



November 13, 2016

Andy Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Attention: CMS-1612-P Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-8013

**Subject: Request for Information Regarding Implementation of the Merit-based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models**

Dear Acting Administrator Slavitt:

The Partnership to Improve Patient Care (PIPC) appreciates this opportunity to comment on the implementation of the Merit-based Incentive Payment System (MIPS), Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models passed as part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). 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 patient voice to the discussion of how to advance patient-centered principles throughout an evolving health care system.

The U.S. has made significant progress in advancing patient-centeredness over the last several years. The progress we have made is the fruit of a movement that spans several decades, and PIPC is proud to have lent its voice to this effort. Advances in policy such as the authorization of PCORI in 2010 and Patient-Focused Drug Development at the Food and Drug Administration (FDA) highlight the recognition by policymakers that patients should not be in the back seat. Instead, patients should be driving research, and given the recognition that they are capable of translating patient-centered research into health care decision-making.

At the same time, much work remains to be done. While most health policy experts agree on the notion of developing a “patient-centered health care system,” we do not yet have a delivery system that entirely incorporates or is modeled on delivering patient-centered health care. PIPC promotes policies that apply patient-centered principles throughout the health care system – from development of evidence (i.e. PCORI) to the design of new payment and delivery reforms (i.e. alternative payment models (APMs)). We strive to raise awareness about the value of well-designed comparative clinical effectiveness research, the important role of continued medical innovation as

part of the solution to cost and quality challenges in health care, and the importance of shared decision-making between patients and providers that empowers truly patients to play a more active role in their own healthcare decisions. PIPC members, representing a diverse, broad-based group of health care stakeholders, are dedicated to working together to promote giving a voice to patients, giving choice to patients, and advancing value for patients.

Implementation of MACRA provides an opportunity to advance a health system that meets the principles of patient-centeredness and therefore empowers and activates patients in their own care. In furtherance of this goal, PIPC provides the following broad recommendations for payment and delivery of healthcare:

- Provide a meaningful voice to patients. Policymakers should establish formalized mechanisms that provide a meaningful voice to patients throughout the healthcare system.
- Prioritize policies that promote patient-centeredness and ensure new payment and delivery models do not define success as simply meeting financial targets or promote a “one-size-fits-all” approach to cost-containment.
- Catalyze the expansion of available quality measures and ensure they are appropriately incentivized in health systems. Policymakers should recognize the need to improve the patient-centered infrastructure for measuring and rewarding improved health outcomes. There are significant gaps in quality measurement that will require expanded support for measure development and endorsement.
- Foster informed choices from the range of clinical care options through shared decision-making, transparency of the incentives (financial and otherwise) that drive care decisions, and by empowering patients with accessible, understandable evidence.
- Support patient access to high quality individualized care.

This Request for Information (RFI) is a positive first step to receive input from stakeholders related to the development of policies to implement MIPS, promote APMs, and implement incentive payments for participation in eligible APMs. Nevertheless, we would emphasize that achieving meaningful input from beneficiary stakeholders, particularly patients, people with disabilities, and their families, is a continuous process that requires targeted strategies beyond a regulatory notice and comment. We believe such input from the beneficiaries whose care relies on getting this right will be vital to achieving the statute’s goals. Ultimately, the transition to value-based health care must look at value from the perspective of patients served by the system of care.

### **MIPS Quality Performance Category**

What types of measures (that is, process, outcomes, populations, etc.) used for other payment systems should be included for the quality and resource use performance categories under the MIPS?

The Centers for Medicare and Medicaid Services (CMS) should structure the MIPS program to incentivize providers to deliver care that is consistent with achieving the outcomes that matter to

the individual patient. There is a noticeable lack of focus in the RFI on potential measures that capture patient-centeredness of the care being received. We urge the use of patient-centered quality measures, including patient-reported outcomes, care coordination, patient engagement, and quality of life measures. We also urge CMS to place a greater emphasis on quality of care in the scoring calculations for MIPS as a way to encourage a greater focus on improving the patient experience of care.

Section 1848(q)(10) of the Act requires the Secretary to consult with stakeholders in carrying out the MIPS. Under section 1848(q)(2)(D) of the Act, the Secretary must, through notice and comment rulemaking by November 1 of the year before the first day of each performance period under the MIPS, establish the list of quality measures from which MIPS EPs may choose for purposes of assessment for a performance period for a year. Input from beneficiaries, including patients, people with disabilities, and their families, will require more than a notice and comment period. Patients should be directly engaged in a process of defining the measures that best capture outcomes that matter to patients, as well as the components of care planning and shared decision-making. In addition to the process outlined by statute, we propose that the agency leverage multi-stakeholder processes, such as the National Quality Forum process, and also develop new strategies for outreach to patients and patient groups soliciting feedback on the quality measures available to capture outcomes that matter to patients.

Should we require that certain types of measures be reported? For example, should a minimum number of measures be outcomes-based? Should more weight be assigned to outcomes-based measures?

Patient organizations representing the populations targeted by quality measures should be directly consulted in the determination of which measures are most representative of outcomes that matter to patients. Where outcomes-based measures are available and endorsed by the patient community, their use should be prioritized, especially patient-reported outcome measures.

Should we require that reporting mechanisms include the ability to stratify the data by demographic characteristics such as race, ethnicity, and gender?

Yes, PIPC would agree that reporting mechanisms should capture demographic characteristics. It is important to recognize that in creating PCORI, Congress clearly prioritized that research should look at the clinical impacts on various subpopulations and outcomes reflecting patient preferences and quality of life. Congress did so recognizing the potential for this information to drive personalized and precision medicine that allowed patients to better understand the impact of their treatment options based on their unique set of circumstances, instead of being treated as averages. By capturing demographic information in health delivery and care, we can carry through from research to practice the intent of Congress toward personalized and precision medicine that also addresses disparities in care.

## **MIPS Clinical Practice Improvement Category**

Section 1848(q)(2)(B)(iii) of the Act specifies that the measures and activities for the clinical practice improvement activities performance category must include at least the following subcategories of activities: expanded practice access, population management, care coordination, beneficiary engagement, patient safety and practice assessment, and participation in an APM. We believe it is critically important for these activities to emphasize meaningful patient-engagement; including care planning that captures patient preferences and relies on practices of shared decision-making. CMS, with opportunities for feedback from patient advocates, should evaluate all potential clinical practice improvement activities (including APMs that are clinical practice improvement activities) through this lens.

The RFI seeks comment on the following additional subcategories, in particular how measures or other demonstrations of activity may be validated and evaluated:

A subcategory of Promoting Health Equity and Continuity, including (a) serving Medicaid beneficiaries, including individuals dually eligible for Medicaid and Medicare, (b) accepting new Medicaid beneficiaries, (c) participating in the network of plans in the Federally- facilitated Marketplace or state exchanges, and (d) maintaining adequate equipment and other accommodations (for example, wheelchair access, accessible exam tables, lifts, scales, etc.) to provide comprehensive care for patients with disabilities.

On behalf of people and patients with disabilities and their families, PIPC would strongly support a subcategory recognizing the need to maintain adequate equipment and other accommodations (for example, wheelchair access, accessible exam tables, lifts, scales, etc.) to provide comprehensive care for patients with disabilities. In our work with organizations representing this community, we have been strong proponents of research that underscores the challenges faced by people with disabilities in the health care system and the benefits of addressing those challenges. As an example, a patient with a disability cannot receive appropriate cancer screenings without an accessible exam table. Examples are abundant, but the Americans with Disabilities Act clearly intends that accessibility be an enforced component of our health care system.

A subcategory of Achieving Health Equity, as its own category or as a multiplier where the achievement of high quality in traditional areas is rewarded at a more favorable rate for EPs that achieve high quality for underserved populations, including persons with behavioral health conditions, racial and ethnic minorities, sexual and gender minorities, people with disabilities, and people living in rural areas, and people in HPSAs.

Consistent with our above statement, PIPC supports a subcategory that would indicate improved quality for underserved populations. With the growing amount of evidence on treatment options and strategies that achieve improved outcomes for certain subpopulations, as is being conducted by PCORI, it is inexcusable for health disparities not to diminish over time.

## **Alternative Payment Models**

We appreciate that the RFI seeks to obtain input on policy considerations for APMs and for physician-focused payment models. MACRA lays out a specific process to guide the selection of “physician-focused payment models,” including establishment of a related technical advisory committee. While engaging providers in the development and selection of APMs is important, it is even more critical that patients have a voice in the selection and development of models that will impact their care.

Per MACRA’s definition of an APM, the majority of APMs are likely to come out of the Center for Medicare and Medicaid Innovation (CMMI). As an overarching recommendation, we strongly recommend the creation of a Patient Advisory Panel by CMMI to help ensure new payment models are aligned with care that patients’ value. With so many issues to consider, we believe that creating a standing Patient Advisory Panel that is meaningfully connected to CMMI’s work is the single most important step that can be taken in the near term to achieve the goal of patient-centeredness in APMs.

The Patient Advisory Panel should be positioned to provide guidance to CMMI in identifying the key areas that would benefit from patient input, including APM development, model design features that will promote effective patient engagement, and metrics (e.g., patient-centered quality measures and other tools) on which to assess the success of these efforts. As you know, CMMI’s authorizing statute recommends that CMMI consider a number of patient-centered factors in its work, including: whether models include a regular process for monitoring and updating patient care plans in a manner that is consistent with the needs; preferences and choices of applicable individuals; and whether models place the applicable individual—including family members and other informal caregivers of the applicable individual—at the center of the care team of the applicable individual. These additional considerations outlined by Congress point to the importance of ensuring that APMs reflect patient needs, preferences, and choices; the Patient Advisory Panel can provide critical insight to CMMI to ensure these goals are fulfilled.

The Patient Advisory Panel should also assist CMMI and its contractors in the evaluation of APMs by identifying patient-centered quality measures. With the funding in recent legislation to support measure development and endorsement, there lies an opportunity to drive a business model for achieving outcomes that matter to the individual patient. As discussed above related to MIPS, we propose that the agency leverage multi-stakeholder processes, such as the National Quality Forum process, and coordinate with a Patient Advisory Panel for feedback on the quality measures available to capture outcomes that matter to patients, including patient-reported outcomes. Achieving increased quality and decreased costs on average requires an extra step to get behind those numbers to determine for whom new payment models are working and for whom they are not necessarily working. Quality measurement that identifies how patient needs, preferences, and choices are being achieved in care can help to address this gap and further personalized and precision medicine.

In addition, the Patient Advisory Panel should develop and apply the required patient-centeredness criteria to APMs. 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 by CMMI. Establishment of these criteria will provide a structured patient-focused framework to guide CMMI’s work and the selection of APMs under MACRA. For example, the panel could assist CMMI in factoring whether models selected for testing include a regular process for monitoring and updating patient care plans in a manner that is consistent with the needs, preferences, and choices of applicable individuals, as well as in determining whether a model being considered for expansion denies or limits coverage of benefits for Medicare beneficiaries.

Finally, the panel should also serve as an invaluable conduit connecting CMMI staff with the broader patient community. In this role, the Patient Advisory Panel would assist CMMI in the development of targeted methodologies to solicit input from patient organizations, including a simple and streamlined process for soliciting patient participants in advisory roles.

### **Creating a Culture of Patient Engagement**

As we work toward formalizing and standardizing methods for patient input, we recognize there is a continuum of patient engagement that will require engaging the right patients and the right time with continuity, whether an individual patient, a patient advocate, a patient organization, or a caregiver. This lesson has been learned in Patient-Focused Drug Development efforts and in patient-centered outcomes research. Too often, a preferred outcome is thrust upon a patient without their input including their values and preferences.

As discussed, the Consumer and Patient Affinity Group recently created to meaningfully engage patients in the Health Care Payment and Learning Action Network (LAN) will be a valuable contribution to these efforts, and we look forward to contributing to that group’s evolving role. However, the LAN is just one venue for these important discussions. If APM policies are to truly reflect the patient perspective and reward patient-centered care, patients must have a meaningful role in policy development and ongoing evaluation. The efforts of a new Patient Advisory Panel with direct input into CMMI, combined with a strong LAN Consumer and Patient Affinity Workgroup, can help us progress toward a culture of patient engagement within new payment models. We urge your consideration of the establishment of a Patient Advisory Panel within CMMI and would be pleased to provide additional input as this panel takes shape.

PIPC urges policymakers not to lose focus on the building blocks for patient-centered health care incorporated into the early phases of evidence development, translation and implementation, all the way through to the design and implementation of new payment and delivery reform models. In this way, our health care system will be built to improve health outcomes by identifying the treatments that work best for individual patients – not by limiting access or pushing “one-size-fits-all” treatment solutions.

Sincerely,

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

Tony Coelho  
Chairman, Partnership to Improve Patient Care