

November 17, 2017

Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5524-P
P.O. Box 8013
Baltimore, MD 21244-1850

Dear Administrator Verma:

The Partnership to Improve Patient Care (PIPC) appreciates that the Centers for Medicare and Medicaid Services (CMS) issued a Request for Information (RFI) seeking insights on a new direction to promote patient-centered care. We are excited that stakeholders have an opportunity to provide feedback on how CMS might test market-driven reforms that empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes.

PIPC deeply appreciates the strong and prominent commitment you have made – both within the RFI and in media statements – to putting patients first at CMMI. We now urge you to match this commitment with concrete reforms in four key areas:

- Defining a clear, consistent process for engaging patients and other stakeholders in development and implementation of CMMI evaluations;
- Defining and adopting detailed criteria for patient-centeredness in CMMI evaluations
- Building on and strengthening the patient safeguards articulated in the RFI
- Pursuing demonstrations that embody these reforms and put patients at the center of the health care.

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. Over the years, PIPC has heard many policy-makers commit to patient-centeredness; we have seen far fewer act on it. 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.

Many of the recommendations we make below build on a position paper we released last year on CMMI and Alternative Payment Models, which we have attached for your reference.

I. Establish an open, transparent process for engaging patients and other stakeholders in the identification, development and implementation of new CMMI demonstrations.

First and foremost, we would like to reiterate from prior comments to the agency that we view this as an opportunity for CMMI to forge a new path forward on engaging stakeholders, particularly patients. Without patients and people with disabilities at the table, it will be impossible to determine whether alternative payment models (APMs) drive patient-centered care, meaning that they are built to achieve outcomes that matter to patients.

We 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.¹

We found that despite the progress that the 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. 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.

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

- Informal engagement of patients and patient organizations in the early development of APMs, allowing for the generation and incorporation of patient perspectives into early model designs. Patient organizations have the capacity to survey patients in their networks to learn about their experiences, preferences and characteristics.
- A mechanism for patients and advocates to proactively propose new model designs and model elements to CMMI, particularly in a process designed to achieve consensus with provider groups engaged in designing APMs;
- Improved advanced communication about CMMI’s work plan for new model tests, as modeled by the current RFI;
- Formal opportunities for early input into potential model tests (e.g., through specific RFIs and/or a design concept paper); and

¹ See http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_cmami_white_paper_-_a_roadmap_to_increased_patient_engagement_at_cmami.pdf

- A mechanism for regular informal engagement with patients – as well as other stakeholders – throughout the implementation process.

In addition to informal engagements, CMMI should consider formally convening patients and people with disabilities to promote accountability for CMMI to make good on its commitment to putting patients first. We believe the needs and perspectives of patients and people with disabilities are equally important to those of physicians, who already benefit from a standing CMMI advisory committee. A patient advisory panel or work group could, for example, provide a leadership role in developing the criteria for patient-centeredness that is mandated by statute, and evaluate the success of early demonstrations in meeting these standards.

II. Codify criteria for patient-centeredness in CMMI demonstrations

Criteria for Patient-Centeredness

As you know, Section 1115A of the Affordable Care Act calls for evaluation of alternative payment models (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. We would strongly urge CMMI to develop criteria for patient-centeredness, so that there are clear standards against which demonstrations can be held to ensure that the needs of patients are being put first.

Establishment of patient-centeredness criteria will provide a structured patient-focused framework to guide the agency’s work and put patients first, thereby committing to clear standards and safeguards for future models that will help protect access to care for patients. By applying these standards, the Innovation Center would be building an infrastructure for patient engagement that goes beyond a notice and comment period and that provides a model for all payers seeking to achieve care that patients value. Criteria could include:

- Identify and test 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 as suggested in your guiding principles;
- 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
- Require use of decision-support tools (e.g., shared decision-making) that meet criteria for patient-centeredness.

III. Build on and strengthen core principles in support of patient-centeredness

In general, we support the principles you have outlined. Below, we provide some guidance on how your proposed principles can be translated into actionable criteria, and recommend that each principle place greater emphasis on the role of the informed, engaged patient in achieving value-based health care.

Market-based Reforms

Market-based health care insurance reforms require an effective public-private partnership. The private sector can deliver on innovation. However, private market-based payers need administratively-defined rules of the road and criteria for accountability to ensure they deliver care that patients value. We urge CMMI to use its authority to ensure that its contracted entities in the private sector deliver innovation that improves health care outcomes that matter to patients.

We support competition based on quality, outcomes, and costs. To this end, CMMI must address the immediate challenge that patients and consumers don't have access to data and tools that would allow them to compare quality, outcomes and costs. To begin addressing this challenge, patients should be educated about the factors driving their care. Most patients have little information about their treatment options outside of what is covered by insurance despite that, upon diagnosis, a patient is confined to the health insurance plan that they have until the next enrollment period. The patient's plan was likely not chosen in anticipation of having a serious medical condition. Care planning that captures patient preferences over time and effective shared decision-making would obviously increase the level of patient education about their treatment options and impacts.

Therefore, if CMMI is to be true to principles of patient-centered care, they must require patients and providers be informed of their participation in an APM, be informed of the financial incentives driving their care, and the evidence base that supports those financial incentives. We also have to consider society's moral obligation to value the individual lives of patients and people with disabilities, and therefore not to allow payers to dictate the terms of the "volume to value" debate solely based on a treatment's cost effectiveness. Only then can patients and consumers effectively be self-advocates to question how a payment model may or may not be driving them to care that they value.

Provider Choice and Incentives

We strongly support the language in this section of the RFI that asserts the principle of giving "beneficiaries and health care providers the tools and information they need to make decisions that work best for them."

We were deeply troubled by CMMI proposals issued in 2016 that would have replaced individual patient and physician choice about which treatment is most valuable to them with one-size-fits-all decisions by payers and government bureaucrats. We appreciate you have not moved

forward with these proposals, which would have seriously undermined patient-centeredness and patient access to treatment options. Now it is vital to move forward with alternatives that support patients, physicians and caregivers in the decision-making process, and to provide incentives in care delivery and payment that enable those alternatives. We recommend that CMMI rename this principle as “Patient and Provider Choice and Incentives” and build models that support and test this critically important principle.

Patients and providers can and should be engaged collaboratively in the development, implementation and evaluation of APMs. We hope that CMMI’s new direction fosters this kind of collaboration so that new models represent consensus-driven reforms, including the patient voice. Additionally, it is important to note that organizations representing patients and clinicians often have robust clinical registries and networks that can be tapped for data on the real-world impact of treatments and to identify the outcomes that matter most to patients. That kind of data is invaluable to inform and prioritize your work.

We believe it is imperative that demonstrations foster a strong relationship between providers and their patients that is aimed at achieving care that patients value. We wholeheartedly agree that this starts by giving beneficiaries and healthcare providers the tools and information they need to make decisions that work best for them. Cost and quality are vital components of a process of shared decision-making, whereby the patient and provider can access information about treatment options, the tradeoffs for achieving certain outcomes and the out-of-pocket costs associated with each.

Patient-Centered Care

We agree that it is a priority to empower beneficiaries, their families, and caregivers to take ownership of their health and ensure that they have the flexibility and information to make choices as they seek care across the care continuum. A key consideration is how to avoid standardized, one-size-fits-all models that undermine the patient voice in care decisions. I would point you to an opinion published recently in the Washington Post about a son’s personal experience with a bundled payment model governing his mother’s hip replacement.² It represented the stories I often hear from patients and their families, except that more often than not, they are not even aware of being in a bundled payment model and therefore unable to effectively be self-advocates.

We recognize that efforts to advance value-based health care are rooted in attempts to lower health costs, without undermining health care quality. Yet, there is growing concern from health care stakeholders that standardized care decisions create barriers to certain treatments for individuals that don’t meet “average” thresholds, leading to increased costs when treatments fail the patient. When patients cannot access treatments that work for them, our health care system

² https://www.washingtonpost.com/national/health-science/when-his-elderly-mother-broke-her-hip-things-didnt-go-well/2017/09/15/e5339060-7317-11e7-9eac-d56bd5568db8_story.html?utm_term=.eb27eb19dc5e

bears the cost of reduced treatment adherence, increased hospitalization and other acute care episodes, as well as the societal costs of increased disability over time.

The fundamental question that CMMI should be asking is whether any proposed demonstration aligns payment with personalized medicine. Today, there is little incentive to meaningfully incorporate shared decision-making tools into health care when such tools may drive patients to a personalized care decision that deviates from a predetermined standard of care for the average patient. Yet, no patient is average, and CMMI has stated a commitment to put patients first.

In this age of personalized medicine, we can reduce costs by better targeting treatments shown to work on patients with similar characteristics, needs and preferences, thereby avoiding the waste of valuable resources on care that patients do not value and that ultimately raise premiums. Providing patients with a pre-existing condition a therapy tailored to their individual needs early in their disease process can prevent them from requiring more aggressive and expensive treatments in the future. Additionally, there are opportunity costs associated with *not* providing patient-centered care. Overall, providing truly patient-centered care is cost effective at the population level.

Transparent Model Design and Evaluation

We strongly agree with CMMI's focus on partnerships and collaborations with public stakeholders as the foundation for developing, testing and evaluating APMs. Let patients and providers partner with you to identify what models can and should be designed to achieve care that patients value. Below, we will identify steps for CMMI to consider embedding engagement in its model design and evaluation process.

Small Scale Testing

Today, there are too few patient-reported outcome measures being incorporated into quality measurement for health systems and providers. Even process measures typically do not identify whether patients were asked about their treatment goals and preferred outcomes, or whether they were educated on all their treatment options and how they may impact outcomes that matter to patients. Therefore, we look forward to CMMI testing smaller scale models that may be scaled up if they meet criteria for patient-centeredness and the other requirements of the law. Small scale testing could be extremely valuable to create an evidence base of effectiveness for patient-reported outcome measures, shared decision-making tools and other decision aids, long-term services and supports, etc. Ultimately, more health systems will incorporate their use if the evidence shows them to be effective for improving health outcomes, thereby lowering system costs.

IV. Implement demonstrations that embody these principles and recommendations

Aligning with its principles stated above, CMMI could ease the transition from a one-size-fits-all coverage mentality at the payer level to a patients-first perspective aligned with personalized and

precision medicine by testing decision aids that are based on the best available evidence, and working with PCORI to ensure that indeed those decision aids are evidence-based and clearly articulate the limitations of the evidence. To foster effective use of evidence-based decision support, benefit designs should be accountable for *not* seeking to limit access to certain care options, but should instead drive care that is identified as most valuable to the individual patient.

We urge you to collaborate with the Patient-Centered Outcomes Research Institute (PCORI), which is currently comparing the effectiveness of tools for dissemination of research findings, and working to identify how to best implement shared decision-making tools. We also urge you to look to PCORI and to the National Quality Forum to assist the agency in setting standards for evidence-based decision-support and require their use in demonstrations (shared decision-making, patient education, clinical pathways, etc.) PCORI has the capacity and authority to conduct evidence synthesis reviews that could then be translated into decision-support tools, clearly articulating both the strengths and limitations of the evidence, and providing assurance that the tool is capturing the best available evidence.

Additionally, PCORI's contracted researchers are required to engage patients to identify and measure their desired outcomes in comparative clinical effectiveness research, providing a wealth of information about outcomes that matter to patients that could be made available to the public and adopted in quality measurement and APM design and evaluation. The tremendous federal investment in PCORI has great potential for informing health system transformation as long as the evidence being generated is embraced by payers and used to ensure accountability for achieving outcomes that matter to patients.

Conclusion

In closing, we believe that CMMI has a unique opportunity to change the culture of health care to truly put patients first. Doing so requires significant engagement with patients. We have learned from PCORI's experience that changing the culture of research to be patient-centered required them to mandate engagement, and to enforce it as part of their contracts with researchers. Driving a culture of patient-centeredness in how we pay for health care will require CMMI to similarly mandate and enforce engagement of patients in developing, implementing and evaluating APMs.

Changing culture is not easy. But there are plenty of supportive health care stakeholders, especially providers and patients. Provider burn-out is a topic that comes up routinely, and we can do something about it by supporting providers to engage with their patients in a more meaningful way. If you take the tough steps to change the culture of how we pay for care, i.e. push back on the "fail first" mentality and support concepts like shared decision-making, we will both achieve better outcomes for patients and make the practice of medicine more fulfilling and appealing. Ultimately, patients, providers and payers will all win when patients get the right care at the right time, thereby achieving outcomes that matter to patients and avoiding costly adverse events.

Thank you for soliciting our feedback. We look forward to helping CMMI pave the way for this new direction.

Sincerely,



Tony Coelho
Chairman, Partnership to Improve Patient Care