

March 23, 2018

Honorable Bill Cassidy
U.S. Senator

Honorable Michael F. Bennett
U.S. Senator

Honorable Chuck Grassley
U.S. Senator

Honorable Tom Carper
U.S. Senator

Honorable Todd Young
U.S. Senator

Honorable Claire McCaskill
U.S. Senator

Dear Senators:

The Partnership to Improve Patient Care (PIPC) appreciates this opportunity to provide comments related to price and information transparency. Empowering patients is the missing step to improving quality of healthcare and lowering healthcare costs. Innovation and patient-centered outcomes research makes care tailored to individual patients possible based on our increased understanding of the differential impact of treatments on diverse patients. With increased availability of information about treatments, patients will be empowered to be self-advocates for higher quality healthcare.

Having driven the concepts of patient-centeredness and patient engagement in the conduct of research, PIPC also brings the voices of patients and people with disabilities to the discussion of how to advance patient-centered principles throughout an evolving health care system. Over the last few years, we have held several roundtables and other events with patients around the issue of patient engagement and value in healthcare, many relevant to this discussion (see www.pipcpatients.org). The result has been enlightening and points to tremendous challenges for policymakers.¹

When patients do not have access to information that allows them to assess the best available treatment 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. While insurers may see those costs in different buckets, patients do not. Your work could drive a more holistic perspective of healthcare centered on the patients and people with disabilities that are the ultimate beneficiaries of healthcare.

Therefore, we propose the following steps to address barriers to price and information transparency:

¹ See

http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_esc_oncology_roundtable_summary_and_recommendations.pdf

- Charge PCORI to Prioritize High-Impact Disease Areas and Treatments
- Create Publicly Available Databases
- Advance Use of Shared Decision-Making To Empower Patients
- De-Mystify Out-of-Pocket Costs
- Anticipate Future Out-of-Pocket Costs

Charge PCORI to Prioritize High-Impact Disease Areas and Treatments

Patients and persons with disabilities are increasingly concerned about whether they can afford the tests and treatments they need. As stated by PIPC in 2010, comparative effectiveness research can form the foundation for meeting “the critically important challenge of controlling health care costs while avoiding oversimplified rationing of patient care.” Now more than ever, we need solutions that are both evidence-based and patient-centered.

The Patient-Centered Outcomes Research Institute (PCORI) offers important infrastructure to meet this challenge. With key reforms included with its FY2019 reauthorization, PCORI’s work can be focused to ensure its research is timely and responsive to the needs of those making decisions about new drugs and other treatment options, and that its research findings are more readily available to decision-makers.

As PCORI’s reauthorization is considered, it should include provisions that align the organization with the evolving needs of health care decision makers. *To ensure PCORI’s work is supporting the shift towards a patient-centered value in health care, PIPC proposes to strengthen PCORI and drive accountability for value by directing PCORI to set research priorities that target particular diseases, conditions, and care interventions that impose significant burdens on patients, family caregivers, the health care system, and the broader society. In setting priorities, PCORI should specifically target a portion of its resources to fund research on comparative clinical effectiveness of high cost items and services, including innovative drugs, a step that has been called for by a range of stakeholders.² Additionally, PCORI should annually develop a Priority Therapies List of interventions with significant financial implications for the health system.³*

² Center for American Progress “Enough is Enough: The Time Has Come to Address Sky High Drug Prices.” September 2015. Available at: <https://cdn.americanprogress.org/wp-content/uploads/2015/09/15131852/DrugPricingReforms-report1.pdf>.

³ See http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pcori_solution_3__002_.pdf

Create Publicly Available Databases

There is a clear need for improved access to patient-centered evidence on value. Too often, patients “Google” diseases and conditions, and get an overwhelming amount of information and misinformation in the process. A range of decision-makers, and particularly patients, need access to data and evidence on the value of treatments to support their decision-making. Policymakers should consider steps to the develop a national, accessible database on comparative treatment value to lower costs, without sacrificing patient access to care tailored to the individual.

We urge collaboration 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, outcomes that matter to patients, as identified by patients and measured in PCORI-funded research, should be listed in a national registry. This information will be useful to inform quality measure development, indicators of quality improvement for value-based payment programs, and innovation, thereby promoting a patient-centered health system that seeks to achieve outcomes that matter to patients.⁴

Advance Use of Shared Decision-Making To Empower Patients

In many cases, formulary and benefit designs undermine the ongoing efforts among patients and providers to advance patient-centered value frameworks, and especially information tools such as shared decision-making. Insurers have no incentive to give patients information that would cause them to deviate from their formulary and covered benefits, making consumer-directed care impossible in this paradigm. Decision aids can empower patients and their providers with information about their treatment options, particularly the differential impact of treatments on diverse subpopulations, and the out-of-pocket costs associated with their treatment options. To truly test the effectiveness of shared decision-making requires deference to it in terms of what insurers will prefer in their coverage. 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.

Additionally, FasterCures, in collaboration with Avalere and stakeholders including PIPC, are developing a Patient Perspective Value Framework that outlines five broad domains of value, each of which contributes different types of information important to patient decision-making. The domains include Patient Preferences, Patient-Centered Outcomes, Patient and Family Costs

⁴ *Id*

(including future costs), Quality and Applicability of Evidence and Usability and Transparency. This ongoing work to conceptually understand the components of healthcare decision-making could be useful as policymakers seek to operationalize valid shared decision-making tools. It is an effort that represents significant patient and stakeholder engagement.⁵

Therefore, we urge policymakers to implement policies that will lead to increased deference to health decisions emanating from use of high-quality decision aids and shared decision-making tools. CMMI has an opportunity to test decision aids that are based on the best available evidence, thereby easing 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.

We also urge a role for PCORI to ensure that decision aids are evidence-based and clearly articulate the limitations of the evidence based on their existing evidence synthesis where available. PCORI is currently comparing the effectiveness of tools for dissemination of research findings and working to identify how to best implement shared decision-making tools. PCORI and to the National Quality Forum could assist in setting standards for evidence-based decision-support. 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 to patients and people with disabilities and providing assurance that the tool is capturing the best available evidence.

De-Mystify Out-of-Pocket Costs

During our roundtable discussions, representatives of patients and people with disabilities have consistently concluded that policies are needed to drive accountability from insurers, including Medicare and Medicaid, for advance notice to patients about the out-of-pocket costs of anticipated services and treatments.

In one example, a Medicare FFS beneficiary was unable to determine the coverage and cost of a certain treatment upon calling the Medicare hotline. The beneficiary was provided a disclaimer that Medicare does not guarantee coverage based on the information provided on the call. Only after being billed will Medicare make a formal determination of coverage in writing. In another example, a patient had not received prior authorization for a treatment, and needed the treatment immediately, so the physician asked the patient to sign a financial release from the physician's liability for covering the treatment cost if insurance denied its coverage. The patient was left in a very difficult position not knowing the personal financial implications of that treatment decision. This

⁵ See <http://www.fastercures.org/programs/patients-count/patient-perspective-value-framework/>

lack of transparency is a significant challenge to patients and beneficiaries seeking to make informed decisions about their health care.⁶

Therefore, we recommend policymakers require that patients have access to information about the associated out-of-pocket costs for each of their treatment options through an online tool. Such a technological solution requires the data input from insurers, including federal programs such as Medicare. There are many intermediaries in addition to the health insurer that would need to input into a tool providing transparency on out-of-pocket costs. Additionally, a tool would have to be routinely updated in a central repository with a host of intermediaries feeding into it.

Anticipate Future Out-of-Pocket Costs

Patients are also very concerned about future out-of-pocket costs, such as lab tests, biopsy, imaging, etc.⁷ Often, patients are faced with tough choices when they cannot afford the proper follow-up care associated with a treatment option. Tools intended to help patients and providers engaged in meaningful shared decision-making should provide information about predictable future treatment needs associated with treatment options. For example, the Patient-Perspective Value Framework being developed by FasterCures in collaboration with Avalere includes a domain of value that includes future costs of care.⁸ Based on input from patients, we know that future non-medical costs are a central concern for patients, such as travel costs, lost time at work, and caregiving. *Standards for decision aids used in health care decision-making should include incorporation of anticipated future costs to the extent they can be anticipated.*

Conclusion

We strongly support your efforts to empower patients with information that will drive improved health decisions and higher quality care. By supporting quality shared decision-making and increased availability of patient-centered outcomes research and other patient-centered sources of data, we will both achieve better outcomes for patients and make the practice of medicine more fulfilling and appealing as medicine becomes increasingly personalized. Ultimately, patients, providers and payers will all win when patients and people with disabilities get the right care at

⁶ See

http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_csc_oncology_roundtable_summary_and_recommendations.pdf, page 21

⁷ See

http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_csc_oncology_roundtable_summary_and_recommendations.pdf

⁸ See <http://www.fastercures.org/programs/patients-count/patient-perspective-value-framework/>

the right time, thereby achieving outcomes that matter to patients and avoiding costly adverse events.

We appreciate this opportunity to provide comments. Please contact me at any time with questions or additional information.

Sincerely,



Tony Coelho
Chairman, Partnership to Improve Patient Care