

November 13, 2023

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

Re: Discrimination on the Basis of Disability in Health and Human Service Programs or Activities

Dear Secretary Becerra,

The 45 undersigned organizations write to express our support for the Office for Civil Rights (OCR) in its efforts to safeguard the rights of people with disabilities, regardless of age, throughout their lifespans. We commend the OCR for its dedication to combating discrimination and advancing equal access to healthcare services. In this letter, we focus on the segments of the proposed rule related to medical treatment and the assessment of value, especially concerning people with disabilities and older adults, who experience marginalization in healthcare decision-making.

An estimated one in four Americans lives with a disability. However, for individuals ages 65 and older, this number rises to two in five.¹ Though Section 504 pertains to disability-related discrimination, the large percentage of the aging population living with one or more disabilities underscores the importance of examining the intersectionality of age and disability-related discrimination. **As OCR moves forward on a final rule, we ask the agency to consider incorporating relevant protections for older adults, including clarified language on value assessment.**

§ 84.56 Medical Treatment

Older Adults Face Elevated Risks for Developing Disabilities

As individuals age, the likelihood of developing disabilities such as mobility impairments, hearing loss, and limitations in activities of daily living significantly increase. Moreover, as older adults advance in age, their vulnerability to complex healthcare issues such as dementia further compound their healthcare needs. While age is a protected class, these differences impact care. Failure to recognize these impacts and define protections can

¹ Centers for Disease Control and Prevention. "Prevalence of Disabilities and Health Care Access by Disability Status and Type Among Adults." 16 Sep 2020. <https://www.cdc.gov/ncbddd/disabilityandhealth/features/kf-adult-prevalence-disabilities.html>

lead to substandard outcomes. Therefore, **it is imperative that the Department of Health and Human Services (HHS) consider the intersection and combined impact of aging and disability discrimination in the final rule.**

Discrimination Against Older Adults

Discrimination in healthcare is often rooted in problematic assumptions about the quality of life individuals lead. This is illustrated well in section § 84.56(b)(1) of the proposed rule. In this particular case, a person with Alzheimer's disease (AD) is denied care due to the attending physician's prejudiced judgment regarding the value of that person's life. Such a scenario is not unique to AD; it reflects a broader issue in healthcare discrimination. The COVID-19 pandemic also brought to light numerous ethical and healthcare challenges pertaining to discrimination against older adults, particularly when it came to allocating limited resources such as ventilators. As the virus spread rapidly, healthcare systems faced the daunting task of managing a surge in critically ill patients, many of whom required mechanical ventilation to survive. The shortage of ventilators necessitated the development of crisis standards of care, which aimed to guide healthcare providers in allocating these life-saving resources.²

One of the concerning trends that emerged during this period was the assumption that older adults had a lower chance of survival, and in some instances, they were deprioritized in the allocation of ventilators. This practice was driven by the assumption that younger individuals had a longer remaining life expectancy or, more concerningly, that their lives were inherently more valuable because they had more time to live them. This form of age-based discrimination was not only ethically problematic but also medically flawed. While it is true that older adults may face a higher risk of severe illness from COVID-19, age alone should not have been the sole determinant for access to ventilators. Many older adults maintain a high quality of life and may live for many more years. Medical decisions should be based on individual medical factors, not age-based criteria.

These examples reveal a striking similarity and significant overlap between the discrimination faced by older adults and that faced by individuals with disabilities. The denial of life-saving treatment based on assumptions about quality or length of life is a shared concern among these two groups. Discriminatory practices, whether in the context of crisis standards of care, life-sustaining treatment, or participation in clinical research, often stem from misconceptions about the value and duration of life.

² Alliance for Aging Research. "Advocacy Groups Call on HHS Office of Civil Rights to Issue Guidance on Fair Medical Resource Allocation During COVID-19." 14 Apr 2020. <https://www.agingresearch.org/blog/advocacy-groups-call-on-hhs-office-of-civil-rights-to-issue-guidance-on-fair-medical-resource-allocation-during-covid-19/>

§ 84.57 Value Assessment Methods

We appreciate the OCR'S recognition of the potential discriminatory impacts of certain value assessment methodologies on older adults and individuals with disabilities. As a result, we are in staunch support of the addition of provision § 84.57.

OCR's discussion of value assessment's impact on patient access to treatments and services as framed in the proposed rule acknowledges concerns that have long been expressed by the patient community. Specific patient advocacy efforts are noted in citation 142 in the rule. Currently, there is a push to expand the Affordable Care Act's (ACA) ban on the use of the quality adjusted life year (QALY).³ While we remain supportive of that effort, we are concerned that an explicit QALY ban does not go far enough to protect people with disabilities and older adults as it leaves open the possibility of utilizing similar methods that do not resolve the discriminatory effects of QALY-based value assessment. Therefore, we appreciate the wide lens focus of the guidance to consider any measure, assessment, or tool that discounts the value of life extension on the basis of disability.

Value Assessment's Increasing Prominence in the US Healthcare Decision Making Process

The use of traditional value assessment is steadily gaining prominence throughout federal health agencies, with several already incorporating these methods into their decision-making processes in order to control program costs. This results in rationing of care that can disproportionately affect individuals with disabilities or older adults, as their treatment needs are often more complex and require specialized care. When treatments are denied or delayed based on cost-effectiveness calculations, affected beneficiaries may be subject to complicated utilization management or abandon their treatment, which can lead to worsened health outcomes and decreased quality of life. Medicare, the Veteran's Administration, and state Prescription Drug Affordability Boards (PDABs) are all considering the use of or already using methods of value assessment to set prescription drug prices.⁴ This trend signifies a move towards a more comprehensive evaluation of healthcare interventions and treatments. However, as value assessment becomes increasingly pervasive, it also opens the door for potential discrimination. QALY bans alone are not enough to meaningfully address this issue.

The first PDAB was created in Maryland in 2019, and since then seven other states have followed suit. Five of these boards have the power to set upper payment limits (UPL) for a specified number of prescription drugs: Washington, Oregon, Colorado, Maryland, and

³ Protecting Healthcare for All Patients Act, H.R. 485, 118th Cong. 2023.

<https://www.congress.gov/118/bills/hr485/BILLS-118hr485ih.pdf>

⁴ National Academy for State Health Policy. "2023 State Legislative Action to Lower Pharmaceutical Costs." 13 Oct 2022. <https://nashp.org/2023-state-legislative-action-to-lower-pharmaceutical-costs/>

Minnesota.⁵ In May, the Minnesota legislative body passed a PDAB law that will link any forthcoming UPL determined by the board to the Medicare maximum fair price set by the Inflation Reduction Act.⁶

The ACA explicitly banned the use of Quality-Adjusted Life Years (QALYs) and similar metrics in Medicare. While this is a positive step, it has not done nearly enough to curb the potential for discriminatory methods of value assessment to be used to set prices. As the agency goes through the process of designing the direct negotiation program they have announced that they are still considering reports that include and are informed by the QALY. Additionally, they have announced that they are actively contemplating the adoption of metrics including the equal value of life years gained (evLYG, or evLY) despite its underlying basis and potential to carry over the discriminatory impacts of the previously banned QALY.⁷

EvLYG's and the Discriminatory Lineage of the QALY

The evLYG represents a major issue in curbing the use of discriminatory metrics: when key stakeholders become persuaded that a particular metric has adverse effects on healthcare access for a specific patient group, it creates an opportunity for the introduction of a new metric with comparable issues, essentially restarting the entire process.

The evLYG, while intended as an alternative to the QALY, regrettably does not adequately address the shortcomings of the QALY. The evLYG was initially designed to work in conjunction with the QALY rather than as a standalone metric. Its primary purpose was to serve as a comparative tool, particularly when the outcomes from the evLYG analysis significantly deviated from those of the QALY. Consequently, the evLYG inherits the same discriminatory lineage as the QALY.

Neither the National Council on Disability (NCD) or the Disability Rights Education and Defense Fund (DREDF) endorse the evLYG, with the DREDF emphasizing that neither the evLYG nor the QALY accounts for the full value of life extension and quality of life

⁵ Avalere. "State legislatures are increasingly considering prescription drug affordability boards and upper payment limits to lower state expenditures and patient costs." 15 Aug 2023. <https://avalere.com/insights/states-turn-to-drug-price-boards-to-reduce-spending#:~:text=PDAB%20legislation%20has%20since%20been,Colorado%2C%20Maryland%2C%20and%20Minnesota>

⁶ National Academy for State Health Policy. "Medicare Drug Price Negotiations Create Opportunities for States to Lower Drug Costs across Payers." 05 Sep 2023. <https://nashp.org/medicare-drug-price-negotiations-create-opportunities-for-states-to-lower-drug-costs-across-payers/>

⁷ Center for Medicare. "Letter, subject: Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026." 30 Jun 2023. <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>

improvement.⁸⁹ The NCD points out that under the evLYG system, the possibility of denying coverage still exists, even when a drug offers substantial clinical benefits, including life extension.

The evLYG perpetuates a significant bias in terms of lifespan assumptions. This bias stems from the underlying assumption that older individuals have fewer potential life years to gain from therapeutic interventions compared to their younger counterparts. As a result, conditions that disproportionately impact the aging population are consistently undervalued by the evLYG.

Furthermore, the methods used for collecting and analyzing the underlying data for the evLYG are currently incomplete and underdeveloped. Organizations like ICER primarily rely on clinical trial data, which often exclude individuals based on factors like comorbidities and age.¹⁰ Consequently, clinical trial data often fails to accurately represent the broader real-world user population, leading to evLYG calculations and broader cost-effectiveness calculations that do not reflect a therapy's complete impact.

Over an extended period, the persistent use of metrics such as the QALY and evLYG will lead to an unequal distribution of healthcare investments, disproportionately impacting people with disabilities and older adults. When treatments are denied or delayed based on cost-effectiveness calculations, these vulnerable populations may be left without viable options, which can lead to worsened health outcomes and decreased quality of life.

In summary, our organizations are in support of OCR's efforts to broadly ban discriminatory methods of value assessment in federal healthcare programs.

Value Assessment Methods Question 1: The Department seeks comment on how value assessment tools and methods may provide unequal opportunities to individuals with disabilities.

The Department's request for feedback on how value assessment tools and methods may lead to unequal opportunities for individuals with disabilities is a crucial inquiry. It's essential to acknowledge the inherent math of the QALY and similar metrics as a starting point. A recent article published in the *Journal of Health Economics Outcomes Research*

⁸ National Council on Disability. "Quality-Adjusted Life Years and the Devaluation of Life with Disability: Part of the Bioethics and Disability Series." 6 Nov 2019.

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

⁹ Disability Rights Education & Defense Fund. "Pharmaceutical Analyses Based on the QALY Violate Disability Nondiscrimination Law." 21 Sep 2021. <https://dredf.org/2021/09/23/pharmaceutical-analyses-based-on-the-qaly-violate-disability-nondiscrimination-law/>

¹⁰ Alliance for Aging Research. "ICER Reviews and the Aging Population." Dec 2022.

<https://www.agingresearch.org/wp-content/uploads/2022/12/ICER-Reviews-and-the-Older-Population-Final.pdf>

states, “Our review of the mathematical properties of QALYs, including an analysis of quality-of-life utility (QOL utility) data recently collected from patients with inflammatory bowel disease (IBD), has led us to conclude that QALYs are an inappropriate metric of drug and treatment cost-effectiveness for all people, both disabled and nondisabled, and should not be the basis for US healthcare policy decisions.”¹¹

This mathematical analysis brings to light a critical aspect of the QALY's shortcomings. The QALY is not rooted in the individual patient's perspective, but rather looks at a treatment's population-wide impact. Almost universally, individuals place a high value on the meaningfulness and quality of their lives, but if a person is assigned a negative QALY (i.e., below 0), they are assigned a health state value below death and therefore any health interventions will be valued as a net negative for the population as a whole.¹² Patients, regardless of their health conditions, frequently express a strong desire to continue living and experiencing their lives. Their perspective encompasses not only the quantitative aspect of life extension but also the qualitative dimension of well-being and fulfillment. This is nearly impossible to quantify, and as a result the QALY and similar metrics are unable to capture this deeply personal and subjective experience. It tends to focus on a narrower set of health-related quality of life factors and is more inclined to make utilitarian judgments.

In fact, it is nearly impossible for these methods to account for the long-term benefits, indirect societal effects, or nuanced outcomes that certain treatments can provide. As a result, the value of therapies that significantly improve the lives of individuals with disabilities and older adults may be underestimated or overlooked, leading to unequal opportunities in accessing those treatments. This discrepancy creates ethical and practical challenges in healthcare resource allocation and decision-making. It is crucial that the Department comprehensively assess the limitations of these value assessment techniques and their impact on individuals with disabilities to ensure equitable healthcare decision-making.

Value Assessment Methods Question 2: The Department seeks comment on other types of disability discrimination in value assessment not already specifically addressed within the proposed rulemaking.

While aging itself is not a disability, it's essential to emphasize that older adults are more likely to experience disability and face unique healthcare challenges and disparities that deserve careful consideration. We ask that the Department consider and outline this point

¹¹ Sawhney TG, Dobes A, O'Charoen S. “QALYs: The Math Doesn't Work”. J Health Econ Outcomes Res. 27 Jul 2023. <https://pubmed.ncbi.nlm.nih.gov/37522031/>

¹² Schneider, P. “The QALY is ableist: on the unethical implications of health states worse than dead.” 9 Dec 2021. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9023412/>

more fully in the final rule. One critical aspect to address is the disproportionate impact of value assessment discrimination based on age, particularly in healthcare decision-making. This includes the problematic assumptions that often underlie these assessments. When examining age-related components of discrimination, a few specific areas come to the forefront.

1. *Clinical Trials*: Clinical research protocols often include age cut-off criteria. The exclusion of older adults over a certain age (e.g., age 65 or 75) can lead to inadequate representation and understanding of how aging affects healthcare outcomes, as well as the impact of treatments on older populations.
2. *Symptomatic Treatments*: The emphasis on symptomatic treatments in value assessments often falls short in capturing the full range of benefits for people with disabilities. This limitation can significantly affect the quality of life for those reliant on these treatments.

These are just initial examples, and there are more highlighted throughout this document. It is crucial for OCR to consider and address age-related components of discrimination in value assessments, as they are closely intertwined with the experiences of people with disabilities.

Value Assessment Methods Question 3: The proposed value assessment provision applies specifically to contexts in which eligibility, referral for, or provision or withdrawal of an aid, benefit, or service is being determined. The preamble discussion of the provision clarifies that the provision would not apply to academic research alone. However, the Department seeks comment on the extent to which, despite this intended specificity, the provision would have a chilling effect on academic research.

We appreciate OCR's focus on academic research. However, we believe the following factors support the expeditious finalization and acceptance of the proposed rule's provisions:

1. *Development of Alternatives*: The ban on QALYs and other discriminatory metrics will likely stimulate intense interest and activity in developing alternative methods. This period of exploration and development of alternative approaches is likely to lead to increased funding and active research. Competition among methodologies may emerge, fostering innovation.
2. *Limited Use of QALYs in the US*: Value assessment methods have not been widely used for coverage or payment decisions in the United States, in contrast to countries such as the UK. Therefore, the ban on QALYs is likely to have a lesser

impact on decision-making in the US healthcare system than it would in other countries.

3. *QALYs as Part of Broader Research*: QALYs and other discriminatory metrics are rarely the sole focus of research projects. They are often used in conjunction with cost-related and other outcome measurements. With the ban on QALYs, these other findings will continue to hold importance, potentially even increasing in significance.
4. *Shift in Grant Processes*: Grant-giving and grant-seeking processes in the academic research community may shift as a result of the ban on QALYs and other discriminatory metrics. Granting agencies have been able to quickly adapt in the past and issue requests for proposals on alternative research topics, mirroring the rapid response to emerging trends, such as health equity and disparities.

Conclusion

We commend the OCR's commitment to ensuring equitable access to healthcare services and combating discrimination in the field of medical treatment and value assessment methods. We ask that the OCR proceed in finalizing the proposed rule with a heightened focus on protecting older adults. Our shared goal is to ensure that all individuals, regardless of age or disability, receive equitable access to healthcare services and treatments.

With questions, please contact Adina Lasser, Public Policy Manager at the Alliance for Aging Research, at alasser@agingresearch.org.

Sincerely,

ADAP Advocacy
Aimed Alliance
Alpha-1 Foundation
ALS Association
Alzheimer's Foundation of America
American Foundation for Women's Health/StopAfib.org
American Society of Consultant Pharmacists (ASCP)
AnCan Foundation
Arachnoiditis & Chronic Meningitis Collaborative Research Network (ACMCRN)
Autistic Women & Nonbinary Network
Caregiver Action Network
Community Access National Network

Davis Phinney Foundation for Parkinson's
Family Voices of California
Foundation for Sarcoidosis Research (FSR)
Genetic Alliance
Global Coalition on Aging Alliance for Health Innovation
Health Hats
HealthyWomen
Heart Valve Voice US
KCNT1 Epilepsy Foundation
Lupus and Allied Diseases Association, Inc
Lupus Foundation of America
National Fabry Disease Foundation
National Association For Continence
National Association of Directors of Nursing Administration
National Rural Health Association
Neuropathy Action Foundation
Nevada Chronic Care Collaborative
Organic Acidemia Association
Partnership to Fight Chronic Disease
Patients Rising
PlusInc
PXE International
RASopathies Network
RetireSafe
Second Wind Dreams
SYNGAP1 Foundation
The Bonnell Foundation: Living with cystic fibrosis
The Coelho Center for Disability Law, Policy and Innovation
The Headache and Migraine Policy Forum
The Mended Hearts, Inc.
Triage Cancer
TSC Alliance
Voices of Alzheimer's