PHILIPS

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-5527-P,
P.O. Box 8013,
Baltimore, MD 21244-1850.

Re: [CMS-5527-P]; RIN 0938-AT89. Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures

Dear Ms. Verma:

On behalf of Philips HealthCare (Philips), I am pleased to have the opportunity to respond to the Centers for Medicare and Medicaid Innovation (CMMI) proposed radiation oncology (RO) demonstration project ("the Demonstration Project"). 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. Of greatest relevance here, Philips provides a wide range of products and services designed to improve the safety and efficacy of radiation treatment, including Big Bore RT, a CT scanner and simulator designed for radiation oncology; Pinnacle Treatment Planning, which offers advance treatment planning; and the state-of-the-art Ingenia MR-RT platform, which features MR systems that provide high-quality MR images acquired when the patient is in the treatment position.

Philips strongly supports the transition of the Medicare program from pay-for-service to pay-for value payment methodologies, and we understand that the institution of well-designed episode based payment can constitute a significant step toward value-based payment. However, we urge CMMI to proceed with caution in clinical areas, such as radiation oncology, that relate to cancer and other potentially critical disease processes. In light of the potential impact of the Demonstration Project on this vulnerable patient population, we urge CMMI to reconsider a number of significant elements of the Demonstration Project and to refrain from implementing the Demonstration until these issues are addressed.

I. Patient Safety, Clinical Efficacy and Hypofractionation

While CMMI projects that net reductions in Medicare payment for radiation oncology procedures under the RO Demonstration Project will be in the range of 3-4%, our understanding from providers is that the potential impact could be substantially higher—in the range of 10-20%, depending on patient mix. Payment reductions of this magnitude, in conjunction with the institution of an episode based payment methodology, have the potential to significantly incentivize hypofractionation; in fact, we understand that removing disincentives to hypofractionation is among the primary objectives of the Demonstration Project. However, it is not yet clear how much hypofractionation is safe or what clinical factors are significant in

making this determination in individual cases, and the clinical acceptance of hypofractionation varies by cancer type.

Since the project design and magnitude of payment reductions have the potential to increase the incentive to hypofractionate, we believe that it would be advisable for clinical outcomes measures related to patient safety (including the incidence of various side effects that may accompany overexposure of healthy tissue to radiation) and the efficacy of treatment to be included in the RO Demonstration. We are therefore troubled that the Proposed Rule includes no clinical outcomes measures related to either patient safety or the clinical efficacy of new treatment protocols that may be instituted by demonstration participants to meet the Demonstration Project's financial constraints.

II. Breadth and Scope of the Demonstration Project

The potential patient safety concerns of the RO Model are magnified by the breadth of the Demonstration Project which, as proposed, would mandate the participation of radiation oncology providers that furnish 40% of all treatment in the United States. In light of the potential side-effects of over-radiation and the importance of radiation in extending the life expectancy of cancer patients, demonstration participants' implementation of clinical protocols that hypofractionate treatment should be monitored carefully. Yet, we believe it highly unlikely that CMMI has the resources to effectively monitor the large pool of demonstration participants anticipated by the proposed project design.

III. Implementation Date

Along these lines, in order to ensure patient safety and efficacy of treatment and in order to make sense of the results of the demonstration, it will be critical for demonstration participants as well as the control group to submit patient-specific clinical information. While the Demonstration Project calls for those that provide the PC of radiation oncology services to submit patient specific data for a number of the more common cancer types, it appears that neither the integration of the necessary data elements into CEHRT nor the establishment of a reliable and HIPAA compliant mechanism for submission of this data has been established. We urge CMMI to delay implementation of the new RO Model until the data necessary to ensure patient safety can be collected using established data systems through CEHRT.

IV. Administrative Burden

We also note that one of the stated goals of the Demonstration Project is to "reduce provider burden by moving toward a simplified and predictable payment system." However, this is not achieved by the Proposed Demonstration for two reasons. First, as illustrated by the quality scoring system that will apply to demonstration participants (Proposed Rule Tables 8 and 9) and as elaborated in the over 400 page explanation of Demonstration Project in the preamble to the Proposed Rule, providers must navigate through considerable complexity in order to understand the proposed model, and this type of complexity will surely increase the administrative burden for demonstration participants. Furthermore, since it is expected that providers continue to

submit CPT codes as if they were still operating under the pay for service model, the Demonstration Project essentially doubles the administrative work for participants by requiring them to adhere to both the new and the old systems at the same time. These features of the Demonstration Project are inconsistent with the goal of reducing administrative burden for cancer centers. Also, in light of the fact that the financial impact could be higher than anticipated, it may be difficult for demonstration participants to absorb the additional costs involved in complying with the new system.

V. Technical Issues

Finally, we believe that a number of technical aspects of the RO Demonstration should be reconsidered:

- Since the RO Demonstration will apply to both freestanding and hospital-facilities and since freestanding facilities provide almost 40% of the radiation treatment in the country, we believe that exclusion of all data from freestanding centers from the calculation of the national base rates is not supportable. If, as the preamble to the Demonstration Project suggests, CMMI is not confident of the RO rate-setting methodology under the Physician Fee Schedule, appropriate adjustments should be made, but the cost and utilization data of so significant a proportion of radiation oncology providers should not be disregarded in the calculation of the base rates.

- While we understand that CMMI typically incorporates a "discount factor" into its demonstration projects, this discount factor is included primarily to protect CMS from the financial risk resulting from a voluntary project design. When, as in the CPCI bundling demonstration(s), participation is voluntary, it can be anticipated that demonstration participants will include only those providers that have determined that participation is in their financial best interests—that is, that they will be paid more under the demonstration than they would be paid otherwise. Under these circumstances, building into a voluntary demonstration design features—such as a discount rate-- that protects Medicare against significant financial loss is prudent. However, the RO Demonstration is NOT voluntary, and there is no particular reason to believe that a properly designed episode based payment model will necessarily result in higher payment to demonstration participants as a whole than they would receive under Medicare FFS. Under these circumstances, requiring demonstration participants who have no choice but to participate essentially imposes on an arbitrarily selected provider group the costs of a CMS payment experiment.

- We note that the Demonstration Project design does not include any element that takes into consideration new technology. We urge CMMI to include a mechanism for providers that institute new technology that improve patient care to obtain an adjustment of their episode payments. For example, if providers move toward hypofractionation as the result of the implementation of the RO Model, patient safety and treatment efficacy may require the increased use of MR simulation, and we believe that the RO Model should be revised to authorize a payment adjustment for the use of this and other new

technologies that were not commonly in use during the period used to establish baseline rates.

- We note that the episode rate paid to an individual provider is adjusted based on its historical costs. However, even the most efficient providers receive only 90% of the cost adjustment factor, and those that were historically less efficient are penalized even more. We are concerned that this, as well as other features of the RO Demonstration, has the potential to drive smaller facilities and those associated with less financially secure hospitals out of business. The RO sector of healthcare industry has consolidated substantially over the past five to seven years, and we do not believe that further consolidation would be in the interests of Medicare patients or the Medicare program. .

VI. Recommendation

Recommendation: For the reasons set forth above, we urge CMMI to consider restructuring the RO Demonstration as a voluntary demonstration, structurally similar to the CPCI bundling demonstrations that have been in effect for the past several years. In the event that CMMI continues to believe that a mandatory RO Demonstration is necessary to test episode based payment for radiation oncology services, we strongly urge CMMI to scale the demonstration back such that the demonstration participants provide no more than 10% of radiation episodes; to include robust clinical outcomes measures geared toward ensuring the safety of beneficiaries and the clinical efficacy of the radiation treatment they receive; and to institute appropriate monitoring systems. Taking this approach would allow CMS to conduct a more meaningful experiment with simpler guidelines for the new payment system, coupled with the complete removal of fee for service reporting requirements, and compare the results with those of the fee for service payment system. A smaller group, in other words, would mitigate some of the risk of changing the system more dramatically and allow CMS to conduct a more robust demonstration. We also strongly urge CMMI to delay implementation of the Demonstration Project until the appropriate monitoring and coding systems are in place and have undergone any necessary testing.

Philips appreciates the opportunity to comment on this important demonstration proposal. If you have any questions or if we can be of further assistance please do not hesitate to contact me at Lucy.McDonough@Philips.com.

Sincerely yours,

Lucy McDonough
Director Market Access North America
Philips