CMS' Proposed Use of Comparative and Cost-Effectiveness Standards: What It Means for Patients

On March 8, 2016, the Center for Medicare and Medicaid Services (CMS) proposed a new Part B Drug Payment Model. Among its provisions, the proposal calls for use of comparative effectiveness research (CER) and cost-effectiveness reports as the basis for national Medicare policy, in direct conflict with the patient-centeredness movement. Since its inception, the Partnership to Improve Patient Care (PIPC) has been strongly opposed to misuse of CER and cost effectiveness in government policies. This proposal appears to have been rushed forward with little or no patient input. The phase involving centralized use of CER and cost-effectiveness begins early in 2017, eventually covering 50% of providers and patients, leaving little time for meaningful patient engagement.

PIPC highlights the following significant implications for patients:

- **Centralized Value Assessments Rely on Average Results that Ignore Patient Difference:** The proposal undermines progress toward a patient-centered health system spurred by Congress in creating the Patient-Centered Outcomes Research Institute (PCORI) and advancing shared decision-making. Average assessments routinely fail to consider differences in patient outcomes, needs and preferences and do not recognize the unique nature and value of targeted therapies that benefit specific groups of patients, particularly those with rare and orphan diseases. Even when average study results suggest treatments are "clinically similar," different treatments are valued differently from patient-to-patient and among patient subgroups based on subtle, but real, differences. Instead, patient-centered outcomes research allows patients to distinguish the potential impact of treatments on their unique characteristics. No patient is average.
- **Relies on Payer-Centered Approach:** CMS' proposal to set national policy based on assessments such as those generated by the Institute for Clinical and Economic Review (ICER) contradicts PIPC's mission to support patient-centered approaches to CER and payment/delivery reform. Relying on centralized value judgments results in standardized national care protocols and one-size-fits-all assessments that impede physicians' ability to tailor care to individual patient needs.
- **One-Size-Fits-All Policies Set Back the Drive for Patient-Centeredness**: The approach to centralized value assessment proposed by CMS does not bode well for patients and people with disabilities. In the United Kingdom, patients with cancer and other serious diseases face significant barriers to access due to sue of similar thresholds in that country. Most recently, people with disabilities in the U.K. have been on the receiving end of benefit cuts. By contrast, the United States is at the forefront of the patient-centeredness movement, a position we will lose if we advance models that take a paternalistic approach.
- **Undermines ACA Protections**: The Affordable Care Act (ACA) includes explicit protections for patients that prevent CER from being used to limit access. In creating PCORI, Congress was clear that the goal was to empower patients with information on the clinical effectiveness of treatments on the outcomes that matter to patients and to improve health decision-making by supporting the translation of patient-centered outcomes research to shared decision-making tools accessible to patients and their providers Ultimately, these patient-centered policies are what will make the health system more efficient and effective. This proposal disregards those protections by embracing paternalistic policies that leave patients with fewer choices.

CMS should not move forward with its proposal. While no doubt a well-intentioned effort to advance value-driven health care, the approach it takes would represent a major step back for patient-centeredness. PIPC hopes to continue working with CMS to ensure that, as it seeks to advance value-based health care, it is supporting care that patients value. PIPC and its members will develop their own comments to the agency in the near future and will share them in advance of the May 4, 2016 deadline.