

April 19, 2017

Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5519-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: 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; Delay of Effective Date

Dear Administrator Verma:

As Chairman of the Partnership to Improve Patient Care (PIPC), I am writing to provide comments on the delay of the effective date for the final rule entitled “Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model”. We applaud the agency for taking a step back to get additional feedback about proposed new payment models. We view this as an opportunity for the agency to forge a new path forward on engaging stakeholders, particularly patients, in the development, implementation and evaluation of alternative payment models. Without patients at the table, it will be impossible for new models to be truly patient-centered, meaning that they are built to achieve outcomes that matter to patients. Additionally, this is an opportunity to consider input from stakeholders about the scope and impact of new payment models and apply that feedback to episode payment models being implemented by the Centers for Medicare and Medicaid Innovation (Innovation Center).

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.

Overview of Concerns About Episode Payment Models

We urge the Innovation Center to review PIPC’s recent report entitled, “A Roadmap to Increased Patient Engagement at CMMI” as reference for engagement practices. We reviewed the following six engagement strategies: 1) Engaging with stakeholders early in the process 2) Holding public meetings 3) Developing standards or guidelines for public engagement 4) Creating advisory panels or workgroups 5) Making information readily available to public, and

6) Formal comment opportunities. We found that despite the progress that Innovation Center has made in incorporating the design elements for effective stakeholder engagement into some of its programs, a number of Innovation Center programs feature limited stakeholder involvement and transparency.

One such model is Comprehensive Care for Joint Replacement (CJR). The aim of CJR is to test bundled payments for hip and knee replacements. CJR represents the Innovation Center's first mandatory model and requires participation across all hospitals in one of every five U.S. metropolitan areas – encompassing many hospitals that chose not to participate and bear risk in previous voluntary models testing bundled payments (i.e., Bundled Payments for Care Improvement Initiative).¹ Despite CJR being a mandatory model, the Innovation Center did not involve patients or other stakeholders in the initial formation of the proposal nor was it demonstrated to meet criteria for patient-centeredness. Similar to CJR, in July 2016, CMS released the Advancing Care Coordination through Episode Payment Models Episode Payment Models Rule as a proposed mandatory program that introduces bundled payments for cardiac care.² This proposed rule was also developed without prior input from stakeholders and, as a result, contained elements that were concerning to patients and providers from a clinical perspective. The agency has not developed criteria for patient-centeredness nor an infrastructure for patient engagement, causing significant concerns about the leap to these mandatory models.

We conclude that patient engagement must occur early in the model design process to positively shape the direction of the Innovation Center's proposals. Additionally, new models should be tested and validated as meeting criteria for patient-centeredness before being considered for widespread implementation as mandatory models. With patient engagement, new models could be introduced with support and buy-in from the impacted patient communities that will be integral to their success.

Process for Development of Patient-Centeredness Criteria

We appreciate that the final rule acknowledged PIPC's request for a Patient Advisory Panel and process for developing patient-centeredness criteria. The response provided by the agency was, "Although the establishment of a Patient Advisory Committee for all Innovation Center models is beyond the scope of this rule, we believe that stakeholder engagement is essential to the success of these models and our learning and monitoring contractors as well as our evaluation contractor will be soliciting beneficiary feedback on their experiences with the EPMs."

We continue to be concerned that mechanisms are needed to ensure new payment models are consistently developed and evaluated in ways that support patient-centered care and are aligned

¹ Comprehensive Care for Joint Replacement Model. CMS. Available at: <https://innovation.cms.gov/initiatives/CJR>. Accessed on October 21, 2016.

² 42 CFR Parts 510 and 512. 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). CMS. Available at: <https://innovation.cms.gov/Files/x/advancing-care-coordination-nprm.pdf>. Accessed on October 21, 2016.

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. Patients should be engaged in developing patient-centeredness criteria and ensuring they are applied to the work of the Innovation Center. By doing so, the Innovation Center would be building an infrastructure for patient engagement that goes beyond a notice and comment period and is therefore more effective in achieving care that patients value.

Recommendations: To ensure alternative payment models are aligned with care that patients value, the Innovation Center should directly engage patients to:

- Create criteria for patient-centeredness per the Innovation Center’s statutory guidance;
- Develop an infrastructure for meaningful patient engagement within all CMMI teams, including the team developing episode payment models;
- Better identify deficits in care that could be addressed by new model tests;
- Determine patient-centered quality measures; safeguards; and techniques for shared decision-making;
- Assess Innovation Center model designs against criteria for patient-centeredness; and
- Make recommendations with respect to the impact of model expansions on quality and access to care for patients.

Early Engagement with Patients as Partners

We continue to urge the Innovation Center to directly engage with patients impacted by new payment models early in the process so that patient perspectives are incorporated into episode payment models before being proposed formally and implemented. In fact, we urge this type of engagement across the board for any future Innovation Center payment models. By delaying the implementation of episode payment models, the Innovation Center has a great opportunity to demonstrate the sincerity of its commitment to stakeholder engagement. There is an emerging science of patient engagement that could be referenced as the Innovation Center considers additional tactics for patient engagement, including models for engagement being implemented by the Patient-Centered Outcomes Research Institute (PCORI) and the Food and Drug Administration’s (FDA) Patient-Focused Drug Development program.

For example, PCORI utilizes various stakeholder engagement strategies to provide funding for research studies related to comparative clinical effectiveness research (CER) that specifically seek to engage patients, including:

- Engaging with stakeholders early in the process: PCORI encourages stakeholder engagement prior to the initiation of any research study. For example, PCORI provides a formal set of methodological standards and requirements associated with patient-centeredness and engagement that applicants use to best integrate patients into their study

design. In addition, patients and other stakeholders participate on panels that review and select research proposals.³

- Holding public meetings: PCORI holds monthly Board of Governor’s Meetings that are open to the public. During each meeting, the board reviews and approves new research funding awards and discusses other relevant agenda items. The meetings are all held using a teleconference/webinar system to facilitate broad participation.⁴
- Developing standards or guidelines for public engagement: Any application for PCORI funding is required to include an Engagement Plan specifying methods to engage patients and other stakeholders in the design, execution, and dissemination of research.¹⁷ To guide applicants in actively considering stakeholder engagement in their research proposals, PCORI developed an Engagement Rubric that applicants can consult when developing their Engagement Plans. Applicants consult an Engagement Rubric developed by PCORI to provide guidance on how to incorporate patients and other stakeholders into the study design. The rubric underscores PCORI’s Methodology Standards for patientcenteredness and Patient-Centered Outcomes Research (PCOR) Engagement Principles. Applicants are encouraged to demonstrate how they will incorporate the six PCOR Engagement Principles (reciprocal relationships, co-learning, partnerships, transparency, honesty, and trust) into their research plans.⁵
- Creating advisory panels or workgroups: PCORI encourages stakeholder participation through membership on Advisory Panels and through stakeholder roundtables on priority topics (comprised of practicing and research clinicians, patients, and experts in scientific and health services research and delivery), to review and select applications for funding.⁶

Additionally, the Food and Drug Administration’s (FDA) Patient-Focused Drug Development (PFDD) Initiative provides another model for patient engagement. In 2012, the FDA reauthorized the Prescription Drug User Fee Act (PDUFA) V, which included a PFDD initiative to emphasize the importance of incorporating the patient perspective into the agency’s benefit-risk assessment of new therapies. This initiative is designed to solicit the patient perspective on specific disease conditions and currently available therapies, including:

- Holding public meetings. Under PDUFA V (FY 2013 – FY 2017), the FDA committed to hold public meetings covering at least 20 disease areas. Since only some disease areas are chosen by the FDA for PFDD meetings, the agency also encourages patient organizations to hold externally-led PFDD meetings and share meeting deliverables with the FDA.

³ What We Mean by Engagement. PCORI. October 12, 2015. Available at: <http://www.pcori.org/funding-opportunities/what-we-meanengagement>. Accessed on October 21, 2016.

⁴ Board of Governors Meeting. PCORI. Available at: <http://www.pcori.org/events>. Accessed on November 30, 2016.

⁵ Engagement Rubric for Applicants. PCORI. June 6, 2016. Available at: <http://www.pcori.org/sites/default/files/EngagementRubric.pdf>. Accessed on October 21, 2016.

⁶ How We Select Research Topic. PCORI. May 4, 2014. Available at: <http://www.pcori.org/research-results/how-we-select-researchtopics>. Accessed on October 21, 2016.

Patient stakeholders may provide input at the public meetings or share their perspectives through comment submissions to the public dockets.⁷

- Making information readily available to public. After each meeting, the FDA produces public reports entitled “The Voice of the Patient” that summarize the patient and patient representative input for each disease area.⁸

In those entities, patients are engaged as part of advisory panels, within specific disease areas to inform priorities about research and measures of quality, as sources of patient data gleaned from surveys of patients and their families, etc. While we are pleased that CMS welcomes information about existing patient-centered outcome measures that address quality gaps, getting it right will require significant engagement with the impacted patient community outside of the more bureaucratic notice and comment period protocols. Listening sessions with patients are a good start, but to be truly effective, early input from patients must be incorporated into proposed new models so that patients are truly partners in model development, implementation and evaluation and are therefore committed to their success.

Recommendation: CMMI should establish and consistently apply a clear process for seeking input from patients, caregivers and other stakeholders early in the process of developing and testing new APMs. This process should include:

- A mechanism for patients and advocates to proactively propose new model designs and model elements to CMMI;
- Improved advanced communication about CMMI’s work plan for new model tests; o Formal opportunities for early input into potential model tests (e.g., through an RFIs and/or a design concept paper); and
- A mechanism for regular engagement with patients throughout the implementation process.

Support Shared Decision-Making

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. In the final rule, CMS responded to comments urging the agency to incorporate shared decision-making into its episode payment models by agreeing to consider the recommendations in future rulemaking. With the delay in implementation of the existing episode payment model rule, CMS has an opportunity to make progress on implementing the Affordable Care Act’s provisions calling for a shared decision-making program by incorporating

⁷ Patient-Focused Drug Development: Disease Area Meetings Planned for Fiscal Years 2013-2017. April 21, 2016. Available at: <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm347317.htm>. Accessed on October 21, 2016.

⁸ Enhancing Benefit-Risk Assessment in Regulatory Decision-Making. FDA. July 7, 2015. Available at: <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>. Accessed on October 21, 2016.

shared decision-making into all new models going forward. As we have noted in the past, 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. While the program for shared decision-making in accountable care organizations (ACOs) is a good start, we look forward to additional attention to the development of standards for shared decision-making that will assure its implementation in a manner that is transparent regarding the evidence base, understandable to patients, and broadly disseminated for use. We believe that high quality shared decision-making should be a core component of all new models going forward.

Recommendation: Develop standards for shared decision-making that will assure its implementation in a manner that is transparent regarding the evidence base, understandable to patients, and broadly disseminated for use and make a core component of all new models going forward.

Avoid One-Size-Fits-All Policies

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 remain 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 alternative payment models 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. The size and scope of episode payment models forces patients and providers into models that are not fully tested and validated. There is some evidence that bundled payment approaches may provide incentives to increase the number of episodes and that participants may select patients that are less costly to treat.⁹ While final rule claims that there are numerous processes in place under the episode payment models and the Medicare program to protect beneficiary choice, without transparency to the patient that they are indeed part of an episode payment model and a clear articulation of the evidence base for their treatment, beneficiaries are left unaware of the financial incentives driving

⁹ Dummit, Laura A., MSPH, et al. Association Between Hospital Participation in a Medicare Bundled Payment Initiative and Payments and Quality Outcomes for Lower Extremity Joint Replacement Episodes, JAMA, Sept. 19, 2016.

their care and therefore cannot make informed choices. In this age of personalized and precision medicine, it is imperative that patients in alternative payment models or other demonstrations are provided 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.

Recommendation: CMMI should clearly communicate information about its model test designs and their implications for patients. This includes more transparency in:

- The requirements for patient engagement and evidence-based decision-making;
- The measures, particularly measures of patient outcomes and patient centeredness, that are relied upon to evaluate models;
- Model evaluation findings with respect to quality and access to care; and
- Options for patients in CMMI model tests to opt out or seek assistance when they are subject to a CMMI test (e.g., appeals mechanisms, CMMI ombudsman).

Conclusion

In closing, engaging the patient community is a complex task and will require more than the notice and comment process that are traditionally used by regulatory agencies. However, a more structured process for patient engagement that leverages the Innovation Center's own best practices, along with creative methods employed by organizations such as PCORI and the FDA's PFDD Initiative, will ensure that the patient perspective is well represented in the Innovation Center's model tests and improve their likelihood of success.

I look forward to working with you to develop tactics for patient engagement that allow policymakers to get out of the ivory towers, and instead respond directly to the patients and people with disabilities that our programs are intended to serve. Please call on me at any time.

Sincerely,



Tony Coelho
Chairman, Partnership to Improve Patient Care