

November 27, 2017

Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9930-P
P.O. Box 8016
Baltimore, MD 21244-8016

Dear Administrator Verma:

As Chairman of the Partnership to Improve Patient Care (PIPC), I am writing in response to the HHS Notice of Benefit and Payment Parameters for 2019. While proposing flexibility for states in defining essential health benefits, the rule also seeks comment on ideas to standardize care based on determinations of cost effectiveness and the creation of a national default definition of essential health benefits. Unfortunately, these proposals do not address the need for fundamental culture change in how we pay for health care as required to achieve the administration's stated goal of putting patients first.

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.

Paying for care that *patients* value will require a new public/private partnership that emanates from our health system's advanced capability to deliver targeted and individualized therapies to patients. Private plans have the capacity to be truly innovative in paying for care in a manner that aligns with personalized medicine. Yet, the Notice of Benefit is not focused on how to align payment with achieving care tailored to individual patients. Instead, it fluctuates between a policy of "anything goes" by allowing states increased flexibility in defining their benefit packages, and a "one-size-fits-all" policy relying on cost effectiveness reports to determine patient access to care. To truly put patients first, CMS should instead embrace this as an opportunity to change the culture of our payment system to be patient-centered.

Cost Effectiveness and Value are Not the Same

As part of "Other Considerations," the agency seeks to foster market-driven programs that can improve the management and costs of care and that provide consumers with quality, person-centered coverage. One of the specific proposals it raises is the idea of creating value-based

insurance design based on cost-effectiveness standards. Given the significant and well-recognized limitations of cost effectiveness analysis, we would strongly encourage HHS to refrain from referencing such problematic standards, and instead focus on patient-centered reforms. While cost effectiveness has a basic appeal for making population-level decisions (by reducing patient populations to single, aggregate numeric values), it also poses several significant concerns for delivering patient-centered care.

The QALY, which serves as the basis for most cost effectiveness analysis, is a measure developed by health economists to measure and compare the benefits of healthcare interventions for cost effectiveness analyses, often relied on by payers and insurers for determining coverage and access. Traditional QALYs are measured using several survey instruments designed to assess how much patients value different health conditions or “states.” Population-based surveys ask individuals to imagine their response to theoretical scenarios, how much they value their lives in a particular state of health or what they are willing to trade to treat a hypothetical health condition or symptom, with different scales yielding wildly different results. Surveys cast a wide net to construct a single, average measure of patient preference, not reflecting the wide heterogeneity of patient preferences.

QALYs place greater value on years lived in full health, or on interventions that prevent loss of perfect health while discounting gains in health for individuals with chronic illnesses. To define a life as less valuable because a person’s unique circumstances deviate from “average” often leads to a discriminatory impact when applied to access to care for people with disabilities. QALYs assume people with disabilities and serious chronic conditions are less satisfied with their life than another individual with perfect health, which research consistently shows to be false.

Policymakers recognize the dangers of misusing cost-effectiveness standards in ways that undermine high-quality, individualized care. The Patient Protection and Affordable Care Act (ACA) explicitly prohibits PCORI from using the cost-per-QALY as a threshold to establish what type of health care is cost effective or recommended, and further restricts QALYs by precluding their use as a threshold to determine coverage, reimbursement, or incentive programs in the Medicare Program.

Benefits Pre-Defined by Cost Effectiveness Undermine Person-Centered Care

HHS is considering an approach similar to that proposed by the National Academy of Medicine in their report on *Essential Health Benefits: Balancing Costs and Coverage*, and specifically establishing a national benchmark plan standard for prescription drugs. By doing so, HHS would further reinforce the existing paternalistic system that tells patients what to value, instead of asking them what they value. When plans maintain stringent benefit designs that provide little deference to what works for the individual patient, insurers play the role of doctor. This is the fuel for the frustration of both providers and patients trying to function in a health system that does not value their expertise and their voice.

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. While insurers may see those costs in different buckets, patients do not.

The creation of a national formulary and benefit design undermines 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. The only way to advance a person-centered health system is to empower patients and their providers with information about their treatment options, and create measures of success based on achieving the outcomes that matter to patients.

Strategies to Align Payment with Personalized Medicine

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. Benefit design should not seek to limit access to certain care options, but should instead embrace a process of shared decision-making and the use of tools that effectively communicate to providers and patients the full spectrum of treatment options, the evidence of their effectiveness for achieving outcomes that matter to patients, and the out-of-pocket costs associated with each. Unfortunately, the "fail first" mentality that hinders access to innovative treatments only serves to increase costly adverse events and non-adherence. HHS can and should foster collaboration between payers, providers and patients to change the culture and drive policies that are both cost effective and person-centered. These concepts are not mutually exclusive.

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 HHS has stated publicly its commitment to put patients first.

Therefore, in the final Notice of Benefit, we strongly urge HHS to abandon proposals that would exacerbate the existing "one-size-fits-all" mentality, and instead give insurers guidance to make shared decision-making the standard of patient care. This will require payers to give deference to that shared decision-making process when determining coverage of a given treatment for an individual patient. A *patient-centered* value-based insurance design would prevent waste and the provision of services that are not valued by patients, instead focusing care on achieving the outcomes that matter most to patients.

Unfortunately, private payers are especially reliant on the cost-per-QALY as the basis for benefit design, which often has a discriminatory impact on people with disabilities and serious chronic conditions. You have an opportunity to create incentives that change the payer culture, similar to the culture change we have witnessed in research due to the work of PCORI.

In closing, we urge HHS to create incentives for payers that advance a person-centered and patient-centered health system, and to abandon any guidance that would compel payers to further rely on academic cost-effectiveness analyses that rely on averages. Let's improve the health of our population one patient at a time by driving innovative payment systems that embrace shared decision-making.

Sincerely,



Tony Coelho
Chairman, Partnership to Improve Patient Care