



October 3, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5519-P
P.O. Box 8013
Baltimore, MD 21244-1850

Dear Acting Administrator Slavitt:

As Chairman of the Partnership to Improve Patient Care (PIPC), I am writing to provide comments on the Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR). While PIPC is not a disease-specific coalition, we are providing input on how to achieve patient-centeredness in alternative payment models (APMs) based on feedback we have received from our members related to the proposed models.

Since its founding, PIPC has been at the forefront of patient-centeredness in comparative effectiveness research (CER) – both its generation at the Patient-Centered Outcomes Research Institute (PCORI) and its translation into patient care. Having driven the concept of patient-centeredness in the conduct of research, PIPC looks forward to bringing the voices of patients, people with disabilities, and their families to the discussion of how to advance patient-centered principles throughout an evolving health care system.

Patient Engagement

First and foremost, I have made it my ministry that patients and people with disabilities must have a meaningful voice in the development of health policies, particularly in the discussion about what constitutes “value” in health care. As you know, I am a strong advocate for the creation of an infrastructure within the CMS Innovations Office (CMMI) that supports the engagement of patients and people with disabilities, as well as clinical experts, so that APMs are developed to provide the right care and the right time based on patient needs, preferences and outcomes. For example, with early engagement, CMMI could access patient-centered data sources available from patient organizations and clinical specialty societies through their patient and clinical registries. These real-time sources of data should be considered early in the development of APMs, prior to APMs being introduced publicly, and should be recognized throughout the implementation and evaluation process as well. Engagement would also allow CMMI to identify existing models that have demonstrated success, such as the Virginia Cardiac Surgery Quality Initiative, and to build from those successes.

We are concerned that the agency has not taken steps to create the infrastructure that is needed for meaningful patient and stakeholder engagement. We have long proposed that the CMS Innovations Office create a Patient Advisory Panel to oversee and ensure patient-centeredness in the agency's work, yet there is no evidence of an early and meaningful engagement process in the development of these episode payment models. Mechanisms are needed to ensure new payment models are consistently developed and evaluated in ways that support patient-centered care and are aligned with care that patients value. As you know, Section 1115A of the Affordable Care Act calls for evaluation of payment models against "patient-centeredness criteria" – yet no such criteria have been formally developed or publicly released for comment. Establishment of these criteria will provide a structured patient-focused framework to guide the agency's work. As specified in statute, demonstrations should be evaluated against these criteria. The Patient Advisory Panel should play a leading role in developing these criteria and ensuring they are applied to the work of the Innovations office.

Transparency

PIPC urges CMMI to improve its transparency in developing, implementing and evaluating APMs, and particularly adding transparency in the requirements for patient engagement and evidence-based decision-making for episode payment models. We urge CMMI to also make transparent the results of APM evaluations regarding their impact on patient access and engagement, care quality, and cost. Additionally, we urge the agency to ensure patients are fully informed when they are subject to an episode payment, and are made aware of mechanisms to opt out or seek assistance via safeguards like novel appeals mechanisms or an ombudsman.

Suggested Areas of Engagement

We are aware of the following specific issues that will require the expertise and engagement of patients and their providers to fully address. At a minimum, these concerns underscore the need for demonstrations to be just that – demonstrations – as opposed to required participation in a mandatory model that has not been fully tested and could put patients at risk. They also underscore the need for more meaningful stakeholder engagement in the development of APMs to achieve transparency and patient-centeredness. We urge the agency to engage patients and providers to address the following issues:

- Episode Definition: PIPC urges CMMI to incorporate consideration of the long-term implications of treatments in any episode payment model. For example, there can be significant long-term implications for an active Medicare beneficiary at age 65 who needs a lower extremity device that will last 20 years or longer. An incentive to reduce costs could result in providing that beneficiary with a device that requires a revision after 5-10 years, as opposed to providing that beneficiary an innovative treatment option that lasts a lifetime. Achieving personalized medicine requires us to think about the long-term implications of health care, as opposed to the short-term thinking that goes with a hard 90-day episode.

- **Accountability for Improved Health Outcomes:** The proposed rule calls for a retrospective, two-sided risk model with hospitals bearing financial responsibility. Patients and providers have expressed concerns about the accountability for meeting the requirements of the episode payment when patients are transferred early in their care. Collaborations are important, and we urge CMS to engage with patients and providers to achieve a policy that will mitigate any unintended consequences.
- **Quality Measures:** PIPC urges CMMI to identify patient-centered quality and performance measures for use in APMs. To do so, CMS should engage patients throughout the development and use of quality measures to ensure that quality measures reflect patient values and preferences and evolve with the standard of care. This includes patient input at the front end to identify gaps where measures need to be developed, and also at the back end to assess the ability of existing measures to reflect the care an individual patient receives, as well as to help determine if and when measures need to be updated or replaced. There have been significant efforts such as the Core Quality Measures Collaborative and the Institute of Medicine’s Vital Signs work to determine key quality measures that may be useful references, having each having had some level of stakeholder engagement. Ultimately, patients and their providers must have a seat at the table to ensure that success is measured in a manner that reflects patient-centeredness. Underlying this consideration is also the need to manage the administrative burden on clinicians that so often leads to reduced time with patients, and therefore less time to consider the unique needs of each patient.
- **Telehealth:** Telehealth has significant potential to improve outcomes that matter to patients. We urge CMMI to engage with patients and providers to determine the most effective ways to test telehealth in populations that need it most.
- **Risk Adjustment:** We urge CMMI to engage with appropriate specialty societies, providers and patients to determine the appropriate risk adjustment mechanisms for episode payment models to ensure critically ill patients are not left behind. We were struck by a recent article entitled, “The CMS Comprehensive Care Model and Racial Disparity in Joint Replacement” that outlined the potential effect of the model on racial disparity in joint replacement utilization. Engagement is needed not just from patients and providers, but also from organizations specifically representing certain subpopulations to ensure that new care models are not exacerbating health care disparities.

Support Shared Decision-Making and Personalized Medicine

PIPC has long supported the development of standards for sound shared decision-making, and the testing of shared decision-making through patient-focused models in primary care and specialty care settings. CMS included several activities to promote shared decision making in the Clinical Practice Improvement Activities Category of the Merit-Based Incentive Payment System (MIPS) score, an important first step to build on the Affordable Care Act’s provisions

calling for a shared decision-making program. PCORI and others have done significant work to determine what types of shared decision-making tools work best in practice. Patient groups are prioritizing the development of shared decision-making tools, informed by their work to identify and reach patients from whom we can learn in real time what they value in health care. Patients deserve the ability to make informed choices about their care so that we are not wasting health care resources on care that does not work. We look forward to the agency supporting and developing meaningful criteria for meaningful shared decision-making through additional APMs, including accountable care organizations (ACOs).

APMs should work in tandem with our goals for personalized medicine and the Precision Medicine Initiative. President Barack Obama was very eloquent in the Boston Globe last summer stating, “Health care is always personal. As science and technology have advanced, it’s become possible to make it personalized as well, giving us the tools to better understand, prevent, and treat everyone’s individual health needs.”

By contrast, policies that seek to standardize care in a manner that potentially limits patient access to care that is uniquely suited to their needs, preferences and outcomes only serve to hinder the promise of personalized medicine. *Medicare is not a homogenous population.* Patients have varying levels of functionality within Medicare. Some continue to be runners or play sports, while others may be less active. Therefore, it is vital that the device or treatment chosen for each beneficiary be uniquely suited to their personal needs, preferences and outcomes.

We are concerned that there is a lack of robust mechanisms to protect quality and access for patients that are subject to the episode payment models. In particular, mandatory APMs have the potential to drive patients to a narrow choice of providers and undermine the relationship between patients and their providers by creating financial incentives around pre-determined clinical decisions, driving a one-size-fits-all model of care. In this age of personalized and precision medicine, it is imperative that patients in APMs or other demonstrations have access to protections such as a rapid appeals process that would allow for a more individualized approach to their care and to patient and consumer ombudsmen.

Conclusion

In closing, we believe that solutions that center on patients and people with disabilities are the best approach to improving overall health care efficiency and quality. CMS should engage patients, people with disabilities and their families, providers and other stakeholders early and often in the creation of a health system that puts patients and people with disabilities at the center. With early engagement, we can shift away from policies that reinforce the old paternalistic system of health care and work against personalized medicine and the Precision Medicine Initiative, and instead focus on delivery reforms that activate and engage patients and people with disabilities and support shared decision-making between patients, people with disabilities and their providers. We look forward to an engagement process to develop care models for cardiac rehabilitation and joint replacement that reflect the input of patients, people



with disabilities and their providers. In doing so, CMMI will be building the foundation for a patient-centered health system.

Sincerely,

A handwritten signature in black ink that reads "Tony Coelho". The signature is written in a cursive style with a stylized initial.

Tony Coelho
Chairman, Partnership to Improve Patient Care