



May 9, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services 200 Independence Avenue, S.W.
Washington, DC 20201

Dear Acting Administrator Slavitt:

The Partnership to Improve Patient Care (PIPC) and the undersigned organizations appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed Part B Drug Payment Model.¹ Since its inception, PIPC, including patients, physicians, caregivers and people with disabilities, has been a leading proponent of patient-centered comparative effectiveness research. We also have strongly opposed misuse of comparative effectiveness research (CER) and cost effectiveness in one-size-fits-all government policies.² Our comments will focus on concerns over the agency's proposed use of CER and cost effectiveness as national Medicare standards in Phase 2 of the proposal.

The U.S. has made significant progress in advancing patient-centeredness in clinical and health systems research over the last several years. At the same time, much work remains to be done. The progress we have made is the fruit of a movement that spans several decades, and we are proud to have lent our voices to this effort.

The approach CMS has taken in the proposed rule would represent a major step back for patients and people with disabilities. We urge CMS not to move forward with its proposal. Instead, we hope to continue working with the agency and other stakeholders to ensure that, as it seeks to advance value-based health care, it is supporting care valued by patients and people with disabilities. The Patient-Centered Outcomes Research Institute (PCORI), the Food and Drug Administration (FDA) and others have advanced patient engagement strategies to identify and achieve outcomes that matter to patients and people with disabilities that should be modeled by CMS before advancing policies with such far-reaching consequences. Otherwise, the agency should defer to Congress on such a fundamental policy change.

OVERVIEW OF PIPC CONCERNS

We highlight the following significant implications for patients related to Phase 2 of the proposed Part B Drug Payment Model:

¹ 81 FR 13229

² see <http://www.pipcpatients.org/about.php>

- Reliance on Centralized Value Assessments That Are Based on Average Results and Ignore Patient Differences
- Use of Payer-Centered Assessment Standards and Methods Including Those from the Institute for Clinical and Economic Review
- Focus on One-Size-Fits-All Policy Standards and National Protocols Will Set Back the Drive for Patient-Centeredness and Disadvantage People with Disabilities
- Undermines ACA Protections Against Misuse of CER and CEA in Medicare
- Excluded Patients and People with Disabilities from a Seat at the Table in the Development of a Major Shift in Public Policy

We urge CMS not to move forward with its proposal. While no doubt a well-intentioned effort to advance value-driven health care, the approach it takes would represent a major step back for patients and people with disabilities. Instead, we hope to continue working with CMS to ensure that, as it seeks to advance value-based health care, it is supporting care valued by patients and people with disabilities.

CENTRALIZED VALUE ASSESSMENTS RELY ON AVERAGE RESULTS, IGNORE PATIENT DIFFERENCES

The agency proposes to provide “equal payment for therapeutically similar drug products,” assuming that the “most clinically effective drug” in the group can be identified as the basis for a price benchmark.³ While we appreciate the agency’s proposal not to allow for “balance billing” of beneficiaries, patients who are not “average” will be disadvantaged by a clear financial incentive to the provider to drive care to the benchmark treatment or a less expensive treatment that may be less effective based on that particular patient’s needs, outcomes and preferences.⁴

Average assessments routinely fail to consider differences in patient outcomes, needs and preferences and do not recognize the unique nature and value of targeted therapies that benefit specific groups of patients and people with disabilities, particularly those with rare and orphan diseases. Even when average study results suggest treatments are “clinically similar,” different treatments are valued differently from patient-to-patient and among patient subgroups based on subtle, but real, differences. No patient is average.⁵

USE OF PAYER-CENTERED ASSESSMENT STANDARDS, INCLUDING THOSE FROM ICER

CMS’ proposal to set national policy based on assessments such as those generated by the Institute for Clinical and Economic Review (ICER) contradicts our mission to support patient-centered approaches to CER and payment/delivery reform. ICER’s Governing Board consists mainly of payers, with no representation from patients or people with disabilities. Yet, as discussed below, their reports hold significant implications for the communities we serve.

³ 81 FR 13243

⁴ *id*

⁵ PIPC on Building a Patient-Centered Health System at <http://www.pipcpatients.org/PIPC-APM-White-Paper.pdf>

Reliance on average value assessments is not a policy that drives “value for the patient” – it is a policy intended to contain short-term costs for payers. Yet, the result is a less effective and efficient system of care. A truly cost effective system of care would include tools to inform patients and people with disabilities about their treatment options, and their impacts on outcomes that matter to them – because patients and people with disabilities will adhere to treatment protocols when they are actively engaged and are less likely to encounter significant (and expensive) adverse events as a result. The idea of clinical decision support tools discussed in the proposed rule holds potential for supporting shared decision-making, but the approach described by CMS is focused on informing clinicians to help them control costs, not informing and engaging patients and people with disabilities.⁶ Real shared decision-making requires that patients, people with disabilities and providers have access to the information they need to ensure care is tailored to the individual with transparency of financial incentives potentially driving their care decisions.⁷

ONE-SIZE-FITS-ALL POLICIES SET BACK THE DRIVE FOR PATIENT-CENTEREDNESS

The agency proposes to set prices for treatments based on a judgment of comparative effectiveness, and notes that it would use reports developed by the Institute for Clinical and Economic Review, which evaluate comparative and cost-effectiveness of treatments as the basis for setting prices. We are very concerned that CMS would propose reliance on ICER reports, because they are developed through a method that provides little or no input from patients and people with disabilities, lack transparency in out patient-focused outcomes are considered, and utilize methods tailored to the needs of payers and not patients. For example, ICER relies on quality-adjusted-life-years or QALYs in determining the “value” of treatments, a policy long opposed by patients and people with disabilities.⁸ Professor Peter Singer, in a 2009 article calling for health care rationing, explained clearly his view that QALYs necessarily (and in his view, appropriately) place less value on the lives of people with disabilities.⁹ It is unimaginable that we would allow public programs to incorporate the use of QALYs as is being proposed.

As a long-time advocate for people with disabilities, I have been open and vocal about my opposition to the use of QALYs and value assessments that look at average impacts. I have seen patients and people with disabilities judged and “valued” by a health care system via the sort of “one-size-fits-all” standards that are often praised by academics. Most recently, people with disabilities in the United Kingdom have been on the receiving end of benefit cuts.¹⁰ I have pointed to the use of cost and QALY thresholds in England, for example, where the standards are so controversial that public pressure forced the country to create a separate fund to ensure patient access to cancer treatments that otherwise would have been rejected.¹¹ In the real world, QALYs are supremely unpopular. By contrast, the United States is at the forefront of the patient-

⁶ 81 FR 13244-13246

⁷ Patient-Driven Health Care and Evidence in Oncology: Setting an Agenda, at http://www.pipcpatients.org/pipc-admin/pdf/a76f47_PIPC%20CSC%20Oncology%20Roundtable%20Summary%20and%20Recommendations.pdf

⁸ Roll Call at <http://www.rollcall.com/news/patient-centeredness-comparative-effectiveness-and-value-commentary>

⁹ New York Times at <http://www.nytimes.com/2009/07/19/magazine/19healthcare-t.html?pagewanted=all&r=0>

¹⁰ The Guardian at <http://www.theguardian.com/politics/2016/mar/19/pique-rather-than-piety-pushed-iain-duncan-smith-over-the-edge>

¹¹ Huffington Post at http://www.huffingtonpost.co.uk/simon-hawkins/cancer-drugs-fund_b_6733754.html

centeredness movement, a position we will lose if we advance models that take a paternalistic approach.

Nowhere in this “value” discussion do we see an honest consideration of the real-world impact these proposals would have on the individual patient or the person with a disability for whom an innovation may have significant value. No academically pristine algorithm is going to capture value to the patient because no patient is average. Even the American Society for Clinical Oncology (ASCO) recognized the shortcomings of QALYs as a measure of value. In developing its own value framework, ASCO decided against using QALYs, stating:

“There are significant limitations to the application of QALYs, because individuals with the same illness may have different preferences for a health state. For example, one individual with advanced cancer may prefer length of overall survival (OS) above all else, whereas another might view minimization of symptoms as the highest priority.”¹²

Even those advocating for use of QALYs would not call such a policy “patient-centered.” In fact, Congress explicitly pointed to QALYs as an example of a policy that is inconsistent with patient-centered principles when it created the Patient-Centered Outcomes Research Institute (PCORI):

“[PCORI] shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended... The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs.”¹³

Congress spoke to the centrality of patient-centeredness when it established PCORI to advance a new model of research that centers on the needs of patients and respects patient differences. We should be building upon this foundation and extending it more broadly into health care delivery and decision-making.

UNDERMINES ACA PROTECTIONS

This is not the first time that policymakers have sought to impose average value assessments within Medicare. The agency has encountered significant opposition from stakeholders to all proposals to include cost effectiveness to national coverage determinations since first proposed in 1989.¹⁴ Thankfully, in creating PCORI, the Congress recognized that the evidence base is not sufficient to assess clinical equivalency between therapies or to reconcile a cost effectiveness standard with the emerging field of personalized medicine and patient-centered care.¹⁵ Understanding the

¹² American Society of Clinical Oncology Statement: A Conceptual Framework to Assess the Value of Cancer Treatment Options at <http://jco.ascopubs.org/content/early/2015/06/22/JCO.2015.61.6706.full>

¹³ 42 U.S.C. 1320e-1 (e)

¹⁴ Comparative Clinical Effectiveness and Cost-Effectiveness Research: Background, History, and Overview, CRS Report, October 15, 2007 at <http://www.healthpolicyfellows.org/pdfs/CRSreportOct07.pdf>

¹⁵ 42 U.S.C. 1320e-1 (d)

consequences for patients and people with disabilities, PIPC and others fought hard for patient protections in the ACA that ensure CMS does not misuse clinical CER to impose “one-size-fits-all” coverage or payment policies.

The ACA sought to empower patients with information on the clinical effectiveness of treatments on the outcomes that matter to patients and people with disabilities and to improve health decision-making by supporting the translation of patient-centered outcomes research to shared decision-making tools accessible to patients, people with disabilities and their providers. Ultimately, these patient-centered policies will make the health system more efficient and effective. This proposal disregards those protections, and ignores the considerable work that PCORI and other organizations have been doing to advance patient-centered decision-support and shared decision-making, by embracing paternalistic policies that leave patients with fewer choices.

PATIENTS DESERVE A SEAT AT THE TABLE IN THE DEVELOPMENT OF A MAJOR SHIFT IN PUBLIC POLICY

Despite our strong advocacy to engage patients and people with disabilities in the development of alternative payment models (APMs), this proposal appears to have been rushed forward with little or no input from our communities.¹⁶ The phase involving centralized use of CER and cost-effectiveness begins early in 2017, eventually covering 50% of providers and beneficiaries, leaving little time for meaningful engagement of patients and people with disabilities.¹⁷

While we understand the agency has stated its intention to engage stakeholders in the implementation of its proposal, there is no explicit pathway for our communities to be engaged, or to trust that our engagement makes a difference. Meaningful engagement must occur earlier in the process – prior to release of a specific proposal. We are deeply concerned that CMS did not consult the patient and disability communities prior to release of the proposed rule.

After announcing the Better Smarter Healthier initiative and the Health Care Payment and Learning Action Network (LAN), almost 80 patients, people with disabilities and their representative organizations sent a letter to HHS asked to be engaged in this work. We noted that we have learned through implementation of PCORI that the goal of patient-centeredness can only be achieved with a meaningful voice for patients and people with disabilities. When patients and people with disabilities feel heard, they feel valued. When they feel valued, they have more confidence, contributing to a greater sense of well-being, which any physician will tell you can only help them in their treatment path.¹⁸

PIPC and several organizations representing patients and people with disabilities reiterated this message at a meeting with Dr. Patrick Conway and his staff on October 16, 2015, and again in a

¹⁶ PIPC letter to HHS September 15, 2014 at http://www.pipcpatients.org/pipc-admin/pdf/bebdc7_PIPC%20Bene%20Engagement%20Comment%20Letter.pdf

¹⁷ 81 FR 13232

¹⁸ PIPC letter to HHS April 30, 2015 at http://www.pipcpatients.org/pipc-admin/pdf/45a8ce_PIPC%20Network%20Letter.pdf

follow-up letter to Dr. Conway, and again in our comments to the agency on MACRA.¹⁹

PIPC specifically proposed a pathway for patient engagement in CMMI's work by creating a Patient Advisory Panel that would help to ensure new payment models are aligned with care that patients value. PIPC proposed the Patient Advisory Panel be positioned to provide guidance to CMMI in identifying the key areas that would benefit from patient input, including APM development, model design features that will promote effective patient engagement, and metrics (e.g., patient-centered quality measures and other tools) on which to assess the success of these efforts. In addition, we advocated that the Patient Advisory Panel develop and apply patient-centeredness criteria to APMs as called for in Section 1115A of the ACA. The panel could also serve as an invaluable conduit connecting CMMI staff with the broader patient community, including a simple and streamlined process for soliciting patient participants in advisory roles.²⁰

Despite our continuous efforts, this proposal reflects precisely what we most feared. Instead of our voices being heard and valued, we are faced with the reality that our voices are not as valuable as those of other stakeholders despite that we are the stakeholders that these policies are supposed to be serving. In meetings, in letters, and in public comments, patients and people with disabilities have stated their unequivocal opposition to "one-size-fits-all" policies grounded in cost effectiveness and average value assessments. We are at a loss for why our concerns were so explicitly dismissed.

While there are models for patient engagement that are used to identify outcomes that matter to patients (PCORI, FDA, etc), these have yet to be translated into CMS policy-making. After this proposal is withdrawn, we would propose that CMS prioritize building an effective patient engagement strategy that appropriately connects the dots between its policies and achieving outcomes that matter to individual patients and people with disabilities.²¹ Without that infrastructure, there is no way to evaluate the impact on "quality of care, access to care, timeliness of care, and the patient experience of care" as proposed. Although a Pre-Appeals Payment Exceptions Review process to dispute payments is an interesting idea to consider more broadly, it is not sufficient to mitigate the consequences of the policies being proposed nor are there sufficient details provided in the proposed rule about it.²²

CONCLUSION

Instead of policies that reinforce the old paternalistic system of health care, policymakers should focus on delivery reforms that activate and engage patients and people with disabilities and support shared decision-making between patients, people with disabilities and their providers. We

¹⁹ PIPC MACRA comments November 13, 2015 at http://www.pipcpatients.org/pipc-admin/pdf/704409_PIPC%20MACRA%20Comments.pdf

²⁰ PIPC Roundtable on Strategies to Engage and Empower Patients in Care Delivery June 11, 2015 at http://www.pipcpatients.org/pipc-admin/pdf/bca6af_Executive%20Summary%20-%20PIPC%20HHS%20Roundtable%20Summary%20and%20Recommendations.pdf

²¹ *id*

²² 81 FR 13250

believe that solutions that center on patients and people with disabilities are the best approach to improving overall health care efficiency and quality. We also know that meaningful engagement requires that patients and people with disabilities trust in the system and their care providers, embrace the principles of shared decision-making, and recognize the benefits of being activated. We should be embracing the ACA's provisions to translate patient-centered outcomes research into shared decision-making tools that improve health decision-making, not taking a leap backward to reconsider policies that were determined by Congress to undermine the very core of the ACA's goals for advancing a patient-centered health system.

We strongly urge CMS not to move forward with this flawed policy. Instead, CMS should work to engage patients, people with disabilities and their families, providers and other stakeholders in the identification of models that put patients and people with disabilities at the center, as well as in the development of thoughtful policies that balance progress toward a patient-centered health system and overall health costs. We continue to stand ready to convene our members and other organizations representing patients and people with disabilities in the development of APMs. Let's work together toward patient-centered solutions.

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 and the undersigned organizations:

Academy of Spinal Cord Injury Professionals
Advocrat Group
ACCSES - (formerly American Congress of Community Supports and Employment Services)
Alliance for Patient Access (AfPA)
American Association of Neurological Surgeons (AANS)
American Association of People with Disabilities (AAPD)
American Association on Health and Disability
American Association on Intellectual and Developmental Disabilities (AAIDD)
American Congress of Rehabilitation Medicine (ACRM)
American Foundation for the Blind (AFB)
American Gastroenterological Association (AGA)
American Network of Community Options and Resources (ANCOR)
American Therapeutic Recreation Association
Association of University Centers on Disabilities
Autistic Self Advocacy Network
The Bazelon Center
Brain Injury Association of America
California Chronic Care Coalition
Cancer Support Community (CSC)
CancerCare

Caring Ambassadors Program, Inc.
Center for Independence of the Disabled, NY
Center for Medicare Advocacy
Christopher and Dana Reeve Foundation
Cutaneous Lymphoma Foundation
Disability Rights Education and Defense Fund (DREDF)
Easter Seals
Epilepsy Foundation
Epilepsy Foundation Central and South Texas
Epilepsy Foundation of Arizona
Epilepsy Foundation of California
Epilepsy Foundation of the Chesapeake Region
Epilepsy Foundation of Georgia
Epilepsy Foundation of Greater Cincinnati and Columbus
Epilepsy Foundation Heart of Wisconsin
Epilepsy Foundation of Indiana
Epilepsy Foundation of Long Island, a Division of EPIC Long Island
Epilepsy Foundation of Metropolitan New York
Epilepsy Foundation of Michigan
Epilepsy Foundation of Minnesota
Epilepsy Foundation of Missouri & Kansas
Epilepsy Foundation of Nevada
Epilepsy Foundation of New England
Epilepsy Foundation of North/Central IL, IA, NE
Epilepsy Foundation of Northeastern New York
Epilepsy Foundation Northwest
Epilepsy Foundation Texas-Houston/Dallas-Fort Worth/West Texas
Epilepsy Foundation of Utah
Epilepsy Foundation of Vermont
Epilepsy Foundation of Virginia
Epilepsy Foundation Western/Central Pennsylvania
Epilepsy-Pralid, Inc.
FH (Familial Hypercholesterolemia) Foundation
Fight Colorectal Cancer
Global Liver Institute (GLI)
Help4Hep
Hepatitis C Association
Hepatitis Foundation International (HFI)
Institute for Educational Leadership, Disability Power & Pride
International Myeloma Foundation
Kidney Cancer Association
Lakeshore Foundation
Lung Cancer Alliance
National Alliance on Mental Illness (NAMI)
National Association of Councils on Developmental Disabilities (NACDD)
National Association of State Directors of Developmental Disability Services (NASDDDS)
National Association of State Head Injury Administrators
National Association for the Advancement of Orthotics and Prosthetics
National Council on Independent Living (NCIL)
National Disability Rights Network

National Infusion Center Association
National Organization of Nurses with Disabilities (NOND)
National Patient Advocate Foundation
National Viral Hepatitis Roundtable
Not Dead Yet
Parent to Parent USA
Patient Services, Inc. (PSI)
Pediatric Congenital Heart Association
RetireSafe
The Arc of the United States
The Hepatitis C Mentor and Support Group (HCMSG)
United Cerebral Palsy
United Spinal Association
U.S. Pain Foundation