



Dear Acting Administrator Slavitt:

On behalf of Philips Health Systems (Philips), we are pleased to have this opportunity to comment on the 2016 Physician Fee Schedule (PFS) 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, pertinent to the Proposed Rule, a complete range of comprehensive telehealth programs.

Our comments are divided into two parts. Part I addresses CMS’ solicitation of comments on PFS payment for care provided to Medicare patients with multiple chronic conditions. Part II addresses a number of technical issues pertaining to imaging, radiation oncology, and other procedural services.

### **Part I. PFS Payment for Services Provided to Medicare Patients with Multiple 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;<sup>1</sup> however, the telehealth program that is most relevant to the Proposed Rule’s solicitation of input is the **Intensive Ambulatory Care (eIAC) Program**, through which Philips partners with providers to manage high-risk patients with multiple chronic conditions in the home.

The eIAC Program is a telehealth-enabled program that uses “high tech” technology and “high touch” services to address the special needs of complex patients who comprise approximately 5% of patients yet utilize almost 50% of healthcare resources.<sup>2</sup> This approach is not only supported by the clinical literature<sup>3</sup>, but is also strongly supported by recently released data from a pilot program involving Philips’

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<sup>1</sup> 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.

<sup>2</sup> Stanton, MW. *The High Concentration of U.S. Health Care Expenditures*. Rockville, MD: Agency for Healthcare Research and Quality; 2006. Research in Action Issue No. 19. <http://www.ahrq.gov/research/findings/factsheets/costs/expriach>. Accessed September 15, 2011.

<sup>3</sup> The most recent and largest study of the potential impact of telemedicine in the management of patients with chronic conditions, titled “The Empirical Foundations of Telemedicine Interventions for Chronic Disease Management”, was published in *TELEMEDICINE and e-HEALTH* in September, 2014. The study, authored by 23 experts in the area of Telemedicine, reviewed the use of telemedicine for the remote care of patients in the home for CHF, COPD, and stroke. The economic effects of telehealth interventions were measured or examined in two ways: (1) changes in rates or volumes of hospital

partnership with Banner Health (Phoenix, AZ), which document overall 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%.

Accordingly, the following comments:

- Describe the successful multi-disciplinary team based approach taken by the e-IAC to address the special needs of patients with multiple chronic conditions;
- Share the lessons learned through our experience; and
- Propose an alternative approach to coverage and payment of the services necessary to treat this patient population under the Medicare Fee-for- Service (FFS) system, including the PFS.

A. *The Proposed Rule's Solicitation of Comments on Management of Patients with Multiple Chronic Conditions*

The Proposed Rule indicates that CMS is considering several potential refinements to improve the accuracy of PFS payments for the types of services required for Medicare patients with multiple chronic conditions. Specifically, the Proposed Rule solicits comments on the following topics:

- Improved payment for cognitive work and other additional resources involved in the provision of care management services to Medicare patients with multiple chronic conditions, potentially through the adoption of add-on codes that could be used with current E&M CPT codes.
- Establishing a separate payment for collaborative care, including, but not limited to, payment for a behavioral condition collaborative care model whose utility has been documented in the clinical literature. Of special interest to Philips, the Proposed Rule solicits input on key technology supports needed to support collaboration between specialist and primary care practitioners.
- Steps that could be taken to further improve beneficiary access to Transitional Care Management (TCM) and Chronic Care Management (CCM) services.
- Information regarding the circumstances under which CCM services are furnished and the costs involved.

Philips applauds CMS for its focus on these important issues in the Proposed Rule, and, we believe that CMS has accurately identified a number of the types of professional services that are critical to meet the

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admissions, re-admissions, length of stay, and/or emergency department visits and (2) cost-benefit analysis and cost-effectiveness analysis of telehealth in terms of specified outcomes. In both instances and with few exceptions, the evidence supported the economic benefits of telehealth compared with usual care among patients with CHF, stroke, and COPD. Based on the 71 studies that met applicable inclusion criteria, the experts concluded that:

[T]he preponderance of the evidence produced by telemonitoring studies points to significant trends in reducing hospitalization and emergency department visits and preventing and/or limiting illness severity and episodes, resulting in improved health outcomes.

needs of patients with multiple chronic conditions, such as enhanced evaluation and management services, collaborative care involving primary care and specialist physicians, and more appropriately priced chronic care management services. As described in more detail below, we believe that these services and other critical items and services should be incorporated into a “high tech/high touch” enhanced chronic care management fee payable under the PFS to highly specialized and specially certified suppliers.

*B. A Successful Model for Treating Patients with Multiple Chronic Conditions*

The eIAC Program successfully addresses the complex needs of patients with multiple chronic conditions by successfully integrating telehealth technologies and team-based multi-disciplinary coordinated care. The “high tech” component of the program includes:

- In-home devices measure blood pressure, heart rate, body weight, and track symptoms and can also be used to measure lab tests, and medication use.
- Sophisticated algorithms monitor these data continuously and flag problems for the eIAC care team.
- During the on-boarding process patients are evaluated for psycho-social needs and categorized into different personality “behavioral phenotypes” that are used by the team to help personalize their messaging.
- Every patient receives a specially designed Personal Health Tablet (PHT) so they can communicate with the eIAC team through two-way audio-video software and email.
- The PHT also delivers educational videos and surveys in the home.

The application of these new technological capabilities has revealed a need for new or previously underutilized members of the care teams to become involved in the management of certain health populations. This “high touch” component of the program includes:

- An intensivist Primary Care Physician (PCP), typically a geriatrician, who is experienced and enjoys taking care of patients with multiple chronic illnesses. Intensivist PCPs are similar to ICU intensivists in their ability to direct the care across many diseases, including psychiatric (depression, anxiety, etc) and therefore, are able to ensure more coordinated care and reduce the number of consultants needed.
- Assignment of a personal Health Coach to help each patient manage his or her health and to deal with their psycho-social needs. These specially trained individuals go to the patient’s home, as needed, and help with a variety of tasks such as providing emotional support and helping patients master the many tasks required to keep themselves healthy.
- The assignment of a team “quarterback” who keeps the work assignments flowing.
- Patient status is monitored on a daily basis and the care team can change and prescribe medications, arrange for home health services or a visit by their Health Coach, and refer patients to their PCP’s office for tests and other urgent services.
- The care team responds to issues that are often considered non-clinical, such as transportation, nutrition, and social support.
- The eIAC Health Coaches utilize software that identifies what social services a patient is eligible for; facilitates access to those services, and escalates to a Social Worker as needed.

- Patient behavioral phenotypes are used as a structured approach to personalize care and enable all providers, but particularly the social workers and health coaches, to provide counseling and information to each patient in a way “that they are designed to accept and understand this information”. Patient phenotypes are categories that use psychological and sociological tools to identify and categorize how patients and their social networks interact to best receive information and modify their behaviors.

### C. Lessons Learned

Our experience in partnering with health care providers in the context of the eIAC program has taught us a number of important lessons that are relevant to the issues identified in Proposed Rule.

First, the complexity of identifying the patients whose condition is sufficiently serious to warrant this level of patient support should not be underestimated; however, accurate patient identification is key to success. Even among those patients with chronic conditions, there is substantial variation in the level and intensity of support required, and a patient’s health care claims history alone may be insufficient to ensure that relatively resource intensive high tech/high touch programs are targeted to a patient population that is truly in need of this level of support. Accurate identification of the target population, and possibly tiering of the target population in a manner that gears the intensity of support to the clinical and psycho-social needs, requires specialized expertise and experience, and there is a learning curve for implementation.

Second, and along a related line, because of the complexity of identifying the appropriate patient population and managing care once the right patients are accurately identified, we believe that care should be overseen by individuals who specialize in this patient population. To the extent that the care of this patient population is provided by providers that also provide care to others, consideration should be given to requiring the establishment of highly specialized divisions or designated personnel charged solely with managing these highly vulnerable patients.

Third, managing the health care needs of this patient population is likely to be only partially successful if it is conceptualized solely in clinical terms and delivered solely through traditional health care providers. In fact, this patient population tends to have a broad array of behavioral, social, and financial needs that must be addressed for clinical interventions to be successful and for positive health care outcomes to be attained and maintained. Generally, many patients in this population are not only underserved by the medical community, but also socially isolated, psychologically fragile (often depressed), and financially strained. The provision of adequate psychosocial supports, including mental health services, case management, and social work support is critical for effective (and cost effective) patient management.

Fourth, this patient population is most effectively treated by regimens that are both high tech and high touch. While these patients may not be technically “homebound”, their conditions generally keep them at home, and more isolated than others with less serious medical conditions. As such, remote monitoring through technologically sophisticated devices and integrated care networks is critical. At the same time, technology alone is not likely to be successful without the continuous involvement of specialized and sympathetic caregivers, caseworkers and advocates (who need not be clinically trained as nurses or physicians). The cost savings and improved care that have occurred in this program come from early identification of clinical deterioration of patients in this population and the ability to rapidly escalate interventions to halt the deterioration to restore the patient’s health before other more costly and severe interventions are required.

Fifth, population management for patients with multiple chronic conditions will be hampered until progress is made on the widespread interoperability of Electronic Health Records (EHRs) and other patient data. Collaboration and communication is central to population health management. These are some of the most powerful capabilities being unleashed by the new telehealth technologies and combinations. But critical patient information resides in EHRs, and until that information can be freely and easily accessed, the full aspirations for improved care at lower cost for these populations of patients with multiple chronic conditions will go unmet. To enable the best care at the lowest cost, all patient health information is critical, including information from payers, pharmacies and other healthcare providers such as skilled nursing facilities.

There are technology developers including Philips who are working assiduously to develop a secure, open, public platform that will collect, store and make assessable all patient data (i.e., the HealthSuite Digital Platform (HSDP)). The data will be available via a public application programming interface (API), for an open eco system of application developers to build innovative applications that can enable providers and patients to facilitate their care. But until that happens we are concerned that some policymakers are treating policies aimed at improving care for patients with multiple chronic conditions and the issue of EHR interoperability in separate policy silos. So, we urge CMS to recognize that this issue of EHR interoperability is integrally related to improving care for patients with multiple chronic care conditions.

We believe that programs that are built around these principles—specialized, team-based, high-tech/high touch, programs that consider these patients’ psychological, behavioral, and social needs as well as clinical concerns-- are most likely to be successful in improving outcomes and reducing costs.

*D. Addressing the Needs of Patients with Multiple Chronic Conditions through the PFS: A Proposed Model*

While CMS has adopted policies that provide for coverage of TCM and CCM services, and we commend CMS for moving in this direction, we do not believe that the piecemeal addition of coverage for chronic care management services that are valued based on the RUC methodology, the addition of add-on codes for enhanced E&M services, or the addition of care collaboration codes is likely to address the complex needs of patients with multiple chronic conditions. While these measures may increase Medicare payment for primary care physicians and help address current perceived disparities between primary care physicians and specialists, a bolder approach is needed to improve outcomes and reduce costs for this patient population—an approach that requires providers to truly integrate and coordinate care and that incorporates human and technological resources that historically have not been eligible for Medicare coverage.

Admittedly, the payment models best suited for the e-IAC and similar programs would enable participants to share in the savings (generally in the form of reduced hospitalization) achieved, and the PFS is not easily adopted to shared savings methodologies. However, we believe that the challenges involved in paying for integrated team based care under the PFS and other fee-for-service systems can be overcome using policies that provide payment at levels sufficient to achieve meaningful results, but that restrict participation to a limited number of dedicated entities that are clearly qualified to perform the necessary tasks and singularly dedicated to the mission of improving outcomes and reducing the costs of care for those with multiple chronic conditions.

In this regard, we note that the current payment levels for CCM are entirely inadequate to achieve these objectives. For example, the per patient costs involved in e-IAC exceed \$400 per month, while the per patient per month allowance for CCM under fee for service Medicare is currently about \$40-50 per

patient per month. We do not believe that the addition of add-on codes for E&M services provided to this complex patient population, the addition of care collaboration codes that would have to be tightly defined to distinguish the services from those routinely provided by physicians, or the revaluation of CCM services using the RUC methodology ensure the kind of programmatic unity or financial stability necessary to duplicate the e-IAC success through the PFS.

We urge CMS to institute a demonstration model through the Centers for Medicare and Medicaid Innovation to test the following alternative payment model for caring for Medicare patients with multiple chronic conditions:

- CMMI should establish criteria for a new category of supplier for entities dedicated to the management of patients with multiple chronic conditions (“Comprehensive CCM Suppliers”) and should establish a comprehensive chronic care management fee (CCCM) payment that, unlike the CCM payment currently payable to physicians, takes into account the full costs of providing necessary team based care and access to the necessary telehealth technologies. We would anticipate that an appropriate monthly management fee likely would be in the cost range of the eIAC program (in excess of \$400 per month).
- Eligibility to bill for such enhanced chronic care management services should be restricted to entities that meet conditions of coverage established by CMMI. Assuming that cost savings and quality improvements are demonstrated, when the program is transitioned to become a part of permanent FFS Medicare program the conditions of coverage for Comprehensive CCM Suppliers should be established through regulation and Comprehensive CCM Suppliers should be subject to established Medicare certification processes, like other Medicare suppliers, such as renal dialysis facilities, ambulatory surgical centers and DME suppliers.
- Patients eligible for coverage should be nominated by the Comprehensive CCM Supplier in conjunction with the patient’s primary care physician and should be required to meet patient selection criteria established by CMMI. Comprehensive CCM Suppliers should be provided with access to de-identified Medicare claims databases for the purposes of patient selection.
- The CCCM fee should include the costs of services provided by the coach, social worker, pharmacist and other members of team described above, as services “incident to” physicians’ services.
- The Comprehensive CCM Supplier should be required to have a medical director who is a primary care physician who has advanced training and wishes to manage only multi-morbid, complex patients. By utilizing this type of physician, the day-to-day care is more tightly managed and the need for sub-specialty consultants is substantially reduced along with the attendant costs.
- The Comprehensive CCCM Supplier should be required to utilize innovative technology like 1) point of care testing such as white blood cell counters, so that patients can be more fully evaluated in their home, avoiding unnecessary ED visits and 2) a patient portal that enables bi-directional audio/video, patient tracking of their physiologic parameters and accomplishments towards structured goals, educational materials and daily tasks, and a family app that promotes greater self-care. The use of bidirectional audio-video is critical to engaging this patient population in managing their own healthcare, insofar as it provides near real-time access to the patient’s support team.

- The Comprehensive CCCM Supplier should be required to use telehealth solutions modeled after well-documented eICU and eHospital care models that are integral to managing a patient population with ongoing needs, and the costs of this technology should be built into the CCCM fee. The costs of necessary telehealth technologies should including “enabling” telehealth technologies and not just those that serve as one-to-one replacements for in-person care without regard to the originating site and geographic restrictions on coverage for telehealth services provided to patients who are not approved for the CCCM benefit.
- Based on experience with similar programs (e.g. Banner Health/Philips partnership ), teams focused on caring for this population need to be dedicated solely to these patients to ensure appropriate focus, consistency of management approach and thorough follow through. Clinical workflows need to address how to handle each clinical scenario (escalations, emergencies, psychosocial/compliance) with the appropriate processes, workflow guides and training materials developed to ensure desired clinical and economic outcomes.
- Under this model, the costs of enhanced E&M services, the services of the patient’s primary care physicians, the medical director, and any specialists associated with the CCM entity, as well as the costs of ancillary personnel such as the health coach, social worker and pharmacist, would be “bundled” into the CCCM fee, eliminating the need to establish any E&M “add-on” allowances or the collaborative care allowances described in the proposed rule. The current TCM and CCM services likewise would be “bundled” into CCCM service payment.

We believe that this integrated approach, involving dedicated, sole-purpose certified providers using multi-disciplinary care teams and enabling telehealth technology, is substantially more likely to secure improved outcomes and lower costs for this patient population than the establishment of isolated individual services, such as E&M add on codes, collaborative care codes, and modifications of the current CCM and TCM payment allowances formulated using the RUC methodology.

We understand that the approach outline above would represent a substantial departure from historical approaches to this patient population. However, our experience suggests that a policy limits the number of provider entities dedicated to the task but provide sufficient payment to do the job well is substantially more likely to succeed than providing piecemeal and modest payment for a wide array of services such as care coordination, medical consultation, etc, to a broad swath of individual physicians and practices that are not required to demonstrate the requisite expertise.

**Part II. Other Comments.**

In addition to our comments on PFS payment for services rendered to patients with multiple chronic conditions, we wish to address a number of more technical issues raised by the Proposed Rule:

*A. Implementation of Payment Reductions for CTs performed using equipment that does not meet radiation standards.*

As in hospital outpatient settings, CMS is proposing to implement legislatively mandated cuts to CT services performed using equipment that does not conform to NEMA radiation standards, by requiring the use of a modifier for such services. We appreciate CMS’ straightforward implementation of the statutory mandate and believe that this payment reduction for non-conforming CT equipment has the potential to substantially reduce radiation exposure for Medicare and non-Medicare patients alike.

### B. Imaging and Other Procedures To be Revalued as Misvalued.

We note that CMS has identified a number of high volume imaging services for review as potentially misvalued codes. As noted in the Proposed Rule, Section 202 of the Achieving a Better Life Experience Act of 2014 (ABLE Law) (Division B of Pub. L. 113-295, enacted December 19, 2014)) amended section 1848(c)(2)(O) of the Act to accelerate the application of the PFS expenditure reduction target to CYs 2016, 2017, and 2018, and to set a 1 percent target for CY 2016 and 0.5 percent for CYs 2017 and 2018. Thus the RUC and CMS are under considerable pressure to reduce Medicare payment for potentially misvalued codes reviewed for the 2017 and 2018 Physician Fee Schedules

We are extremely concerned that the great brunt of this statutory mandate is likely to fall on imaging services, radiation oncology services, and other diagnostic tests. The Proposed Rule makes it quite clear that CMS is searching for ways to increase Medicare payment allowances for primary care services, and believes that these services are undervalued, especially when performed by primary care physicians with substantial patient management responsibilities. In addition, the Proposed Rule indicates that none of the surgical procedures with 10 or 90 day global periods will be reviewed as potentially misvalued codes until after the 2017 and 2018 PFS rulemaking cycles. Together, evaluation and management services and surgical services with global periods constitute the great bulk of services reimbursed under the PFS, leaving imaging, diagnostic tests, and other services performed primarily by proceduralists to meet the ABLE Law targets.

In light of the exclusion of technical payment service providers from the RUC process and the pressure on the RUC and on CMS to meet the targets or leave physicians to face across the board conversion factor reductions, revaluations of technical component services are not likely to be completely objective. For this reason, we request that CMS establish a consultative process with representatives of equipment manufacturers and technical component service providers that are not represented before the RUC, to provide independent input into the revaluation of the practice expense component of potentially misvalued services, and to take this input into consideration as part of the potentially misvalued code initiative.

### C. Radiation Oncology.

CMS is proposing to increase the utilization rate assumption for radiation treatment equipment from 50% to 70%, phasing in this change over a two year period. This proposal would substantially reduce Medicare payment for the treatment of patients with cancer, especially for common forms of prostate and breast cancer. We understand that CMS considered modifying the equipment utilization assumption for treatment equipment for the 2010 Physician Fee Schedule and determined that there was insufficient evidence to move forward with the proposal at that time. While freestanding and hospital-based radiation oncology centers have no doubt moved toward purchasing treatment equipment capable of providing IMRT since that time, there is no evidence that freestanding facilities have reduced the number of treatment units they operate, and, unless a center reduces the number of facilities it operates, the type of treatment units involved does not impact the equipment utilization rate. For this reason, we request CMS to reconsider its proposal to increase the equipment utilization rate assumption for treatment units.

### D. Opportunity to Comment on Payment Rates for New Codes.

We appreciate CMS' change in the rulemaking cycle for new CPT codes, which facilitates the solicitation of comments on valuation of new CPT codes prior to implementation of the new payment rates. Along these lines, we support CMS' proposal to adopt the RUC's recommended valuation for IVUS (CPT codes 3725A and 3725B), and urge that the RVU's as proposed be adopted in the final rule.

E. Low Dose CT Screening for Lung Cancer.

We appreciate CMS' proposal to implement payment for low dose CT screening for lung cancer. However, we are concerned that the proposed Medicare payment for this service may be too low to cover the costs involved, and urge the agency to adopt the proposal of the American College of Radiology (ACR) for valuation of this procedure. We are also concerned that, while Medicare coverage for low dose CT screening for lung cancer was approved for coverage in February 2015, no instructions have been issued to Medicare Administrative Contractors (MACs) or providers, and we urge implementation of this important new preventive health service benefit as soon as practicable.

F. Appropriate Use Criteria.

The Proposed Rule includes provisions implementing the appropriate use criteria (AUC) program for advanced imaging services and, in this regard, limits the AUC that are eligible for approval under this program to those that are developed by “ “provider-led entities” that meet specified regulatory criteria. We believe that this approach to the implementation is consistent with the statutory language and encourage CMS to limit the AUC eligible for approval under this program to those developed by national professional associations to the extent practicable. In our view, the mechanics involved in implementing this program, including the establishment of communications channels between ordering physicians and those entities that provide the services, is likely to be complex, and the fewer the number of approved AUC for any particular advanced imaging service, the more efficient the final system is likely to be.

G. Open Payments Data and Physician Compare.

CMS is proposing to significantly expand the information reported on Physician Compare. While CMS is not specifically proposing to include Open Payments data on individual physician pages at this time, the agency is soliciting information on whether or not this information should be included on individual physician pages. We encourage CMS to exercise caution in including Open Payment data on Physician Compare. We believe that, in its current form, this data can be highly misleading to health care consumers and substantially distort the extent and nature of physicians' financial relationships with manufacturers and others.

We appreciate the opportunity to comment on the Proposed Rule.

Sincerely,



Brent Shafer  
CEO, Philips North America