



WHERE WE STAND: AN AGENDA FOR DEFINING ‘VALUE’ TO THE PATIENT

INTRODUCTION

Health care value is being defined through new payment incentives and value standards proposed and implemented by health care payers, policy-makers and providers. To make sure the patient voice is at the center of any discussion of value, PIPC is advancing policy in three key areas: implementing value-based payment, developing and using tools to inform decisions on care value, and supporting research on comparative value.

ALTERNATIVE PAYMENT MODELS AND THE CENTER FOR MEDICARE AND MEDICAID INNOVATION

The Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare and Medicaid Services (CMS) is playing a significant role in advancing value-based or alternative payment models. In addition, many State health agencies and private payers are exploring similar changes. However, CMMI and other payers lack sound procedures and standards for patient-centeredness. By implementing the reforms described below, policy-makers can ensure that new payment models support value that matters to patients.

Process:

- ***Create a Patient Advisory Panel at CMMI to oversee and ensure patient-centeredness in the agency’s work.*** CMMI lacks mechanisms to ensure new payment models are consistently developed and evaluated in ways that support patient-centered care. In order to ensure alternative payment models are aligned with care that patients value, CMMI’s work should be overseen by a Patient Advisory Panel that is tasked with creating criteria for patient-centeredness per CMMI’s statutory guidance, advising on the infrastructure needed for meaningful patient engagement, and determining patient-centered quality measures and techniques for shared decision-making. In addition, creation of new APMs should be guided by patients and physicians with specific expertise and experience in the clinical areas that the APM is addressing.
- ***Seek input from patients and caregivers early in the process of launching new demonstrations, and throughout the implementation and evaluation process.*** 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. Patients, through advisory panels and through targeted strategies for input, should be positioned to provide guidance to CMMI on APM model designs under consideration, and to identify the key areas that would benefit from patient input, including APM development, implementation, related evaluation metrics and quality measures, and the use of decision-support tools such as care pathways.
- ***Improve the transparency of key APM design features and make available the results of APM evaluations.*** This includes more transparency in the requirements for patient

engagement and evidence-based decision-making such as those relied on by Accountable Care Organizations and referenced in other recently announced APMs like the Cardiac Care Bundle demonstration and the Oncology Care Model. CMMI should also make transparent the results of APM evaluations regarding their impact on patient access and engagement, care quality, and cost.

Standards:

- **Establish criteria for patient-centeredness in CMMI payment models.** 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. As specified in statute, demonstrations should be evaluated against these criteria. The Patient Advisory Committee should play a leading role in developing these criteria and ensuring they are applied to CMMI’s work.
- **Identify patient-centered quality and performance measures for use in CMMI payment models.** 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.
- **Develop standards for sound shared decision-making, and test 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. The Patient-Centered Outcomes Research Institute (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 CMMI supporting and developing meaningful criteria for meaningful shared decision-making through additional APMs, including accountable care organizations (ACOs).

Safeguards:

- **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.** The use of QALYs and cost effectiveness assessments have long been precluded from use in public programs, as they conflict with the goals of the Americans with Disabilities Act (ADA) by de-valuing the life of people with disabilities and patients with serious and chronic conditions, and thereby impeding their access to certain treatments. Congress reaffirmed its commitment not to incorporate use of cost-per-QALY-based standards to determine treatment value when banning the use of QALYs in comparative clinical effectiveness research conducted by the PCORI. PIPC strongly opposes bypassing long-standing protections against use of cost-per-QALY assessments in public programs.

- **Create robust mechanisms to protect quality and access for patients that are subject to CMMI's demonstrations.** 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 CMMI 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.
- **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 via safeguards like novel appeals mechanisms or a CMMI ombudsman.
- **Ensure that any decision-support tools utilized in APMs (e.g., clinical decision-support and clinical pathways) meet criteria for patient-centeredness.** For example, clinical decision support tools and clinical pathways, particularly those backed by financial incentives, must be validated and publicly available. Additionally, patients and people with disabilities must be engaged in the development of decision-support tools to enable effective integration of the specific outcomes that matter to patients in making decisions about the value of treatments for a particular condition and patient. Otherwise, certain long-term considerations and outcomes related to quality-of-life may be ignored.

VALUE ASSESSMENT FRAMEWORKS

PIPC is very concerned that payers, physicians and policymakers are increasingly using value frameworks in the private sector – and potentially in the public sector – to guide patient access. Many of these tools do not accurately capture what patients value. In fact, they often conflict with stakeholder efforts to move towards a more patient-centric health care system and advance access to personalized medicine. Well-designed value frameworks have the potential to support informed treatment decision making between patients and providers. The reforms described below can ensure that value frameworks support value that matters to patients.

Process:

- **Develop a transparent process through which frameworks are developed, implemented and validated.** Value frameworks and assessments should be transparent and available to patients to fully understand the assumptions that serve as their foundation. Value framework developers should also be transparent about the feedback they receive from patients and other stakeholders, noting where the framework incorporates the feedback received or their rationale for doing or not doing so.
- **Meaningfully engage with patient and provider organizations.** Value framework developers should engage with organizations representing the impacted patient communities and clinical experts in the specific treatment area under consideration in advance of scoping their projects to ensure that both frameworks and assessments are achieving consensus on the assumptions, definitions and underlying questions. Engagement should continue throughout the process of developing and updating value frameworks.

Standards:

- **Rely on a range of sound, patient-centered sources of evidence.** Value assessment frameworks should rely on high-quality, rigorously developed methods of evidence that fully capture value that matters to patients. Value frameworks should also be completely

transparent about the evidence on which the assessments are based, as well as the limitations of the evidence. By better articulating the limitations of the data that informs value frameworks, it will be clear where evidence gaps exist to inform future research efforts. For example, PCORI was called upon by Congress to articulate the limits of its research and could provide a useful model for consideration.

- **Reflect patient-centered outcomes.** Quantifying value in a way that is useful and meaningful to patients and people with disabilities requires a basic understanding of their values and preferences. Doing so will benefit both patient and payer as they identify and integrate the appropriate patient-centered criteria in assessing the value of treatments for a particular condition.
- **Address costs holistically, including costs that matter to patients.** Value frameworks and assessments should have a holistic perspective on the economic component of value, and include long-term, personal and societal costs, such as risk of disability and the potential need for caregiving. Broader costs should be considered rather than focusing only on short-term costs so that value assessments are relevant to decision-making by patients, people with disabilities and their providers.
- **Support shared decision-making.** Focus efforts on advancing shared decision-making between patients and physicians. Well-informed decisions by patients and consumers are foundational to advancing value in ways that are patient-centered.

Safeguards:

- **Acknowledge diversity and differences among patients, and avoid the “one-size-fits-all” mentality of value.** Value frameworks should ensure that their models and methods account for important differences in patient preferences, characteristics and treatment goals.
- **Preserve protections in the Affordable Care Act against use of comparative or cost effectiveness research to make centralized value judgements.** Value frameworks have the potential to support informed treatment decision-making between patients and their physicians. However, if used inappropriately to make centralized value judgements, value assessments could also limit patient access to necessary medical treatments.

SUPPORT RESEARCH ON COMPARATIVE VALUE

Patient-centered effectiveness research (CER) can play a positive role in improving patient care and health care delivery, it also can be misapplied in ways that unintentionally undermine patient access to care and physician-patient decision-making. CER results typically are based on broad population averages that don't reflect the differences in needs of individual patients. Any research results need to be considered along with the broader body of evidence, the patient's individual needs and preferences, and the physician's clinical expertise. PCORI, building on the significant progress it has made since its creation, should continue to work to conduct patient-centered comparative clinical effectiveness research in a manner that does not promote misuse of study results to impose blunt, "one-size-fits-all" access restrictions.