



December 16, 2019

The Honorable Diana DeGette  
U.S. House of Representatives  
2111 Rayburn House Office Building  
Washington, DC 20515

The Honorable Fred Upton  
U.S. House of Representatives  
2183 Rayburn House Office Building  
Washington, DC 20515

Dear Congresswoman DeGette and Congressman Upton:

On behalf of the Partnership to Improve Patient Care (PIPC), I appreciate the opportunity to comment on your recent call to action on Cures 2.0 — an important next step in your efforts to advance medical research and foster a new era of medical innovation. The 21<sup>st</sup> Century Cures Act has already had a meaningful impact on patients' lives helping to accelerate innovation and bring treatments to patients and people with disabilities who desperately need them. We look forward to Cures 2.0 being approached with the same commitment to patient-centeredness.

We have summarized our key recommendations below and look forward to providing additional input as your work evolves:

- In your effort to modernize how new cures and medical products are covered, we urge:
  - Consideration of the recent report issued by the National Council on Disability calling on policymakers to avoid use of the discriminatory quality-adjusted life year (QALY) metric, and;
  - Creation of meaningful patient-centeredness criteria in consultation with patients and people with disabilities that will be the benchmark for success of any new models for covering treatments.
- In your work to implement strategies to harness data to empower patients and improve their health, we urge:
  - Consideration of the role that the Patient-Centered Outcomes Research Institute (PCORI) could play in supporting high-value, personalized health care decision-making, and;
  - Consideration of strategies that support high quality shared decision-making and the use of patient decision aids that meet national standards.

## **Modernize how new cures and medical products are covered.**

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 and people with disabilities 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. While insurers may see those costs in different buckets, patients and people with disabilities do not. We urge Congress to avoid rigid "one-size-fits-all" applications of cost and comparative effectiveness research, and instead to advance coverage policies that support a personalized and informed health system.

As we increasingly move toward personalized medicine, we recognize the challenge in determining how to ensure affordable access to new, expensive therapies. We ask that in doing this, Congress keep the patient at the forefront and make a clear statement that our healthcare system will not discriminate in its coverage policies. As you may know, the National Council on Disability (NCD), an independent federal agency, recently concluded in their report on *Quality-Adjusted Life Years and the Devaluation of Life with a Disability* that QALYs place a lower value on treatments which extend the lives of people with chronic illnesses and disabilities. NCD recommended that policymakers and insurers reject QALYs as a method of measuring cost-effectiveness for medical care and avoid referencing international pricing due to its reliance on QALYs.<sup>1</sup> In fact, NCD recommends that the use of QALYs be barred from use in both Medicare and Medicaid programs, and notes its potential for violating the Americans with Disabilities Act.<sup>2</sup> Therefore, we would urge consideration of extending Medicare's existing QALY ban.<sup>3</sup>

Additionally, we would call your attention to the Centers for Medicare and Medicaid Innovation (CMMI). It is concerning that in the drive to "value-based" health care models, CMMI has not established critically important safeguards and principles to ensure their demonstrations are genuinely centered on the needs of patients and people with disabilities. Over the last few years, many of our groups have consistently reached out to CMS leadership to advocate for CMMI to establish, via rulemaking, the "patient-centeredness criteria" under Section 1115A of the Affordable Care Act, which calls for the evaluation of alternative payment models (APMs) against patient-centeredness criteria. When this provision was enacted, we were hopeful that it would help pave the way for a shift to truly patient-centered approaches to value in U.S. health care; unfortunately, this provision has never been meaningfully implemented. CMS has

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<sup>1</sup> [https://www.ncd.gov/sites/default/files/NCD\\_Quality\\_Adjusted\\_Life\\_Report\\_508.pdf](https://www.ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf)

<sup>2</sup> <https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html>

<sup>3</sup> 111th Congress of the United States of America. (2010). H.R. 3590 The Patient Protection and Affordable Care Act. *Section 1182*. Washington, DC.

set goals for demonstrating that its Innovation Center models lower costs and improve quality, yet there are no clear standards against which demonstrations can be held accountable for truly putting patients and people with disabilities first.

To achieve this criteria, we have communicated to CMS strong support for convening patient advisory panels for each of the Innovation Center models under development as well as those currently being implemented, to help ensure each demonstration is meaningfully evaluated against appropriate measures of patient-centeredness.<sup>4</sup> We would urge you to similarly consider working with PIPC and other stakeholders to ensure that the measures of success for any new coverage policy be benchmarked against meaningful criteria for patient-centeredness.

### **Harness data to empower patients and improve their health.**

Now more than ever, we need solutions that are both evidence-based and patient-centered. PCORI offers important infrastructure to meet this challenge. Over the next 10 years, PCORI has an opportunity 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. With reauthorization, PCORI is in a unique position to drive towards a health care system in which all stakeholders, particularly patients and people with disabilities, are armed with evidence to support high-value, personalized health care decision-making.

In addition, we strongly support high quality shared decision making and the use of patient decision aids that meet national standards. We acknowledge great strides in the development and use of shared decision making between patients and providers. However, we are concerned that in many circumstances, the process of shared decision making has not yet evolved to a level of what would be considered “high quality.” Unfortunately, the systemic lack of capacity for high quality shared decision making can pose a barrier to care or it could be simply a “check the box” activity. We share the goals presented in the statute calling for CMS to establish standards for shared decision making that provides patients and providers with information about trade-offs among treatment options and facilitates the incorporation of patient preferences and values into the medical plan. It is imperative that standards be accompanied by meaningful investments in building the capacity for high quality shared decision-making.

Therefore, we urge Congress to engage with patient stakeholders to determine how best to advance the National Quality Forum’s recommendations in the National Quality Partners Playbook on Shared Decision-Making. We stand ready to be your partners on the steps outlined by the Playbook — particularly in developing policies that incentivize shared decision making by paying for it, advance use of high quality decision aids in clinical practice, and support consensus-

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<sup>4</sup> [http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc\\_et\\_al\\_cmml\\_letter.pdf](http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_et_al_cmml_letter.pdf)

based standards for shared decision-making that recognize differing patient characteristics, needs and priorities.<sup>5</sup>

In conclusion, we look forward to working with you to ensure that Cures 2.0 is centered on patients and people with disabilities and supports the goal of innovative treatments reaching those who need them most. We are committed to working with you to advance a personalized, informed health system that works to ensure patients access treatments that work for them, and do not fail them.

Sincerely,

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

Tony Coelho

Chairman, Partnership to Improve Patient Care

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<sup>5</sup> <http://www.pipcpatients.org/uploads/1/2/9/0/12902828/sdm-letter-to-cms-final.pdf>