



July 7, 2017

Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9928-NC
P.O. Box 8016
Baltimore, MD 21244-8016.

Dear Administrator Verma:

I am writing on behalf of the Partnership to Improve Patient Care (PIPC) in response to the Request for Comment on “Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices to Empower Patients.” We are grateful that the administration wants to empower patients and promote consumer choice, as well as enhance affordability. In this age of personalized medicine, we strongly believe that the value of health care is defined by achieving outcomes that matter to patients in our health care system, not by imposing policies that drive one-size-fits-all treatment decisions. We look forward to patients and people with disabilities who are served by health systems having a seat at the table as policymakers determine how best to address the myriad of regulations that impact their 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. 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.

PATIENT ENGAGEMENT

First and foremost, we would like to reiterate from prior comments to the agency that we view this as an opportunity for the agency 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 regulations drive patient-centered care, meaning that they are built to achieve outcomes that matter to patients. Additionally, engagement provides an opportunity to consider input from stakeholders about the scope and impact of existing regulations and apply that feedback to your work to balance the regulatory burden with the need for regulations to drive patient-centered care.

We believe that there are provisions in Title II of the Affordable Care Act that could provide the foundational criteria for patient-centeredness that can also be applied to plans in the Exchanges. For example, Section 1115A of the Affordable Care Act created the Center for Medicare and Medicaid Innovation (CMMI). CMMI presents several opportunities for improved patient engagement. 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.

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.

Recommendations

We have recommended in the past that 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 – as well as other stakeholders – throughout the implementation process.

As you know, Section 1115A of the Affordable Care Act also 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. 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. 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 private payers, including those in the Exchanges, seeking to achieve care that patients value.

EMPOWERING PATIENTS AND PROMOTING CHOICE WITH INCREASED INFORMATION AND ACCESS

Empowering patients and providing consumer choice depends on two things – information and access. Patients want information on the comparative clinical effectiveness of their treatment options as they relate to the outcomes that matter to them, and based on how treatments impact patients that share their characteristics. In this regard, CMS could ally with the Patient-Centered Outcomes Research Institute (PCORI) whose mission is to generate patient-centered outcomes research and disseminate it in a manner that improves health care decision-making. Payers are feeling pressure to better incorporate shared decision-making into their plans, and to achieve outcomes that matter to patients. CMS could ease the transition from a one-size-fits-all coverage mentality at the payer level to a perspective aligned with personalized and precision medicine by supporting and fostering the development and use of decision aids that are based on the best available evidence, and work with PCORI to ensure that indeed those decision aids are evidence-based and clearly articulate the limitations of the evidence.

Patients and consumers look to regulations to protect them in the face of a health care system that does not include them in decision-making, both at the level of governance and policymaking, as well as at the point of care. Patients have little influence on the decisions made by payers about coverage and access. And payers are not accountable to explain those decisions, nor disclose the evidence base for them, to patients. By extension, as discussed above, there is little incentive to incorporate meaningful and evidence-based decision aids such as shared decision-making tools at the point of

care that would possibly inform patients about all their treatment choices and impacts of each treatment on patients that share their characteristics and goals.

The fundamental question that CMS should be asking is how to both reduce regulatory burden and align the insurance market with personalized medicine by increasing the level of transparency to the patient about the factors driving his/her 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 transparency to patients about their treatment options and impacts. Yet, financial incentives that drive decisions about care delivered to the patient are not transparent to the patient. Similarly, 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. No patient is average.

Recommendations

Therefore, we urge the agency to balance its consideration of reduced regulatory burden with the need for patients and consumers to be fully informed about their treatment options, the out-of-pocket costs associated with their treatment options, and incentives for physicians to adhere to care protocols or pathways that could limit their treatment options.

- We urge the agency to support the credible use of evidence in determinations about coverage and access.
- Using evidence-based decision aids, patients should be informed about the evidence supporting treatment options.
- Patients should be made aware of the use of evidence to drive certain treatment decisions, including its validity and credibility.
- Payers should disclose publicly the evidence base used to determine coverage and access decisions at the plan level.

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.

INCREASED AFFORDABILITY WITH LESS WASTE, BETTER OUTCOMES

We appreciate that CMS wants to balance its work to reduce regulatory burden with the need to enhance affordability of coverage. Ultimately, bad health decisions lead to bad outcomes and increased costs – and bad decisions often happen because the patient and provider did not have all the information they needed to make a good decision or they didn't have access to the better option for the patient's individual needs. The result may be that the patient does not adhere to his/her

treatment regimen because its side effects prevented the patient from being able to go to work. Or the patient lands in the hospital with an adverse event because the patient travels for work and really needed a delayed-release dose of that medication, but instead was forced to skip doses. The outcome may be that the treatment leaves the patient homebound, resulting in weight gain and the host of comorbidities that come with it. Or a long-term disability that the patient didn't realize to be a side effect of the treatment that would be most effective for treating the condition in the short term, but would lead to significant losses in quality of life over his/her lifetime. Driving one-size-fits-all care sounds cost effective in theory, but in reality, it's costing this country a fortune and making patients, people with disabilities and their families and caregivers miserable.

We recognize that efforts to advance value-based health care are rooted in efforts 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 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.

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 the first-line therapy 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 certain treatments that may be expensive. Overall, providing truly patient-centered care is cost effective at the population level. 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 value debate solely based on a treatment's cost effectiveness.

Therefore, we are looking to leadership within this administration to change the culture of our health care system to value outcomes that matter to patients, and therefore improve the patient experience whether in an Exchange plan or otherwise. We are off to a good start with a quality measure development program that embraces the development and use of patient-reported outcome measures. We urge increased investments in and use of real world evidence, particularly patient-centered outcomes research, patient-generated data and specialty society registry data, to help patients improve their individual health decisions. A return on that investment will require a cultural and systematic shift away from using evidence to narrow treatment options for patients, and instead to using real world evidence to drive access to the treatment option that is best for that particular patient. We want to work with you to drive this culture change among payers and health systems.

Recommendations

A strong first step to enhanced affordability would be a focus on the rapid generation of head-to-head studies on the value of high-impact treatments, tests and health care interventions. Thankfully, the independent Patient-Centered Outcomes Research Institute (PCORI) is already authorized and funded to conduct comparative clinical effectiveness research and could be an ally to increase information on comparative treatment value. PCORI has the capacity to conduct rapid-cycle systematic reviews of drugs, biologics, and other priority tests, treatments and care interventions on interventions with significant financial implications for the health system. The PCORI Methodology Committee also has authorization to develop methodological standards for research, and could therefore be called upon to ensure that systematic reviews are conducted in a manner consistent with methodologies for determining the evidence base and gaps requiring additional research in priority areas. PCORI's methodologists could also identify processes for PCORI to complete research within those gaps in a shorter timeframe, taking advantage of real world data available from the People-Centered Research Foundation whose mission is to engage patients, families, research participants, clinicians, scientists, and health system leaders in the design, conduct, dissemination, and implementation of research and analysis that leads to improvements in the health and well-being of individuals and populations and the performance of health care delivery systems.

Additionally, the development and use of high-quality decision-support tools would drive value in health care by informing patients and their providers on the impact of treatments stratified by individual health outcomes that represent tradeoffs that patients must consider, as well as patient characteristics and subpopulations. PCORI is charged with conducting research in this manner, and their work could facilitate the identification of high-quality patient-centered decision-support tools that encourage and expand the incorporation of study results on the value of drugs and other items and services. Rigorous systematic reviews conducted by PCORI identify the existing evidence base, and therefore could provide a reference for validating that decision aids used by accountable care organizations, alternative payment models and private insurers in the Exchanges are scientifically rigorous, high quality, and consistent with criteria for patient-centeredness.

We also recommend the development of a national, accessible database on comparative treatment value to lower costs, without sacrificing patient access to care tailored to the individual. A range of decision-makers, and particularly patients, need access to data and evidence on the value of treatments to support their decision-making. We urge HHS to engage with PCORI to establish two complimentary databases to assist decision-makers in identifying patient-centered value. First, a database of evidence on the comparative value of drugs and other items and services would support informed health care decision-making. Second, a national registry of patient-centered outcomes, as identified by patients, would encourage patient-centeredness in clinical trial design, value-based payment models, quality measurement, etc. The registry of patient-centered outcomes would inform quality improvement organizations (QIOs) in the development of patient-reported and patient-focused performance measures, so as to facilitate translation of study results across the health care system.

In closing, thank you for soliciting our feedback. We believe that improving the burden of regulations related to Title I policies requires reference to programs in Title II that were created to improve how care is paid for and delivered to patients. We look forward to a continued dialogue on how to empower patients, promote choice and increase affordability of health care in a manner that is aligned with personalized medicine.

Sincerely,

A handwritten signature in black ink that reads "Tony Coelho". The signature is written in a cursive, slightly stylized font.

Tony Coelho
Chairman, Partnership to Improve Patient Care