

August 4, 2022

Honorable Chuck Schumer
Majority Leader
U.S. Senate
322 Hart Senate Office Building
Washington, D.C. 20510

Honorable Patty Murray
Chair
U.S. Senate HELP Committee
428 Senate Dirksen Office Building
Washington, DC 20510

Honorable Nancy Pelosi
Speaker of the House
U.S. Senate
1236 Longworth H.O.B.
Washington, DC 20515

Honorable Frank Pallone
Chair
U.S. House of Representatives, Energy and
Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Honorable Ron Wyden
Chair
U.S. Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510-6200

Honorable Richard Neal
Chair
U.S. House of Representatives, Ways and
Means Committee
1102 Longworth House Office Building
Washington D.C. 20515

Dear Leader Schumer, Speaker Pelosi, Chairman Wyden, Chair Murray, Chairman Pallone, and Chairman Neal:

We are writing to urge Congress to take 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 from historically underserved and marginalized groups, in any process implementing new health reform legislation that may be enacted under reconciliation rules this year. 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. The omission of such protections in the legislation itself makes it that much more of an imperative that HHS respect existing provisions of law that already protect patients and people with disabilities and assure their voices are heard in the implementation process if or when any legislation is implemented.

We were disappointed that the most recent draft text on Medicare prescription drug pricing omits language from prior versions that called for a process for input from affected stakeholders, a necessary step to understand how treatments may vary in their impact among subpopulations. We are deeply concerned that without this basic safeguard, this legislation could shut the door on patients and people with disabilities and eliminate their ability to have a voice in decisions that impact their health care. If this legislation advances, it is also 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.

First, we urge Congress to convey to HHS that the agency should use its existing authority to establish a decision-making process that is informed by meaningful input from patients and other affected stakeholders related to the legislation’s negotiation process, including any process the Secretary uses for determining the “fair price” for selected drugs under Medicare in instances when evidence of a drug’s value is being considered. The legislative language in Section 1194 of the original Build Back Better Act would have allowed for consideration of information submitted to HHS by “other parties that are affected by the establishment of a maximum fair price for the selected drug” but was omitted from the most recent version shared with the public on July 6, 2022. While this provision did not give stakeholders any guarantees that their input would influence the agency’s ultimate decisions, it had provided the only outlet for patient and disability stakeholders to have a voice in the process, particularly their perspectives on the value of drugs. The new text also seems to exclude a required formal notice and comment process, raising concerns that the agency could forego a process that would facilitate robust stakeholder engagement. We urge Members of Congress to call on HHS to do more, not less, to use its existing regulatory authorities to proactively establish a process to engage affected stakeholders during implementation and to be accountable for considering their input.

Second, we urge Congress to recognize and communicate to HHS that current safeguards against devaluing the lives of individuals with disabilities, older adults and other subpopulations experiencing health disparities, as well as protections regarding the use of comparative clinical effectiveness research in Medicare, under the existing provisions of Section 1182 of the Affordable Care Act must be adhered to as part of the process of negotiation outlined in the legislation.¹ The ACA clearly stated that such research was barred from use in Medicare coverage, reimbursement and incentive programs in a manner that devalued the lives of older adults, people with disabilities or “terminally ill” individuals, and very explicitly barred the use of quality-adjusted life years (QALYs) in Medicare decisions. The legislation also clearly barred Medicare from denying coverage solely based on comparative clinical effectiveness research. The rationale for these provisions 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.²

¹ PPACA sec. 6301(c), § 1182

² 155 Cong. Rec. 1796, Feb 6, 2009.

Our concerns only further underscore the importance of advancing the ongoing recommendations³ of the National Council on Disability to bar the use of QALYs across federal programs consistent with Section 1182 of the Affordable Care Act as part of a strategy to work toward health equity for people with disabilities, as articulated most recently in their Health Equity Framework.⁴ Additionally, the National Minority Quality Forum (NMQF) and others have reported on the health equity implications of value assessments, particularly those relying on QALYs, that are derived from data that excludes people of color and too often is biased against them.⁵ A legal analysis from the Disability Rights Education and Defense Fund (DREDF) concluded that reliance on the QALY in value assessment of pharmaceuticals violates disability nondiscrimination law.⁶ **We believe it is imperative for Members of Congress to separately pass legislation that extends Section 1182 protections across federal programs, thereby establishing the unambiguous ban on the use of QALYs called for by the National Council on Disability, as the country works toward health equity for all.**

If this legislation advances, we hope you will work with us to ensure that HHS creates a process for – and accountability to consider – input from affected stakeholders and that HHS adheres to prohibitions on use of discriminatory metrics such as QALYs that govern Medicare decisions, including decisions made under the negotiation process described in legislation being considered as part of reconciliation.

We appreciate your consideration.

Sincerely,

Alliance for Aging Research
Alliance for Patient Access
American Association of Kidney Patients
American Behcet's Disease Association (ABDA)
Association of University Centers on Disabilities
Autism Insurance for Oregon
Autistic Women & Nonbinary Network
Bone Health and Osteoporosis Foundation
Buscher Consulting
CancerCare
Center for Autism and Related Disorders
Colorado Cross-Disability Coalition
COPD Foundation
Cutaneous Lymphoma Foundation

³ <https://ncd.gov/publications/2021/ncd-letter-qaly-ban>

⁴ See recommendation #8 at <https://www.ncd.gov/publications/2022/health-equity-framework>

⁵ <https://www.nmqf.org/nmqf-media/traditional-value-assessment-methods>

⁶ <https://dredf.org/2021/09/23/pharmaceutical-analyses-based-on-the-qaly-violate-disability-nondiscrimination-law/>

Cystic Fibrosis Research Institute
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Disability Community Resource Center
Disability Policy Consortium
Disability Rights California
Easterseals
GO2 Foundation for Lung Cancer
Health Hats
Hydrocephalus Association
ICAN, International Cancer Advocacy Network
International Pemphigus Pemphigoid Foundation
Lupus Foundation of America
Men's health Network
Multiple Sclerosis Foundation
National Alliance for Hispanic Health
National Down Syndrome Society
National Minority Quality Forum
National Organization of Nurses with Disabilities (NOND)
Not Dead Yet
Partnership to Improve Patient Care
RASopathies Network USA
Rosie Bartel, Self as a Patient Advisor
The ALS Association
The Bonnell Foundation: living with cystic fibrosis
The Coelho Center for Disability Law, Policy and Innovation
The Headache and Migraine Policy Forum
TSC Alliance

CC:

Honorable Xavier Becerra, Secretary, U.S. Department of Health and Human Services