

September 26, 2022

The Honorable Cathy McMorris Rodgers
1035 Longworth House Office Building
Washington, DC 20515

Dear Leader McMorris Rodgers:

We appreciate that House Energy and Commerce Republicans have requested feedback on policies that would address the discrimination against people with disabilities within our health care system that happens all too frequently. Your request for information, *Disability Policies for the 21st Century: Building Opportunities for Work and Inclusion*, and desire to take action on these issues is a helpful step forward as we work to ensure people with disabilities are able to access health care in an equitable manner. We would like to offer the following comments in response to the request for information.

“Should Congress strengthen oversight requirements at HHS and DOJ to ensure compliance with the law?”

We believe that strengthened oversight requirements are necessary to ensure people with disabilities are able to access health care without discrimination. As you may know, recently, the HHS Office for Civil Rights (OCR) recently issued a proposed rule that recognized the importance of enforcement of nondiscrimination laws. We share those concerns. Because so much information is not publicly accessible to determine if a benefit design or coverage decision was based on evidence that itself discriminates, it is difficult to legally challenge coverage denials that may be discriminatory. When a recipient fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR and DOJ should find noncompliance with Section 1557 and initiate the appropriate enforcement procedures. We also would appreciate increased oversight of the activities of state-based Medicaid programs, particularly Pharmacy and Therapeutic (P&T) Committees and Drug Utilization Review Boards (DURBs), to better understand how they make decisions about benefit design, coverage and preferred drugs and whether they are relying on discriminatory value assessments.

We are concerned that many states very explicitly reference one-size fits all value assessments, including those based on the Quality-Adjusted Life Year (QALY), to make decisions within their Medicaid programs. Currently, HHS is reviewing Oregon’s Medicaid waiver which will determine if the state’s Health Evidence Review Commission (HERC), which guides the Oregon Health Plan’s benefit decisions, will be authorized to continue to use a QALY-driven data and analysis in the formula for the prioritized list of services. In New York, their DURB has referenced QALY-based studies from the Institute for Clinical and Economic Review (ICER) to make reimbursement decisions related to treatments for cystic fibrosis, migraines and spinal

muscular atrophy. Similarly, Washington State's Health Technology Clinical Committee routinely commissions QALY-based studies to make coverage determinations for selected health technologies which are followed by state purchased health care programs including Medicaid, Uniform Medical Plan and the Department of Labor and Industries.^{1 2}

Therefore, we are urging HHS OCR to increase oversight and enforcement of state Medicaid programs to determine the extent to which they are relying on discriminatory value assessments to make decisions impacting coverage and access to care. We support your efforts to call for increased oversight of nondiscrimination laws within HHS and DOJ.

“Should Congress increase penalties for failure to meet accommodation requirements?”

We were encouraged that HHS OCR, as part of their proposed rule, outlined specific nondiscrimination requirements for health care programs and activities. Accessibility and effective communication are essential for people with disabilities and people with limited access to technology such as broadband. For example, it is difficult to hold health care decision-makers such as state P&T Committees and DURBs accountable for decisions related to benefit design and coverage if their websites do not meet the accessibility requirements of the Americans with Disabilities Act (ADA) or clearly communicate to the public the information on which they have relied to make decisions. All people should be able to participate in P&T Committee or DURB meetings required to be public, with accessible teleconferencing capabilities and telephone capabilities, as well as sufficient notice to register to participate. The considerations being discussed at the meeting should be clearly stated to the participating public stakeholders, including copies of the evidence under discussion with the exception of legally protected material.

We hope the committee will encourage OCR to provide guidance to state Medicaid program directors on the requirements of the ADA and their obligations to ensure their programs, including P&T Committees, DURBs and their outside contractors, are meeting the ADA's requirements for accessibility to the information on which they make decisions and communicating that information in a manner that does not disadvantage people with disabilities or people with limited access to technology. Meaningful penalties should be imposed where entities do not come into compliance with the law.

We recommend an expansion of your discussion of elements of disability discrimination within health care.

In your request for information, you provide a specific anecdote about Charlotte Woodward, a person living with Down syndrome who received a heart transplant and discuss the unfortunately common practice of denials of organ transplants to people with disabilities. All too often this biased judgement of the quality of life of a person living with a disability occurs in

¹ <https://www.hca.wa.gov/about-hca/health-technology-assessment/health-technology-clinical-committee>

² <https://www.patientaccessproject.org/#State-Tracker>

the medical setting leading to worse health outcomes, and, at times, threatening survival. We appreciate your recognition of this injustice and your desire to ensure federal protections that support people with disabilities' access to health care are followed. We would like to suggest that there is an additional aspect of this that should be considered as you build your disability policy, which is the inappropriate use of value assessments to determine coverage and reimbursement of health care services and treatments.

Patients and people with disabilities have long-held deep concerns about reliance on one-size fits all value assessments, including cost-effectiveness assessments based on the QALY, to determine what treatments will be covered benefits for patients. QALYs and similar metrics relying on averages are referenced in other countries and in studies by third parties, such as ICER to determine whether treatments are "cost-effective." The QALY metric puts a lower value on the life of an individual living with a disability, and, as such, value assessments using this metric devalue treatments for people with disabilities.

In a 2019 report, the National Council on Disability (NCD), an independent federal agency advising Congress and the administration on disability policy, 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.

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. We would encourage the Committee to make clear that the use of the QALY is contrary to federal protections that guarantee people with disabilities access to health care and include it as a measure of which HHS and DOJ are conducting oversight.

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.³ Title II of the Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments.⁴ 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.⁵

The Affordable Care Act (ACA) passed under President Barack Obama directly states that the Secretary of Health and Human Services (HHS) has no authority to deny coverage of items or services "solely on the basis of comparative effectiveness research" nor to use such research "in

³ 29 USC Sec 794, 2017. Accessed August 11, 2022.

⁴ 42 USC Sec 12131, 2017. Accessed August 11, 2022.

⁵ Sullivan, Louis. (September 1, 1992). Oregon Health Plan is Unfair to the Disabled. The New York Times.

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.”⁶ 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).”⁷ The rationale for the ACA’s provisions barring the use of QALYs was articulated by a bipartisan group of Senators in 2009 early in the debate over creation of what became the Patient-Centered Outcomes Research Institute (PCORI), expressing support for comparative clinical effectiveness research, not comparative cost effectiveness, as well as seeking reassurance that such work would be used to improve health decisions and not restrict coverage.⁸ Recognizing the risk for patient access to care, the legislation also clearly barred Medicare from denying coverage solely based on comparative clinical effectiveness research.⁹

More 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 value-based purchasing (VBP) arrangements.¹⁰ Also, the recently-passed Inflation Reduction Act included language barring discriminatory evidence from being a factor in the negotiation process for determining a fair price for prescription drugs, stating, “In using evidence described in subparagraph (C), the Secretary shall not use evidence from comparative clinical effectiveness 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.”¹¹

The law and regulations governing federal health care programs have established clear precedent that QALY-based assessments of cost and clinical effectiveness are discriminatory against people with disabilities and contrary to federal nondiscrimination laws. The Disability Rights Education and Defense Fund (DREDF) published a report in 2021 discussing the elements of QALYs that rely on a set of discriminatory assumptions that devalue life with a disability, thereby disadvantaging people with disabilities seeking to access care based on subjective

⁶ 42 USC Sec 1320e, 2017. Accessed August 11, 2022.

⁷ 42 USC Sec 1320e, 2017. Accessed August 11, 2022.

⁸ 155 Cong. Rec. 1796, Feb 6, 2009.

⁹ 155 Cong. Rec. 1796, Feb 6, 2009.

¹⁰ <https://www.federalregister.gov/documents/2020/06/19/2020-12970/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and>

¹¹ Public Law No: 117-169.

assessments of quality of life. DREDF concluded that, under disability nondiscrimination law, health care programs cannot use measures to determine the drugs worth covering that are based on discriminatory assumptions about the quality of life with a disability, nor can reliance on the measure produce a disproportionately negative impact on the health care services and treatments that people with disabilities uniquely rely on. DREDF stated, “The lives of all individuals regardless of disability are equally valuable; this fundamental principle cannot be ignored for the sake of cost savings.”¹²

We are grateful that you are aware of and prioritize advancing legislation that will bar the use of the QALY across Federal programs, the Protecting Health Care for All Patients Act. We strongly support a comprehensive ban on the use of the QALY in federal programs and urge that the legislation be reintroduced in the next Congress to include a bar on the use of QALYs within the Centers for Medicare and Medicaid Innovation as well. There is robust precedent finding the use of QALYs to be discriminatory against people with disabilities and in violation of the federal civil and disability rights laws, including the ADA. It is an issue that has generated bipartisan concerns from a wide range of health care stakeholders. We encourage the Committee to take steps in the next Congress to more explicitly recognize the QALY as a mechanism of health care discrimination meriting further investigation and legislative action as it develops a disability policy plan.

As the committee engages in oversight related to the implementation of the Inflation Reduction Act, we also urge steps to ensure that the U.S. Department of Health and Human Services (HHS) provides strong safeguards for patients and people with disabilities, including people with disabilities and from historically underserved and marginalized groups, in any process implementing the new health reform legislation. Simply put, we believe policymakers will not be able to achieve a health care system that is truly patient-centered and truly equitable for all patients if the agency does not work intentionally to meaningfully engage affected stakeholders in health care decisions. It is more important than ever for Congress to ensure patients and people with disabilities are protected from use of assessments of treatment value that discriminate or entrench health inequity when these provisions are implemented HHS. To exclusively rely on data sources to attribute a “maximum fair price” as called for by statute that are known to often exclude entire populations, including racial and ethnic communities and people with disabilities, can only serve to perpetuate health care inequity. These perspectives will be essential to contextualize and understand the gaps in the data.

Thank you for your consideration of our comments. We appreciate your dedication to thoughtful disability policy, and we stand ready to work with you towards these goals. Please

¹² DREDF, ICER Analyses Based on the QALY Violate Disability Nondiscrimination Law, September 21, 2021 at <https://dredf.org/wp-content/uploads/2021/09/ICER-Analyses-Based-on-the-QALY-Violate-Disability-Nondiscrimination-Law-9-17-2021.pdf>

don't hesitate to reach out to Sara van Geertruyden at sara@pipcpatients.org if you have any questions or if we can provide further information.

Sincerely,



Tony Coelho, Chairman
Partnership to Improve Patient Care

cc: Energy and Commerce Committee Republicans