PIPC Partnership to Improve Patient Care

September 11, 2017

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-1676-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program

Administrator Verma:

I am writing on behalf of the Partnership to Improve Patient Care (PIPC) in response to the Centers for Medicare & Medicaid Services (CMS) Proposed Rule regarding Medicare Shared Savings Program Requirements. 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. Getting beyond token engagement of patients and people with disabilities will require a strong commitment from this administration, and will result in policies that truly put patients first.

PIPC has significant concerns about CMS's proposal to remove the requirement for accountable care organizations (ACOs) in the Medicare Shared Savings Program to submit supporting documentation related to patient-centeredness in their applications. Specifically, CMS proposes that ACOs will no longer need to submit documentation addressing the required processes and patient centeredness criteria. This documentation includes a description of the ACO's process for promoting evidence-based medicine, beneficiary engagement, and coordination of care. CMS proposes that in lieu of this documentation, ACOs will attest to having these processes in place and only submit a narrative or additional documentation if requested by CMS.

We are concerned that CMS would propose to remove these requirements and accept attestation in their place. Although we understand that CMS is attempting to lessen the burden on ACO applicants, we believe that it is imperative that ACOs be held to the highest possible standard for patient-centeredness. A further underlying challenge is that CMS has not set forth a clear definition for what it means for an ACO, or any other alternative payment model (APM), to be patient-centered, nor does the agency have an ongoing relationship with patients who are beneficiaries of ACOs to attest to meeting any definition of "patient-centeredness." The rule proposes to abdicate responsibility for enforcing that ACOs actually

be patient-centered, instead of proposing a path to defining patient-centeredness in a manner that is understandable and accepted by all stakeholders.

While we strongly support the shift away from fee-for-service models to value-based models for payment and delivery of health care services, we are also concerned about the pace of this shift without basic beneficiary protections that ensure new models are providing value to the patient. Therefore, we are proposing again that the agency consider creating a process to develop patient-centeredness criteria and an infrastructure for patient engagement in the development, implementation and evaluation of APMs.

Develop Patient-Centeredness Criteria

Organizations representing patients and people with disabilities have consistently called upon the agency to develop meaningful patient-centeredness criteria as called for by statute. Therefore, we are gravely concerned that the agency would propose that a self-attestation of patient-centeredness is acceptable in lieu of meeting tangible and meaningful criteria. As you know, Section 1115A of the Affordable Care Act also calls for evaluation of APMs against "patient-centeredness criteria" – yet no such criteria have been formally developed or publicly released for comment. Therefore, while patients and people with disabilities have their own definition for the term "patient-centered," it has no official definition for policymakers. For these reasons, we have recommended that CMMI adopt the following additional standards and safeguards:

- Establish criteria for patient-centeredness in CMMI payment models;
- Identify patient-centered quality and performance measures for use in CMMI payment models;
- Protect patients and people with disabilities by prohibiting application of cost-effectiveness and quality-adjusted-life-years (QALYs) as the basis for coverage and care decisions in APMs supported by CMMI;
- Create robust mechanisms to protect quality and access for patients that are subject to CMMI's demonstrations, such as ensuring that initial demonstrations are limited in size and scope;
- Ensure patients are fully informed when they are subject to a CMMI test, and are made aware of mechanisms to opt out or seek assistance; and
- Ensure that any decision-support tools utilized in APMs (e.g., clinical decision-support and clinical pathways) meet criteria for patient-centeredness.

Establishment of patient-centeredness criteria will provide a structured patient-focused framework to guide the agency's work and put patients first, and commitment to clear standards and safeguards for future models will help protect access to care for patients.

Develop an Infrastructure for Patient Engagement

The Medicare Shared Savings Program, as well as APMs implemented by CMMI, present opportunities for improved patient engagement. By applying patient-centeredness criteria, the Innovation Center would be building an infrastructure for patient engagement that goes beyond a notice and comment period. We would urge you to review PIPC's recent report entitled, "A Roadmap to Increased Patient

Engagement at CMMI" as reference for best practices for engagement. We reviewed the 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.

As a reference, we found that despite the progress that the Innovation Center has made in incorporating the design elements for effective stakeholder engagement into some of it programs, a number of Innovation Center programs feature limited stakeholder involvement and transparency. We concluded 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. 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.

Relevant to the Medicare Shared Savings Program as well, we have recommended in the past that the agency 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;
- Improved advanced communication about work plans for new model tests;
- 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 – as well as other stakeholders – throughout the implementation process.

In closing, thank you for soliciting our feedback. We believe that our recommendations will assist patients and their providers make care decisions that are most appropriate for the individual patient, as opposed to advancing a one-size-fits-all health system. We look forward to a continued dialogue on how to improve beneficiary outcomes and engage patients.

Sincerely,

Tony Coelho
Chairman, Partnership to Improve Patient Care