PIPC Partnership to Improve Patient Care

May 5, 2022

Michael E. Chernew, Ph.D.
Chair
Medicare Payment Advisory Commission
425 I Street NW
Suite 701
Washington, DC 20001

Dear Chairman Chernew:

We are writing about MedPAC's consideration of payment policies for medicines covered under Medicare Part B, particularly related to utilizing metrics of clinical and cost effectiveness. We are very concerned that commissioners engaged in a discussion at the April 7, 2022 meeting suggesting reliance on QALY-based metrics as the basis for Medicare coverage policy. Comments were made at the meeting about how to measure clinical and cost effectiveness, particularly with regard to the use of the quality-adjusted life year (QALY). We urge the commission not to use discriminatory metrics as part of any proposed policy related to coverage and reimbursement.

The typical metric used in cost effectiveness analysis is the QALY. The National Council on Disability, an independent federal agency advising Congress and the administration on disability policy, published a report in 2019 that outlined how cost effectiveness analyses relying on the QALY discriminate in their design and impact, calling on policymakers to avoid its use.[1] The National Minority Quality Forum, sickle cell advocates and Partnership to Improve Patient Care (PIPC) published a review of literature that similarly highlighted how current methods of collecting health data incorporated into these studies is not representative of communities of color and therefore serves to entrench health care discrimination and inequities.[2]

We urge MedPAC to reflect on the debate leading to the creation of the Patient-Centered Outcomes Research Institute (PCORI) in 2010. Members of Congress on both sides of the aisle understood that relying on clinical and cost effectiveness in Medicare coverage and reimbursement decisions was a dangerous proposition for the most vulnerable beneficiaries. Therefore, the statute creating PCORI clearly prohibited the institute from using QALYs or any other similar measure that "discounts the value of a life because of an individual's disability," as a "threshold" for determining what type of health care

[1] https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf
[2] https://www.nmqf.org/nmqf-media/traditional-value-assessment-methods

is cost-effective. It also prohibited Medicare from using QALYs when developing healthcare coverage, reimbursement, and incentive programs.[3] Importantly, in creating PCORI, Congress also set a new bar for patient-centeredness in comparative clinical effectiveness research, one that could be lost in over-simplified Medicare assumptions about clinical similarity. Even with these protections in place, Congress barred PCORI's clinical effectiveness studies from being used as the sole source of a Medicare coverage decision, recognizing the danger of data being used against patients for whom treatments may have a unique therapeutic value.[4] In PCORI's second decade of funding comparative clinical effectiveness research, the institute has an opportunity to implement its new statutory mandate to capture the burdens experienced by patients, economic and otherwise, to fill essential data gaps to improve health care decision-making. Allowing such information to be used against patients would also be contrary to the law passed by Congress in 2010 calling for a shared decision-making program that achieved preference sensitive care.[5]

We strongly recommend that MedPAC staff and commissioners review the recommendations of the National Council on Disability. The council's 2019 report[6] recommends that policymakers avoid reference to QALYs and their recent Health Equity Framework recommends barring QALYs across federal programs.[7] There is no place in federal policy and programs for reference to metrics that discriminate. The impact of QALYs is felt most by people with disabilities and serious chronic conditions, particularly older adults with fewer "life years" to account for in the QALY formula. The statement from former Senator Orrin Hatch as part of a bipartisan colloquy in 2009 on advancing an agenda for comparative clinical effectiveness research on the Senate floor provides important legislative history.

> *We can all agree that the ''one size fits all'' approach is the wrong approach for the American health care system. Based on our own personal experiences we all know that what works best for one person, does not always work the same for another.*[8]

Past policy recommendations relying on studies from entities such as the Institute for Clinical and Economic Review (ICER) have consistently been met with opposition from patients and people with disabilities due to the flawed data and metrics on which they rely to make conclusions. In 2016, over 80

[3] 42 U.S. Code § 1320e-1(e)
[4] *American Recovery and Reinvestment Act of 2009,* 111th Congress, 1st sess., *Congressional Record 155* (February 6, 2009): S1796.
[5] Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148 § 936.
[6] https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf
[7] https://www.ncd.gov/publications/2022/health-equity-framework
[8] *American Recovery and Reinvestment Act of 2009,* 111th Congress, 1st sess., *Congressional Record 155* (February 6, 2009): S1796.

organizations sent a letter opposing a Medicare Part B proposal calling for use of comparative effectiveness research (CER) and cost-effectiveness reports as the basis for national Medicare policy, which was in direct conflict with the patient-centeredness movement and contrary to public support for personalized medicine and policies that allow doctors and patients to decide the best course of treatment.[9] PIPC sent letters to MedPAC in 2014[10] and 2018[11] expressing similar concerns about the potential for misuse of clinical and cost effectiveness research to make coverage decisions, highlighting in particular the methodological flaws of QALY-based studies.

More recently, we applauded efforts by HHS, which recognized that more guidance is needed to ensure that health plans are complying with the Essential Health Benefits (EHB) nondiscrimination policy. As part of its proposed Notice of Benefit and Payment Parameters, HHS stated to plans that "relying on cost alone is an insufficient basis to defend an otherwise discriminatory benefit design." This is important context for MedPAC to consider as it debates policy recommendations affecting Medicare drug coverage and reimbursement – recommended policies need to be consistent with federal civil and disability rights laws that bar discrimination.[12]

In conclusion, affordable access to health care is a priority for us all. We recognize and appreciate that MedPAC has a duty to advise Congress on issues affecting the Medicare program, including access to care, quality of care, and other issues affecting the program. We support improved access to quality health care and look forward to being a resource to MedPAC as the commission considers recommendations to change Medicare drug coverage and reimbursement policy.

Sincerely,

Tony Coelho

Tony Coelho, Chairman
Partnership to Improve Patient Care

[9] http://www.pipcpatients.org/resources/pipc-submits-letter-to-cms-on-proposed-part-b-drug-payment-model
[10] http://www.pipcpatients.org/resources/pipc-responds-to-medpac-consideration-of-lca-for-part-d
[11] http://www.pipcpatients.org/resources/pipc-letter-to-medpac-dont-rely-on-cost-effectiveness-to-make-coverage-and-reimbursement-decisions
[12] http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_nbpp_2023_comments.pdf