (ED) consults for telestroke, telepsych and trauma triage; and the Intensive Ambulatory Care (eIAC) Program, through which Philips partners with providers to manage high-risk patients with multiple chronic conditions in the home.

Coverage of telehealth under Medicare FFS is extremely limited both in terms of geographical limits and in terms of originating site requirements. It is especially troublesome that the current FFS telehealth coverage does not extend to services provided in the patient's home, as home-based services are critical for those with complex multiple chronic conditions (MCCs), a population for which more extensive use of telehealth services is key to improving care and achieving cost savings. Current coverage is also limited to services that substitute for face to face interventions, a limitation that is especially ill suited for those with complex MCCs, since success in managing this patient population is highly dependent on close daily monitoring to identify potential signs of deterioration through both human (high touch) and technological (high tech) means.

Unfortunately, the MACRA Proposed Rule appears to conceptualize telehealth in a manner likely to inhibit these technologies from fulfilling their quality and efficiency-enhancing potential and fails to provide sufficient incentives for physicians to move toward more comprehensive integration of telehealth in their practices. Specifically, the MACRA Proposed Rule continues to conceptualize services provided through telehealth as one-to-one substitutes for services otherwise provided in-person. In fact, it departs from current PQRS definitions by classifying telehealth as "patient-facing" for the purposes of defining patient-facing physicians and for the purposes of applying quality reporting thresholds. While we certainly agree that some telehealth services are direct substitutes for in-person services, we strongly urge CMS to adopt a more expansive definition of—and more robust incentives for the delivery of—telehealth services.

Philips has adopted the following definition of "telehealth", which we believe better captures the broader role that telehealth may service in the delivery of health care services:

Telehealth is the use of remote sensors, communications and data processing technologies that focus on the patient/person and involves dynamic interaction with providers in real-time or near real-time resulting in improved clinical outcomes, lower costs and greater satisfaction. Telehealth technologies include bi-directional audio/video, physiologic and behavioral monitoring, engagement prompts and point-of-care testing. Telehealth programs

utilize remote teams of physicians, nurses pharmacists, social workers and health coaches supported by this enabling technology to provide the highest quality health care.

In this regard, we note that the MACRA Proposed Rule includes very limited incentives for the use of telehealth services. It does not appear that telehealth is included in any of the quality measures reportable under the rule. And there appear to be only two Clinical Practice Improvement Activities (CPIAs) out of the list of 90 that even mention telehealth. A high weighted CPIA that includes remote monitoring of patients on warfarin among a number of patient monitoring methods, and a medium-weighted CPIA that authorizes clinicians to get credit for use of telehealth services and analysis of data for "quality improvement," such as participation in remote specialty care consults, or teleaudiology pilots that "assess ability to still deliver quality care to patients". The first of these is extremely limited in scope, and we are unclear as to the scope of the second. In particular, it is unclear whether this CPIA may be reported outside the context of specialty care consults and teleaudiology or what is meant by the characterization of telehealth as a "quality improvement" tool.

Recommendation: We strongly urge CMS to include a new high-weighted CPIA for those MIPS eligible clinicians who attest that at least 20_% of their patients with chronic conditions are managed in part through remote patient management.

We also concur with AdvaMed's recommendations regarding telehealth.

Recommendation: We urge that CMS include the provision of remote services included on the List of Telehealth Services as a CPIA regardless of whether these services use store-and-forward technologies that may not be covered by Medicare or fail to meet other Medicare coverage requirements. While the provision of telehealth services not meeting Medicare's strict coverage requirements may not qualify for payment, they should qualify for credit as a CPIA.

Recommendation: We recommend that remote monitoring and telehealth CPIA be included not only in care coordination but also in other applicable CPIA subcategories, such as those related to access and safety.

We appreciate the opportunity to comment on the MACRA Proposed Rule. If you have any questions, please do not hesitate to contact Lucy McDonough at lucy.mcdonough@philips.com.

Sincerely yours,

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