

January 27, 2021

The Honorable Xavier Becerra
Secretary, U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Becerra:

I appreciate the opportunity to provide comments on the Notice of Benefit and Payment Parameters 2023 Proposed Rule on behalf of Partnership to Improve Patient Care (PIPC). Since its founding, PIPC has been at the forefront of applying principles of patient-centeredness to the nation's health care system – from the generation of comparative clinical effectiveness research at the Patient-Centered Outcomes Research Institute (PCORI), to the translation of evidence into patient care in a manner that achieves value to the patient. We have advocated strongly for policies that give a voice – and a vote – to patients and people with disabilities. We have also fought hard against policies that inherently discriminate against people with disabilities, people with serious chronic conditions, seniors, ethnic minorities and others that do not fit the average.

PIPC is grateful to HHS for recognizing that more guidance is needed to ensure that health plans are complying with the Essential Health Benefits (EHB) nondiscrimination policy and would encourage you to consider the following comments.

Plans should not be permitted to reference the Quality-Adjusted Life Year (QALY).

Over the past several years, PIPC has had growing concern about payers relying on cost-effectiveness analysis based on the discriminatory Quality-Adjusted Life Year (QALY) to determine what treatments will be covered for patients. In fact, there is a 30-year history of advocacy from the disability community against the use of the QALY to determine cost effectiveness or “value” of treatments. QALYs and similar metrics are referenced in other countries and in studies by independent third parties, such as the Institute for Clinical and Economic Review (ICER). The National Council on Disability (NCD), an independent federal agency advising Congress and the administration on disability policy, recently concluded that QALYs place a lower value on treatments which extend the lives of people with chronic illnesses and disabilities and indicated that the use of QALYs in public programs would be contrary to United States disability policy and civil rights laws.¹

The United States has a thirty-year, bipartisan track record of opposing the use of the QALY and similar discriminatory metrics and establishing appropriate legal safeguards to mitigate their use. Section 504 of the Rehabilitation Act ensures that people with disabilities will not be “excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination,” under any program offered by any Executive Agency, including Medicare.² Title II of the

¹ https://www.ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

² 29 USC Sec 794, 2017. Accessed November 30, 2020.

Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments.³ Based on the ADA's passage in 1990, in 1992 the George H.W. Bush Administration established that it would be a violation of the ADA for state Medicaid programs to rely on cost-effectiveness standards, as this could lead to discrimination against people with disabilities.⁴

The Affordable Care Act (ACA) passed under President Barack Obama directly states that the Secretary of Health and Human Services has no authority to deny coverage of items or services “solely on the basis of comparative effectiveness research” nor to use such research “in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.”⁵ Additionally, the ACA specifically prohibits the development or use of 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 ACA also states, “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 under title XVIII” (Medicare).”⁶ Most recently, the U.S. Department of Health and Human Services (HHS) reiterated in a final rule that it is a violation of section 504 of the Rehabilitation Act, the ADA, the Age Discrimination Act, and section 1557 of the ACA for state Medicaid agencies to use measures that would unlawfully discriminate on the basis of disability or age when designing or participating in VBP arrangements.⁷

Therefore, PIPC encourages HHS to remind health plans of this precedent and make very clear that QALYs discriminate and cannot be used in benefit design.

Research relied on should meet standards of patient-centeredness.

PIPC appreciates HHS making clear that evidence underlying coverage decisions must be high-quality scientific evidence and/or clinical guidelines. We encourage HHS to also require that research and analysis relied upon to make decisions related to coverage and access to healthcare treatments and services by beneficiaries meet standards of patient-centeredness, including the measurement of outcomes prioritized by patients and people with disabilities and consideration of meaningful differences in the characteristics, needs and priorities of patients and people with disabilities. The proposed rule states, “we believe that practice guidelines from U.S. government bodies and government-created bodies, such as the HHS Agency for Healthcare Research and Quality (AHRQ) and the U.S. Preventive Services Task Force to be sufficient.” We appreciate this clarification and would encourage the rule to also specifically name the Patient-Outcomes Research Institute (PCORI) which is charged specifically with conducting patient-centered research. While PCORI’s research cannot be the sole source of information to deny coverage

³ 42 USC Sec 12131, 2017. Accessed November 30, 2020.

⁴ Sullivan, Louis. (September 1, 1992). Oregon Health Plan is Unfair to the Disabled. *The New York Times*.

⁵ 42 USC Sec 1320e, 2017. Accessed November 30, 2020.

⁶ 42 USC Sec 1320e, 2017. Accessed November 30, 2020.

⁷ <https://www.federalregister.gov/d/2020-12970>

under existing law, it can be used as one of many sources of information to understand the clinical benefits of a treatment.⁸

We would also encourage HHS to make clear that research that does not meet certain benchmarks of patient-centricity may not be relied on for decision making, including assessments conducted by ICER. ICER conducts cost-effectiveness assessments of treatments that rely on the QALY and similar one-size-fits-all summary metrics. Frequently, patients, caregivers, and clinicians with firsthand experience with the condition under review are excluded from the voting process. Their analyses are intended for use by insurers, evaluating cost effectiveness from the perspective of payers, and omitting data on outcomes that matter to patients.⁹ Though these studies are not peer reviewed and their results frequently contradict clinical guidelines, payers often reference them when making coverage and reimbursement decisions. Clear guidance that ICER's assessments are not an appropriate source of research would be helpful to mitigating discrimination and preserving patient access.

PIPC supports the clarification that cost may not be the sole reason for a benefit design.

The proposed rule states, “relying on cost alone is an insufficient basis to defend an otherwise discriminatory benefit design.” PIPC applauds HHS for making clear that cost may not be the sole reason for a plan denying coverage to prescription drugs for chronic health conditions. There has been a concerning trend of payers making coverage decisions solely based on the outcomes of QALY-based cost-effectiveness analyses, like those conducted by ICER, while ignoring the input of patient and physician stakeholders who find clinical benefit in treatments.^{10,11} As described by the National Council on Disability in its 2019 report on QALYs, this has led to discrimination against patients with chronic conditions and people with disabilities who have more complex health needs.¹²

We would encourage HHS to further strengthen this portion of the rule by explicitly banning reliance on cost-effectiveness analyses or QALYs as a source for a coverage decision.

Full transparency should be required regarding sources used in decision making.

In addition to requirements for scientific rigor, we would also encourage HHS to require full transparency regarding the use of research and analysis relied upon to make decisions impacting coverage and access to healthcare treatments and services by beneficiaries. To ensure full transparency, health plans should be required to provide beneficiaries with full access to research

⁸ PPACA sec. 6301(c), § 1182(b)(2)

⁹ http://www.pipcpatients.org/uploads/1/2/9/0/12902828/2020_voh_framework_comments_.pdf

¹⁰ Aaron E. Carroll, “Forbidden Topic in Health Policy Debate: Cost Effectiveness,” New York Times, December 15, 2014, <https://www.nytimes.com/2014/12/16/upshot/forbidden-topic-in-health-policy-debateQuality-Adjusted Life Years and the Devaluation of Life with Disability 79 cost-effectiveness.html>; Philip A. Pery and Timothy Hotze, “Oregon’s Experiment with Prioritizing Public Health Care Services,” AMA Journal of Ethics (blog), April 2011, <https://journalofethics.ama-assn.org/article/oregons-experiment-prioritizing-public-health-care-services/2011-04>.

¹¹ <https://www.statnews.com/2018/08/22/cvs-cost-effectiveness-benchmarks-puts-icer/>

¹² https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

and analysis relied upon to make coverage decisions. In the current environment, there is minimal transparency into how health plans make coverage decisions, so often patients are being denied care and are unable to understand the rationale behind the plans' decision-making processes. It is probable that these decisions are being based on discriminatory cost-effectiveness assessments or other analyses lacking scientific rigor and or meeting criteria for patient-centeredness. Full transparency would hold health plans accountable to rely only on high-quality, non-discriminatory research.

Conclusion

We appreciate the Administration's commitment to nondiscrimination and would be happy to remain a resource as you continue to strengthen non-discrimination policies.

Sincerely,



Tony Coelho
Chairman
Partnership to Improve Patient Care