PIPC Partnership to Improve Patient Care

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,

As organizations representing people living with disabilities, including older adults, people with chronic conditions and people with disabilities, we are pleased to comment to the U.S. Department of Health and Human Services (HHS) related to its proposed rule implementing Section 504 of the Rehabilitation Act. We agree with the need to clarify areas not explicitly addressed in current regulations. Our comments include the following recommendations:

- While we appreciate HHS' recognition of the impact of discriminatory measures related to life extension, HHS should advance a final rule that uses language consistent with Section 1182(e) of the Affordable Care Act. Doing so would:
    - Be consistent with current developments and laws and discourage confusion.
    - Allow for consideration of how value assessments may discriminate by classifying people with disabilities as inferior whether in measures of life extension or in quality-of-life improvement.
    - Be consistent with NIH efforts to address ableist assumptions about quality of life that may also drive value assessments.
    - Spur meaningful innovation in the development and use of measures of quality of life and improvement that do not discriminate based on the assumed "worth" of patients with disabilities to treat.
- HHS should explain that the final rule related to Medical Treatment applies to payer policies advanced by recipients of federal financial assistance.
    - Explicitly recognize how recipient payers cannot categorially exclude or limit access to care that is not futile for individuals with disabilities.

- Clarify that it is not a legitimate, nondiscriminatory reason to selectively deny or limit care to a person with a disability based on the determination the person's quality of life is not worth the cost of treatment.
- Further emphasize that exclusion of a subgroup of people with disabilities from a clinical trial should not be considered a nondiscriminatory reason for coverage and utilization management policies restricting access to care for that subgroup.

Value Assessment: The Proposed Rule Should be Consistent with Section 1182(e) of the Affordable Care Act.

As the agency works toward consistency across the legal landscape of disability discrimination laws and protections, we were pleased that the Affordable Care Act (ACA) was referenced by HHS among that legal landscape. In addition to Section 1557 of the ACA, Section 1182 specifically addresses the issue of value assessment, stating:

> (e) The Patient-Centered Outcomes Research Institute established under section 1181(b)(1) shall not develop or employ 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 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.''.

We agree with the proposed rule that the lives of people with disabilities may be devalued in value assessment measures of life extension (i.e. the QALY). Additionally, we agree with Section 1182(e) of the ACA which is not limited to "life extension," recognizing there are a variety of methods to measure the clinical and cost effectiveness of health care that may discount the value of a life because of an individual's disability, similar to the QALY, and therefore would be similarly discriminatory and unlawful. In addition to calling out the QALY specifically as an unlawful measure for use by PCORI and Medicare, Section 1182(e) bars similar measures that discount the value of disabled lives. Section 1182(e) does not distinguish whether disabled lives are discounted in measures of life extension, quality-of-life improvement, or other cost effectiveness measures – it says a similar measure is one that discounts the value of a life based on an individual's disability.

Therefore, we urge the final rule to be amended to be consistent with the language used in Section 1182(e) of the ACA, which is also consistent with the NIH definition of ableism discussed below.

Existing law bars QALYs & similar measures due to evidence of their discriminatory implications.

We appreciate that the proposed rule describes the policy background governing federal health care programs that have established clear precedent that QALY-based value assessments are discriminatory against people with disabilities. QALYs discriminate against patients and people with disabilities by placing a lower value on their lives and insufficiently accounting for outcomes that they value. The National Council on Disability (NCD), an independent federal agency, concluded in a 2019 report that QALYs place a lower value on treatments which extend the lives of people with chronic illnesses and disabilities, and that the use of the QALY violates the Americans with Disabilities Act (ADA). NCD also recognized the challenges associated with the health utilities related to valuing quality of life improvements. NCD recognized, "This speaks to one of the fundamental flaws of the QALY: that the conflation of life extension and quality of life improvement benefits into a single number forces people with disabilities into a cruel trap: picking whether they would rather live longer or have improved quality of life, when both are entirely feasible in a society willing to invest sufficient resources."[1] NCD therefore recommended that policymakers and insurers reject QALYs, indicating that the use of the QALY would be contrary to United States disability policy and civil rights laws. NCD also called out the need for a consistent policy across federal programs.[2]

Additionally, 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 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."[3]

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[1] National Council on Disability, *Quality-adjusted Life Years and the Devaluation of Life with Disability*, 2019, https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.
[2] National Council on Disability, *Quality-adjusted Life Years and the Devaluation of Life with Disability*, 2019, https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.
[3] DREDF, "ICER Analyses Based on the QALY Violate Disability Nondiscrimination Law," September 21, 2021, https://dredf.org/wp-content/uploads/2021/09/ICER-Analyses-Based-on-the-QALY-Violate-Disability-Nondiscrimination-Law-9-17-2021.pdf.

Therefore, we would encourage Section 504 to be interpreted consistently with these developments and laws to ensure conformity with current law and to protect against discrimination on the basis of disability, a stated priority for the agency.[4] To provide that clarity, we urge the proposed rule to align with the language used in Section 1182(e) of the Affordable Care Act.

Biased algorithms lead to discriminatory value assessments.

Biased algorithms and metrics, including the QALY, have long been used to drive health care decisions.[5,6] Historically, measures of clinical and cost effectiveness of treatments have used algorithms biased against the value of lives lived with disabilities and chronic conditions, thereby entrenching health inequity.[7] As policymakers and payers respond to growing concerns about QALYs and similar measures by seeking to root out their use in making health care decisions, particularly related to coverage and reimbursement, it is important to understand the bias and unreliability of the algorithms underlying the QALY and to find alternatives that are truly nondiscriminatory, as opposed to replacing one bad measure for another.

For example, the value sets or weights used in comparative effectiveness studies may be subject to bias and validity challenges.[8] First, they may be constructed by a very small subgroup of a country's population[9] despite purporting to represent all.[10] Second, there is considerable empirical evidence that technologies impact people to different degrees and that society strongly disagrees with treating all conditions, disease states and patient types with the same priority.[11,12] Third, the basic methodological assumptions supporting the value sets used in the

[4] Department of Health and Human Services, "Federal Register/Vol. 88, No. 177/63393/Thursday, September 14, 2023/Proposed Rules," September 14, 2023, https://www.govinfo.gov/content/pkg/FR-2023-09-14/pdf/2023-19149.pdf.
[5] Warren Et. Al, "Letter to HHS OCR Rationing of Care," April 10, 2020, https://www.warren.senate.gov/imo/media/doc/2020.04.09%20Letter%20to%20HHS%20OCR%20re%20Rationing%20of%20Care.pdf.
[6] National Council on Disability, *Quality-adjusted Life Years and the Devaluation of Life with Disability*, 2019, https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.
[7] PIPC, *Aligning Health Technology Assessment with Efforts to Advance Health* Equity, http://www.pipcpatients.org/uploads/1/2/9/0/12902828/aligning_health_technology_assessment_with_efforts_to_advance_health_equity.pdf.
[8] Smith S, Cano S, Browne J. Patient reported outcome measurement: drawbacks of existing methods. bmj. 2019 Feb 27;364:l844.
[9] McClimans L, Browne JP. Quality of life is a process not an outcome. Theoretical medicine and bioethics. 2012 Aug 1;33(4):279-92.
[10] Broome J. Fairness versus doing the most good. The Hastings Center Report. 1994 Jul 1;24(4):36-9.
[11] Weinstein MC. A QALY is a QALY is a QALY—or is it? Journal of health Economics July 1988 289-291.
[12] Whitehead SJ, Ali S. Health outcomes in economic evaluation: the QALY and utilities. British medical bulletin. 2010 Dec 1;96(1):5-21.

QALY equation have been tested empirically and shown to be empirically flawed.[13] Currently, this bad data underlies many value metrics, and we must be careful to evaluate these underpinnings in determining whether a metric or methodology is discriminatory.

There is increasing recognition of the bias of these algorithms that justify recipient payer decisions to restrict coverage of treatments and services for people with disabilities. For example, we recently have seen California's Attorney General investigate hospitals about how healthcare facilities and other providers are identifying and addressing racial and ethnic disparities in commercial decision-making tools, the first step in a Department of Justice inquiry into whether commercial healthcare algorithms – types of software used by healthcare providers to make decisions that affect access to healthcare for California patients – have discriminatory impacts based on race and ethnicity.[14] In response, 15 organizations sent a letter to the Attorney General calling for its investigation to extend to the use of cost effectiveness analyses of medical treatments using metrics that discriminate against people with disabilities.[15]

Also, as part of the proposed rule implementing Section 1557 of the Affordable Care Act, HHS requested feedback on the use of value assessments, stating that a covered entity must not discriminate against any individual on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision-making and requested comment on the use of discriminatory metrics in value assessment.[16] In response, over 80 organizations signed a comment letter to HHS urging the Office for Civil Rights to advance a rulemaking that bans the use of methods for calculating value that penalize individuals or groups of individuals on the basis of race, color, national origin, sex, age, or disability as part of utilization management, formulary design, price negotiations, alternative payment models and other incentive-based programs impacting access to care and affordability of care.

Discrimination in value assessment is not just a life extension problem.

Measures can be constructed with biased estimates of life years.

[13] Beresniak A, Medina-Lara A, Auray JP, De Wever A, Praet JC, Tarricone R, Torbica A, Dupont D, Lamure M, Duru G. Validation of the underlying assumptions of the quality-adjusted life-years outcome: results from the ECHOUTCOME European project. Pharmacoeconomics. 2015 Jan 1;33(1):61-9.
[14] Rob Bonta, "Attorney General Bonta Launches Inquiry into Racial and Ethnic Bias in Healthcare Algorithms," August 31, 2022, https://oag.ca.gov/news/press-releases/attorney-general-bonta-launches-inquiry-racial-and-ethnic-bias-healthcare.
[15] CRFI, "Letter to AG Bonta," November 4, 2022, https://www.cfri.org/wp-content/uploads/2022/11/CA-Letter-to-AG-Bonta-11.4.2022.pdf.
[16] National Archives, "Nondiscrimination in Health Programs and Activities," August 4, 2022, https://www.federalregister.gov/documents/2022/08/04/2022-16217/nondiscrimination-in-health-programs-and-activities.

During the construction of the QALY and similar measures in any comparative effectiveness exercise, the gains in both the survival and health-related quality of life must be estimated as a consequence of different treatments – both of these estimates are prone to biases long before QALYs are produced. For example, life years lost (LYL) requires a chosen estimate of life expectancy at the point of treatment. Even if the sources of these life-expectancy estimates are valid, if the source for disease A is older in age or contains more people with disabilities or chronic conditions than the data source for disease B, different diseases will have different weightings for the potential life year gains that could accrue to a successfully treated individual. Therefore, the estimates for two treatments that might hypothetically have equal health benefits would still produce two different estimates of life years gained, because of the disparity between populations used, not as a function of the therapies' relative effectiveness. The end result could be that the measure relies on lower, or discounted, life expectancy measures for people with disabilities, which then attributes a lower value to treating disease A.

Value assessment methods should be consistent with the NIH efforts to eliminate ableism.

As an example of a similar measure, the equal value of life year gained (evLYG) is not a better substitute for the QALY and in fact has many of the same underlying shortcomings of the QALY. For example, the evLYG measure fails to recognize the value of medications that improve symptoms for patients where the outcome benefit is quality of life versus life extension, as is commonly the goal for people with disabilities for whom a cure is not the goal, but instead improved quality of life.[17] As PIPC has stated in the past, the evLYG "posited an untenable choice between two flawed metrics: the QALY, which incorporates some measures of value reflecting quantity and quality of life, but discriminates against patients and people with disabilities, or the 'equal value of life year gained,' the evLYG, which disregards any value of a medicine other than its ability to extend life. This is a false choice and it further demonstrates that current, conventional cost-effectiveness assessments are not fit for making vital health care decisions."[18] The point has also been made by DREDF.[19]

[17] Joshua Cohen Et. Al, "Will ICER's Response to Attacks on the QALY Quiet the Critics," December 18, 2018, https://cevr.tuftsmedicalcenter.org/news/2018/will-icers-response-to-attacks-on-the-qaly-quiet-the-critics.
[18] PIPC, "Chairman's Corner: Will ICER's Response to Attacks on the QALY Quiet the Critics?: A Reply from the Partnership to Improve Patient Care," February 8, 2019, http://www.pipcpatients.org/blog/chairmans-corner-will-icers-response-to-attacks-on-the-qaly-quiet-the-critics-a-reply-from-the-partnership-to-improve-patient-care.
[19] Id at DREDF, stating "Thus, adding the evLYG is not a solution; it merely forces payers to choose between one measure that undervalues life extension (the QALY) and one that affords no value to quality of life improvements (the evLYG). Neither accounts for both the full value of life-extension and the value of quality of life improvement."

Inherent in measures such as evLYG is ableism – valuing a treatment goal as reducing disability as opposed to valuing living a full life with a disability. The NIH definition of ableism states, "Ableism characterizes people as defined by their disabilities and classifies disabled people as inferior to non-disabled people." As part of efforts to eliminate ableism in health care, a recent NIH funding announcement encourages research to understand how ableism contributes to health disparities for people with disabilities and/or to develop systems level interventions to combat the negative health impacts of ableism. In doing so, NIH has an opportunity to align its projects with efforts to advance innovative research methods to understand the impact of ableism on health outcomes that do not devalue disabled lives, whether as reflected in the health utilities or in the values associated with life extension.[20] The NIH is also seeking to amend its own mission statement to eliminate its ableist language, which currently includes, "to reduce illness and disability." The proposed language supported by many disability advocates changes the mission "to optimize health and prevent or reduce illness for all people."[21]

Therefore, we urge HHS to advance a proposed rule that recognizes how value assessments more broadly may discriminate, classifying people with disabilities as inferior whether in life extension or in quality-of-life improvement. Alignment with Section 1182(e) of the ACA would achieve consistency across HHS agencies in how they seek to advance health equity and nondiscrimination.

Similar measures using utility weights such as the EQ-5D, like the evLYG, also devalue people with disabilities.

Utility weights such as the EQ-5D are built on ableist, discriminatory inputs. It fails to account for the full nuance in patient conditions when translating condition-specific measures into utility weights. Oftentimes, dimensions of data are lost when translating condition specific patient-reported outcome measures (PROs) into utility weights, and more frequently, entities conducting value assessment such as the Institute for Clinical and Economic Review (ICER) will rely on generic PROs, like the EuroQoL instrument (EQ-5D). It is important to consider that continued use of the EQ-5D is wholly inconsistent with NIH efforts to dismantle ableism in research. As an example, the EQ-5D questionnaire asks patients whether they have problems in "walking about."[22] A negative answer will thereby lower the health-related quality of life score, as inability to "walk about" is seen as a low quality of life using the ableist standard that walking

[20] Department of Health and Human Services, "Understanding and Mitigating Health Disparities Experienced by People with Disabilities Caused by Ableism,: https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-24-007.html.
[21] Department of Health and Human Services, "Understanding and Mitigating Health Disparities Experienced by People with Disabilities Caused by Ableism,: https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-24-007.html.
[22] EuroQol Research Foundation, "EQ-5D-5L About," https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/.

is needed for a high quality of life. As in the above example related to Duchenne Muscular Dystrophy, the result is devaluing quality of life for people who are non-ambulatory.

It Is important that the dimensions used by instruments such as the EQ-5D bear some relationship to the QOL of patients, as emphasized by the U.S. Food and Drug Administration (FDA) in their guidance to industry on the use of the patient reported outcome (PRO).[23] As such, the FDA notes that *"PRO instrument item generation is incomplete without a range of patients with the condition of interest to represent appropriate variations in severity and in population characteristics such as age or sex."* The EQ-5D, translated into QALY utility weights, does not meet this standard as it relies upon weightings constructed by populations unfamiliar with the conditions being evaluated and therefore does not have the legitimacy obtained by consulting with patients. Criticism of this disconnect is widespread and growing.[24,25] The EQ-5D often underestimates both the baseline burden of these diseases in patient populations, as well as the impact of treatments, compared to the more accurate disease-specific measures that were developed with those diseases in mind.[26] Studies have shown that the content of the EQ-5D is often poorly aligned with patient perceptions in diseases such as asthma[27], mental health[28] and cancer,[29] and whole population groups such as older adults.[30] Without a nuanced, patient-driven lens, a generic scale like EQ-5D will fail to account for health-related quality of life impacts outside the dimensions that are included in the scale.[31] The NCD report published in 2019 also expressed these concerns.

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[23] US Food and Drug Administration *Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims.* 2009. [2020-07-15].

[24] Cubi-Molla P, Shah K, Burström K. Experience-Based Values: A Framework for Classifying Different Types of Experience in Health Valuation Research. *Patient.* 2018 Jun;11(3):253–270.

[25] Helgesson G, Ernstsson O, Åström M, Burström K. Whom should we ask? A systematic literature review of the arguments regarding the most accurate source of information for valuation of health states. *Qual Life Res.* 2020 Jul;29(6):1465–1482

[26] Payakachat N, Ali MM, Tilford JM. Can the EQ-5D detect meaningful change? A systematic review. *Pharmacoeconomics*;2015;33:1137–1154.

[27] Whalley D, Globe G, Crawford R. et al. Is the EQ-5D fit for purpose in asthma? Acceptability and content validity from the patient perspective. *Health Qual Life Outcomes*;2018;16:160.

[28] Keetharuth AD, Rowen D, Bjorner JB, Brazier J. Estimating a preference-based index for mental health from the Recovering Quality of Life Measure: valuation of Recovering Quality of Life Utility Index. *Value Health*. 2021;24(2):281-290.

[29] Garau M, Shah K, Towse A, Wang Q, Drummond M, Mason A. Assessment and appraisal of oncology medicines: does NICE's approach include all relevant elements? What can be learnt from international HTA experiences? Report for the Pharmaceutical Oncology Initiative (POI) February 2009.

[30] van Leeuwen KM, Jansen APD, Muntinga ME, Bosmans JE, Westerman MJ, van Tulder MW, et al. Exploration of the content validity and feasibility of the EQ-5D-3L, ICECAP-O and ASCOT in older adults. *BMC Health Serv Res.* 2015;15:1–10.

[31] Avalere and The Partnership to Improve Patient Care, *Use of Patient-Centered Outcomes in ICER* Assessments, July, 25, 2023, http://www.pipcpatients.org/uploads/1/2/9/0/12902828/avalerepipc_icer-use-of-pcos-whitepaper.pdf.

Therefore, it will be important for the final rule to allow for policymakers to determine whether a value assessment used to make a coverage decision has utilized discriminatory measures or methods or ableist standards for defining quality of life. Otherwise, organizations such as ICER that are entrenched in developing value assessments using traditional methods will continue to shift focus to similar measures such as the evLYG in the wake of criticism about the QALY – without really innovating at all. The evLYG does not solve many of the baseline issues that exist with the QALY as it continues to use generic scales like the EQ-5D that use ableist questions to define quality of life.

The EQ-5D is Widely Used Beyond Measures of Life Extension.

The quality-of-life part of the value assessment equation can have implications for discrimination. The EQ-5D is the most commonly used PRO within cost-per-QALY calculations but has also been found to be used in several non-economic contexts as well. In one review of the literature, in 2019 only 1 out of 12 papers used EQ-5D to calculate cost per QALY. The study found use of EQ-5D as a quality-of-life outcome measure, a tool for methodological research, a comparison with other quality of life questionnaires, as well as in mapping studies and value sets.[32] A policy consistent with Section 1182(e) of the ACA would allow policymakers to consider whether the use of a measure such as the EQ-5D to value health care devalued people with disabilities, whether used in a QALY-based assessment or otherwise.

PROs and Utility Weights May Reflect Public Bias Against People with Disabilities and Fail to Reflect the Outcomes that Matter to People Experiencing the Disease or Condition.

Although the EQ-5D purports to represent a consensus about the perceived value of different health states, this is generally not the case. Surveys reveal enormous heterogeneity (i.e., disagreement) within populations. For example, the EQ-5D health-state '12213' (no problems with mobility or pain/discomfort, some problems with self-care and performing usual activities, extreme anxiety/depression) received a median rating of 0.5 (on a scale where, by convention, 0 represents death and 1 represents full health) in a recent survey, but the inter-quartile range of valuations was 0.338 to 0.725.[33] In other words, half of the general public rated the value of this health state outside an already wide range. This lack of societal consensus is apparent across life states[13] and is a function of the methods used to derive values for health states. The values

[32] Springer Link, "The Remarkably Frequent use of EQ-5D in Non-Economic Research," November 30, 2021, https://link.springer.com/article/10.1007/s10198-021-01411-z.
[33] Bansback N, Tsuchiya A, Brazier J, Anis A. Canadian valuation of EQ-5D health states: preliminary value set and considerations for future valuation studies. *PLoS One*. 2012;7:e31115.

produced by these methods are known to vary substantially across respondent characteristics such as age, sex and marital status.[34]

Also, studies have confirmed inherent bias against people with disabilities in the general public, finding much of the public perceives that people with disabilities have a low quality of life.[35] Therefore, the potential for discrimination is significant when value assessments rely on public surveys.

Exemplifying the concern around generic PROs, a recent Avalere study of four reports (SMA, ALS, HCM, MG) published by ICER found a disconnect between ICER statements about patient-centeredness and the actual use of patient-centered outcomes in their reviews that raises concerns as to how generic preference-based measures, which carry significant implications for survey bias, influence value assessment. These studies did not integrate PCOs quantitatively into modeling, resulting in final valuations with limited incorporation of the patient perspective. ICER's stated preference for generic preference-based measures, especially EQ-5D, was found to often ignore or undervalue patient-relevant outcomes.[36]

Alignment with Section 1182(e) Will Drive Innovation in Methods Measuring Quality of Life and Improvement.

Policymakers and payers should use caution before attempting to selectively use QALYs, or just as importantly, selectively use the components of data inputs that make up QALY calculations in comparative effectiveness studies. Use of the QALY's component data inputs is just as dangerous as the blanket use of QALYs as a marker to eliciting the value of a drug to a patient or to society. The biases that patients and people with disabilities want to avoid are built into the methodological construction of QALYs and similar measures at multiple levels. As payers and policymakers seek to avoid the use of discriminatory metrics, they must also recognize the risk of cherry-picking components of QALY estimates that have their own inherent biases, particularly related to older adults and people with disabilities and chronic conditions. Going forward, the development and use of alternative metrics should explicitly aim to exclude these inherent biases and better represent the needs, preferences and outcomes of patients and people with disabilities.

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[34] Dolan P, Roberts J. To what extent can we explain time trade off values from other information about respondents. Soc Sci Med 2002;54:919-29.
[35] Ne'eman Et. Al, "Identifying and Exploring Bias in Public Opinion on Scarce Resource Allocation During the COVID-19 Pandemic," October 2022, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00504.
[36] Avalere and The Partnership to Improve Patient Care, *Use of Patient-Centered Outcomes in ICER* Assessments, July, 25, 2023, http://www.pipcpatients.org/uploads/1/2/9/0/12902828/avalerepipc_icer-use-of-pcos-whitepaper.pdf.

By prohibiting the use of measures in value assessment that devalue people with disabilities, the agency will spur innovation in the development and use of quality of life and improvement measures that do not discriminate. A policy that is inconsistent with the current law at Section 1182 of the ACA will be confusing and could discourage meaningful innovation.

The final rule should use language consistent with Section 1182(e).

Therefore, we urge HHS to align the proposed rule with Section 1182(e) of the Affordable Care Act. Doing so will allow HHS to determine on a case-by-case basis whether a value assessment relied upon in decision-making by a recipient of federal financial assistance has violated Section 504. If the referenced value assessment methodology uses QALYs or another measure that discounts the value of a life because of an individual's disability, it is discriminatory.

Medical Treatment: The Bias and Stigma Driving Discriminatory Health Decisions is Exacerbated by Coverage and Utilization Management Policies.

We appreciate that the proposed rule seeks to address shortcomings in existing regulations in order to promote high-quality health care that is accessible and affordable for all people.[37] Achieving this important goal will require enforcement against not only the bias and stigma that underlies clinical decisions, but also the payer policies advanced by recipients of federal financial assistance (recipient payers) that drive how care is covered and reimbursed with implications for day-to-day treatment decisions.

Recipients of federal financial assistance include payers such as Medicaid.

The proposed rule's discussion about medical treatment states the proposed rule is intended to be broad and inclusive,[38] yet the discussion about it does not reference how recipient payers of federal financial assistance such as Medicaid programs make coverage decisions that drive medical treatment and thereby impact the care prescribed and recommended by medical professionals, which impacts whether beneficiaries with disabilities are able to access the care they need. Reduced access to medical treatment leading to health disparities and poor health outcomes is too often associated with coverage and utilization management policies that create barriers to medical treatment for people with disabilities. We agree that unmet health care

[37] Department of Health and Human Services, "Federal Register/Vol. 88, No. 177/63392/Thursday, September 14, 2023/Proposed Rules," September 14, 2023, https://www.govinfo.gov/content/pkg/FR-2023-09-14/pdf/2023-19149.pdf.

[38] Department of Health and Human Services, "Federal Register/Vol. 88, No. 177/63395/Thursday, September 14, 2023/Proposed Rules," September 14, 2023, https://www.govinfo.gov/content/pkg/FR-2023-09-14/pdf/2023-19149.pdf.

needs contribute to various indicators of health inequity experienced by people with disabilities and recognize that recipient payer policies contribute to that inequity.

For example, the P&T Committees making decisions about coverage and utilization management typically include physicians, other prescribers, pharmacists, nurses, administrators, quality-improvement managers, and other health care professionals and staff who participate in the medication-use process.[39] Their biased perceptions related to the quality of life of people with disabilities, which the proposed rule discussed in detail, can also result in decisions about coverage that link underlying disabilities to restricted access to care through coverage and utilization management policies. Additionally, P&T Committee decisions are not necessarily informed by specialists in the disease or condition that may hold less biased views against patients with disabilities than more general practitioners and would have more knowledge of the clinical appropriateness of treatment for subgroups of patients that have disabilities. We urge the final rule to explicitly recognize how recipient payer decisions, in the form of coverage and utilization management decisions, may violate the rule related to Medical Treatment when relying on assumptions that a person with a disability is not worth treating.

Coverage and utilization management policies based on biased perceptions of quality-of-life lead to discriminatory judgments about a person's worthiness of treatment.

We applaud that the proposed rule recognizes how judgments about a person's quality of life lead to decisions not to treat people with disabilities or to treat them differently than a similarly situated individual. With regard to medical futility determinations, we agree with the rule's assertions that certain definitions used to deny care to people with disabilities are likely to be discriminatory, motivated by inappropriate consideration of cost or value judgments regarding the quality of life of individuals with disabilities. We also agree with the proposed rule that denying a medical treatment on the basis of judgments about the worth of a person's life is discriminatory if treatment would be provided to a similarly situated patient without a disability.[40] Similarly, with regard to Crisis Standards of Care, we applaud the proposed rule for

[39] ASHP, "ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System," https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/pharmacy-and-therapeutics-committee-and-formulary-system.ashx#:~:text=The%20P%26T%20committee%20is%20composed,in%20the%20medication%2Duse%20process.

[40] Department of Health and Human Services, "Federal Register/Vol. 88, No. 177/63399/Thursday, September 14, 2023/Proposed Rules," September 14, 2023, https://www.govinfo.gov/content/pkg/FR-2023-09-14/pdf/2023-19149.pdf.

stating that recipients of federal financial assistance may not categorically exclude individuals with disabilities from critical care, provided that the care is not futile.[41]

The same logic should apply to recipient payers, and below, we cite examples of where a payer policy may selectively restrict coverage based on the need for mechanical ventilation, a mobility impairment or a substance use disorder, and which are motivated by cost or value judgements related to the quality of life of individuals with disabilities rather than clinical appropriateness. We urge the final rule to explicitly recognize how recipient payers cannot categorially exclude or limit access to care that is not futile for individuals with disabilities under the final rule.

Hepatitis C and Substance Use Disorder

In its discussion about discrimination prohibited, the proposed rule describes situations where a recipient declines to treat persons with a substance use disorder based on a belief that these persons are less likely to comply with treatment protocols. The proposed rule also describes refusing a person with Opioid Use Disorder a referral for medication due to belief that the person will not be adherent would be prohibited under the proposed rule. The same rationale could be applied to recipient payer policies. For example, we are aware of payer policies that have restricted coverage to highly effective and curative treatments for hepatitis C for people with substance use disorders as a condition triggering discriminatory restrictions.[42]

Duchenne Muscular Dystrophy and Ambulatory/Non-Ambulatory

A person with Duchenne Muscular Dystrophy who is considered ambulatory is similarly situated to a person who is non-ambulatory for treatment purposes. The underlying disability, being non-ambulatory, does not translate into the treatment not being clinically appropriate simply because the person who is non-ambulatory may continue to need accommodations and supports and may not achieve being ambulatory in the future with treatment. As in the case of Terrie Lincoln, a person who experiences disability should not be denied treatment for Duchenne Muscular Dystrophy simply because of a lack of mobility when that person would benefit from the quality-of-life improvements and/or life extension provided by that treatment,

[41] Department of Health and Human Services, "Federal Register/Vol. 88, No. 177/63400/Thursday, September 14, 2023/Proposed Rules," September 14, 2023, https://www.govinfo.gov/content/pkg/FR-2023-09-14/pdf/2023-19149.pdf.
[42] Hepatitis C: State of Medicaid Access, "Report Cards," https://stateofhepc.org/report-cards/.

even if the quality-of-life improvement is not ultimately going to mean that the person is ambulatory.[43,44,45,46]

Spinal Muscular Atrophy and Use of a BiPAP

A person with spinal muscular atrophy who is dependent on a BiPAP is similarly situated to a person who is not dependent on a BiPAP for treatment purposes. The underlying disability, being dependent on a BiPAP, does not translate into the treatment not being clinically appropriate simply because the person dependent on a BiPAP may continue to need it in the future.[47] This example is analogous to the example provided in the proposed rule related to a patient with Alzheimer's on a ventilator – the recipient payer, like the physician in the rule's example, is denying coverage of life-sustaining care for the patient based on judgments about the patient's quality of life.

Selectively denying or restricting access to care for people with disabilities based on cost is discrimination.

When a recipient payer restricts access to care to a subgroup with underlying disabilities based on whether it is "cost effective" for that subgroup, rather than whether it is clinically appropriate, the decision reflects assumptions about a person's worth and should be considered a 504 violation. The proposed rule discussion provides several analogous examples of potential violations of Section 504, from denying a heart transplant to a person with Down Syndrome to denying a person with spinal muscular atrophy treatment for COVID-19.[48] We urge the final rule to clarify that recipients of federal financial assistance, including payers, may not deny clinically appropriate treatment that would be offered to a similarly situated individual whether directly or because of a coverage policy. It is not a legitimate, nondiscriminatory reason to selectively

[43] Mass.gov, "Table 76: Neuromuscular Agents-Duchenne Muscular Dystrophy and Spinal Muscular Atrophy," https://mhdl.pharmacy.services.conduent.com/MHDL/pubtheradetail.do?id=373.
[44] State of Iowa Department of Health and Human Services, "Amondys 45," https://hhs.iowa.gov/sites/default/files/Amondys%2045%20%28casimersen%29%20-%20PAM-044%20%28v.2%29.pdf.
[45] Maryland Department of Health, "Exondys 51," https://health.maryland.gov/mmcp/Documents/Exondys%2051%20Clinical%20Criteria.pdf#search=exondys.
[46] United Healthcare Community Plan, "Exondys 51," https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medicaid-comm-plan/exondys-51-eteplirsen-cs.pdf.
[47] Khrystal Davis, "Testimony," May, 4, 2021, https://docs.house.gov/meetings/IF/IF14/20210504/112551/HHRG-117-IF14-Wstate-DavisK-20210504.pdf.
[48] Department of Health and Human Services, "Federal Register/Vol. 88, No. 177/63405/Thursday, September 14, 2023/Proposed Rules," September 14, 2023, https://www.govinfo.gov/content/pkg/FR-2023-09-14/pdf/2023-19149.pdf.

deny or limit care to a person with a disability based on the determination the person's quality of life is not worth the cost of treatment.

Exclusion from clinical trials is not a nondiscriminatory reason for coverage and utilization management decisions that deny or restrict access to care.

When current medical knowledge or best available objective evidence indicates a treatment is clinically appropriate, then creating coverage and utilization management barriers for people with disabilities to receive that treatment when others similarly situated are covered to receive that treatment is discriminatory.[49] Knowing that people with disabilities are too often excluded from clinical trials, we agree with the proposed rule's assertion that it would not be a nondiscriminatory reason to deny a patient with a disability access to a treatment or service because of exclusion from a clinical trial. Too often such decisions are made based on perceptions that people with disabilities are not worth treating or have a low quality of life, rather than based on any evidence indicating the treatment or service would not be effective or would be dangerous or harmful. [50]

When a coverage policy differentiates those eligible for treatment based on disability simply because of a lack of evidence from a clinical trial directly related to the clinical effectiveness for the population of people with disabilities – as opposed to evidence of ineffectiveness, danger or potential harm – there is no legitimate nondiscriminatory reason to deny coverage or impose utilization management barriers that those similarly situated do not face. Underlying the gaps in evidence, as alluded to in the proposed rule, people with disabilities are often excluded from trials because the accommodations to include them (i.e. making forms accessible, having ASL interpreters, having accessible clinic sites) is a barrier. Researchers often view accommodations as too expensive, or do not understand what is needed to include people with disabilities in trials.[51] Coverage policies only serve to exacerbate the discrimination when the exclusion from clinical research experienced by people with disabilities has significant implications not only for research results, but also for coverage and utilization management decisions.

[49] Department of Health and Human Services, "Federal Register/Vol. 88, No. 177/63403/Thursday, September 14, 2023/Proposed Rules," September 14, 2023, https://www.govinfo.gov/content/pkg/FR-2023-09-14/pdf/2023-19149.pdf.
[50] Department of Health and Human Services, "Federal Register/Vol. 88, No. 177/63407/Thursday, September 14, 2023/Proposed Rules," September 14, 2023, https://www.govinfo.gov/content/pkg/FR-2023-09-14/pdf/2023-19149.pdf.
[51] Bonnielin Swenor and Jennifer Deal, "Disability Inclusion as a Key Component of Research Study Diversity," https://doi.org/10.1056/NEJMp2115475.

We applaud the recent NIH decision to include people with disabilities as a health disparities population.[52] The decision is consistent with the proposed rule's recognition that people with disabilities experience health disparities. It is also consistent with the Patient-Centered Outcomes Research Institute's designation of people with disabilities as a health disparities population early in its prioritization of topics a decade ago.[53] We are hopeful that the impact of treatment and services on people with disabilities will increasingly be the subject of research as people with disabilities are included in medical research and clinical trials, thereby allowing treatment decisions to be made based on knowledge of clinical effectiveness for subgroups with disabilities. Yet, the ongoing exclusion of people with disabilities from clinical trials only makes it more important to gather real world evidence that will allow for improved decisions related to clinical appropriateness.

Therefore, exclusion of a subgroup of people with disabilities from a clinical trial should not solely be considered a nondiscriminatory reason for coverage and utilization management policies restricting access to care for that subgroup.

Collect, Analyze, and Publicly Report Disability Data.

It is important to recognize that driving innovation in value assessment and enforcing against discrimination in Medical Treatment goes hand-in-hand with efforts to improve data collection on people with disabilities. Requirements for data collection should serve to support accountability and transparency, thereby allowing for improved oversight of compliance with Section 504. Disability data collected in healthcare settings will provide insight on care decisions and whether they are based on clinical appropriateness versus unlawful discrimination. Disability researchers have long sought to improve the collection of disability data in Electronic Health Records, providing important recommendations to the Office of the National Coordinator for Health Information Technology.[54] Additionally, disability researchers have advocated for a national task force to develop a plan for improving and expanding disability data collection across the federal government, which could holistically address the long-standing challenges with disability data collection.[55]

Conclusion

[52] NIH, "NIH Designated People with Disabilities as a Population with Health Disparities," September 26, 2023, https://www.nih.gov/news-events/news-releases/nih-designates-people-disabilities-population-health-disparities.
[53] https://www.pcori.org/about/about-pcori/our-programs/healthcare-delivery-and-disparities-research
[54] Morris Et. Al, "Closing Disability Disparities: EHR Data as First Step," https://www.healthit.gov/sites/default/files/facas/2022-03-01_Documenting_disability_brief.pdf.
[55] Swenor Et. Al, "Letter to U.S. Census," October 18, 2023.

We are very pleased that the agency is advancing this update to the regulations governing Section 504 of the Rehabilitation Act. We strongly urge the agency to make it clear that recipient payers can also discriminate in the context of Medical Treatment by excluding people with disabilities from covered treatments and services that are clinically appropriate. We also support the agency's efforts to interpret Section 504 in a manner that is consistent with other existing laws, and therefore urge the final rule related to Value Assessment to use language aligned with Section 1182 of the ACA.

Thank you for your consideration.

Sincerely,

Alliance for Aging Research
Allies for Independence
ALS Association
American Association of People with Disabilities
American Association on Health and Disability
Asthma and Allergy Foundation of America
Autistic Self Advocacy Network
Axis Advocacy
Buscher Law Office
Cancer Support Community
Cancer*Care*
Caring Ambassadors Program
Center for Autism and Related Disorders
Center For Black Equity
Charlie's Cure
Coalition of Texans with Disabilities
Colorado Cross-Disability Coalition
COPD Foundation
Cystic Fibrosis Research Institute
Davis Phinney Foundation for Parkinson's
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Disability Community Resource Center
Disability Policy Consortium
Disability Rights Education and Defense Fund (DREDF)
Dravet Syndrome Foundation
Epilepsy Advocacy Network
Epilepsy Alliance America
Epilepsy Foundation
Epilepsy Foundation Alabama
Epilepsy Foundation Alaska

Epilepsy Foundation Arizona
Epilepsy Foundation Arkansas
Epilepsy Foundation Eastern Pennsylvania
Epilepsy Foundation Florida
Epilepsy Foundation Greater Orange County
Epilepsy Foundation Indiana
Epilepsy Foundation Iowa
Epilepsy Foundation Louisiana
Epilepsy Foundation Maryland
Epilepsy Foundation Metro D.C.
Epilepsy Foundation Mississippi
Epilepsy Foundation Montana
Epilepsy Foundation Nebraska
Epilepsy Foundation Nevada
Epilepsy Foundation New ENgland
Epilepsy Foundation New Jersey
Epilepsy Foundation New Mexico
Epilepsy Foundation North Carolina
Epilepsy Foundation North Dakota
Epilepsy Foundation Northwest Illinois
Epilepsy Foundation of CO & WY
Epilepsy Foundation of Connecticut
Epilepsy Foundation of Greater Chicago
Epilepsy Foundation of Michigan
Epilepsy Foundation of Northeastern New York, Inc.
Epilepsy Foundation of San Diego County
Epilepsy Foundation Ohio
Epilepsy Foundation Oklahoma
Epilepsy Foundation Oregon
Epilepsy Foundation South Carolina
Epilepsy Foundation South Dakota
Epilepsy Foundation Utah
Epilepsy Foundation Washington
Epilepsy Foundation West Virginia
Epilepsy Support Network of Orange County
Euthanasia Prevention Coalition-USA
Family Resource Network: Autism Family Services of NJ; Caregivers of NJ and Epilepsy Services of NJ
Genetic Alliance
Global Liver Institute
Health Hats
HealthHIV
Heart Valve Voice US
ICAN, International Cancer Advocacy Network

Infusion Access Foundation
International Pemphigus Pemphigoid Foundation
Lakeshore Foundation
Lupus and Allied Diseases Association, Inc.
MLD Foundation
Multiple Sclerosis Foundation
National Association of ProLife Nurses (NAPN)
National Coalition for LGBTQ Health
National Fabry Disease Foundation
National Hispanic Council on Aging
Partnership to Improve Patient Care
Patients' Rights Action Fund
RASopathies Network
South Carolina Advocates For Epilepsy
Texas Rare Alliance
The Bonnell Foundation: Living with cystic fibrosis
The Coelho Center for Disability Law, Policy and Innovation
The Headache and Migraine Policy Forum
The Latino Coalition
The National Puerto Rican Chamber of Commerce
United Spinal Association
Cherie Poirier
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Mary Hodges
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Marie Ashby