



November 8, 2023

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

Submitted via Regulations.gov

RE: 0945-AA15 - Discrimination on the Basis of Disability in Health and Human Service Programs or Activities

Dear Secretary Becerra,

Families USA (FUSA) is a leading national voice for health care consumers, dedicated to the achievement of high quality, affordable health care and improved health. For more than 40 years, Families USA has been working to achieve this vision of a nation where the best health and health care are equally accessible and affordable to all. We are very proud of our decades-long partnership with the disability community and appreciate the opportunity to comment on proposed changes to Section 504 of the Rehabilitation Act as it relates to people with disabilities' access to high quality care – in particular on the issue of the use of value assessments.

Drug prices in the United States are higher than in any other peer country, resulting in an affordability crisis for families and individuals.¹ Almost 30% of adults skip or ration doses of their medication and it is known that medication nonadherence results in an estimated 125,000 deaths annually.^{2,3,4} Drug prices in the U.S. are under the control of drug companies that have monopolies on new drugs, limit competition, and charge whatever the market will bear regardless of its impact on consumer affordability and access to the lifesaving and sustaining medications.

To address these high prices, it is imperative that there be available a comprehensive process – one that includes both value assessments and cost effectiveness measures – to determine a fair drug price. Value assessments help set the stage for establishing fair prices by assessing clinical evidence on drug performance. Cost effectiveness analysis, in turn, relies on value assessments to then ensure that drug companies are fairly compensated for the therapeutic value of their product while ensuring a reasonable cost for families and health care systems.⁵ Without cost-effectiveness analysis there is no consistent, evidence-based way to suggest a fair price for drugs across different conditions.

Families USA supports the Department of Health and Human Services (HHS) in its proposal to ban discriminatory applications of the quality adjusted life year (QALY). We urge HHS to explicitly clarify in the final rule that non-discriminatory measures allowing cost-effectiveness analysis using alternative measures that value life extension equally for all patients, such as the equal value of life years gained (evLYG), will be utilized to establish fair compensation for drug makers.

§ 84.57 Value Assessment Methods

The proposed rule prohibits the use of assessment methods that value the extension of life for a non-disabled person over the extension of life for a disabled one when the assessment is used to limit or extend access to aids, benefits, and services. The proposed rule would ban use of QALYs by all branches of HHS and any entity doing business with HHS, outside of narrowly defined research efforts. Importantly, the proposed rule only prohibits the use of those methods that discount the value of life extension for people with a disability, while continuing to allow for the use of other, non-discriminatory, methods such as the equal value of life years gained (evLYG). This measure is used to determine how much a medical treatment can extend the life of a patient exclusively considering the length of life rather than the quality of life for the patient.⁶

Families USA believes measures such as evLYG are critical to ensuring affordable drug prices and must remain available to policymakers to consider. Utilizing accurate and non-discriminatory cost-effectiveness measures when assessing the value of prescription drugs is particularly important given that U.S. drug companies set abusively high drug prices and maintain monopolies on new drugs in order to charge whatever drug prices the market will bear. Research demonstrates that alternatives to QALYs, such as the evLYG, can support essential cost-effectiveness assessments without being discriminatory.^{7,8} As a result, measures that assess length of life rather than the quality of life in cost-effectiveness analysis are essential for establishing fair benchmarks for drug prices and driving higher value health care services and drugs into the health care system.

A drug price that is set abusively high creates significant access concerns, including for people in our nation living with disabilities. The language in the proposed rule must explicitly permit cost-effectiveness assessments and other value assessment measures, like the evLYG, that value life extension equally and are central to ensuring the prices for prescription drugs are fair and accessible to all people, including those living with disabilities.

To provide high value health care and ensure improved health for all we must ensure that any measure being used in health care decision-making is able to accurately capture the people's multifaceted lives, including the lives of people living with disabilities, and does not inadvertently undervalue their lives or experience. We appreciate the opportunity to comment on this proposed rule and important issue. For any additional information or questions contact Hazel Law at hlaw@familiesusa.org.

Sincerely,



Frederick Isasi
Executive Director
Families USA

¹ Kurani, Nisha, Dustin Cotliar, and Cynthia Cox, "How do Prescription Drug Costs in the United States Compare to Other Countries?" Peterson-KFF, Feb 8, 2022, <https://www.healthsystemtracker.org/chart-collection/how-do-prescription-drug-costs-in-the-united-states-compare-to-other-countries/#Prices%20of%20select%20prescription%20drugs%20in%20the%20United%20States%20and%20for%20comparable%20countries,%202017>

² Kirzinger, Ashley, Lunna Lopes, Bryan Wu, and Mollyann Brodie, "KFF Health Tracking Poll - February 2019: Prescription Drugs," KFF, March 1, 2019, <https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>

³ Kirzinger, Ashley, Alex Montero, Grace Sparks, Isabelle Valdes, and Liz Hamel, "Public Opinion on Prescription Drugs and Their Prices," KFF, Aug 21, 2023, <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>

⁴ Bosworth, Hayden, Bradi Granger and et al, "Medication Adherence: A Call for Action," AM Heart, Sep 2011, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3947508/>

⁵ "Cost-Effectiveness, the QALY, and the evLYG," ICER, <https://icer.org/our-approach/methods-process/cost-effectiveness-the-qaly-and-the-evlyg/>

⁶ "Cost-Effectiveness, the QALY, and the evLYG," ICER, <https://icer.org/our-approach/methods-process/cost-effectiveness-the-qaly-and-the-evlyg/>

⁷ Frank, Richard, and Len Nichols, "Threats to Medicare's New Drug Negotiation Power," Brookings, March 15, 2023, <https://www.brookings.edu/articles/threats-to-medicare-s-new-drug-negotiation-power/>

⁸ Sullivan, Sean, Darius Lakdawalla, Beth Devine, and et al, "Alternatives to the QALY for Comparative Effectiveness Research," Health Affairs, April 21, 2023, <https://www.healthaffairs.org/content/forefront/alternatives-qaly-comparative-effectiveness-research>