



November 13, 2023

SUBMITTED ELECTRONICALLY

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
Attn: RIN: 0945-AA15
200 Independence Avenue, SW
Washington, DC 20201

Re: DRRC Comments on Proposed Rule Updating Section 504 Regulations: Discrimination on the Basis of Disability in Health and Human Service Programs or Activities (RIN: 0945-AA15)

Dear Secretary Becerra:

The undersigned members of the Disability & Rehabilitation Research Coalition (DRRC) appreciate the opportunity to provide comments to the U.S. Department of Health and Human Services (HHS) in response to the landmark proposed rule that would update and advance protections for people with disabilities pursuant to Section 504 of the Rehabilitation Act of 1973.¹

The DRRC is a coalition of 26 national research, clinical, and consumer non-profit organizations committed to improving the science of rehabilitation, disability, and independent living. We seek to maximize the return on the federal research investment in these areas, with the goal of improving the ability of Americans with disabilities to live and function as independently as possible following an injury, illness, disability, or chronic condition.

As a coalition advocating for investment in medical research for people with disabilities to improve health and function, we wholeheartedly support the proposed rule's overarching goal of ensuring nondiscrimination in the provision of health programs and activities to improve health care access and improve health outcomes for people with disabilities. We urge HHS to expeditiously finalize this rule to protect the ability of all individuals, whether they are blind, deaf, hard of hearing, or deafblind or have low vision, seizure disorders, limited manual dexterity, speech disabilities, learning disabilities, or cognitive disabilities, to access the health care services they need without fear or impact of discrimination.

¹ *Discrimination on the Basis of Disability in Health and Human Service Programs or Activities*, 88 Fed. Reg. 63,392 (Sept. 14, 2023) (to be codified at 45 CFR 84), <https://www.federalregister.gov/documents/2023/09/14/2023-19149/discrimination-on-the-basis-of-disability-in-health-and-human-service-programs-or-activities>.

Consistent with the DRRC's commitment to improving the science of rehabilitation, disability, and independent living, this comment letter focuses on the proposed rule's prohibition of discriminatory selection criteria for patient participation in clinical research trials that inappropriately exclude people with disabilities to the detriment of those individuals, their communities, and ultimately medical science.

The DRRC supports HHS's recognition in the proposed rule that people with disabilities experience health disparities as a result of unequal access to health care including inappropriate exclusion from clinical research trials. These exclusions can limit the generalizability of research findings and potentially limit access if payers determine coverage with cost and efficacy assessments derived from research studies that excluded persons with disabilities from participation. Additionally, participating in clinical research has enormous potential benefit for individuals that people with disabilities miss by inappropriate exclusions, such as increased access to innovative diagnostic, preventative, or therapeutic interventions and treatments, often when their health is most at risk.

The proposed rule would implement new requirements prohibiting recipients of federal financial assistance from discriminating against people with disabilities in medical treatment decisions including in the selection of participants for clinical research trials. The proposed rule also would prohibit imposing or applying eligibility criteria that screen out individuals with disabilities from fully and equally participating in any program or activity including research.

The proposed rule recognizes the pervasive issue of individuals with disabilities being excluded from participation in clinical trials due to overly broad study exclusion criteria stemming from biases, stereotypes, or misunderstandings about people with disabilities. For people with disabilities, study exclusions can fail to account for the availability of reasonable modifications to a study protocol that would allow more people with disabilities to participate, such as websites that are accessible for screen readers for individuals with low vision or the provision of American Sign Language translators for people who are deaf. We applaud the proposed rule for recognizing that overly broad exclusion criteria that screen out potential participants with disabilities that can be reasonably accommodated or participants with disabilities that are unrelated to the research is discriminatory.

Although frequently explicit in nature, discriminatory decision-making in clinical research can also be grounded in implicit or unconscious bias, which is more difficult to detect and can be hidden behind professional judgment. This reality makes the proposed rule, and its prohibition of discriminatory decisions, critical to ensuring equal access for people with disabilities. In addition to the examples of discrimination in overly broad research criteria, we believe that the final rule would benefit from examples of best practices to mitigate the risk of discriminatory judgments in clinical trials exclusion criteria. We encourage the Department to include such examples in the final rule. The DRRC also wishes to note that enforcement of personal rights requires systematic, accurate, timely, and comprehensive collection, analysis, and public reporting of disability data, including functional disability data for demographic purposes, as recommended by the Consortium for Constituents with Disabilities (CCD).

Ensuring that people with disabilities are included in clinical research is a priority for the DRRC. This proposed rule makes significant strides toward achieving this goal, and the DRRC supports and appreciates HHS's focus on inclusion. We strongly support these proposed protections and urge HHS to

expeditiously finalize this rule to protect the ability of all individuals to access the health care services they need without fear or impact of discrimination.

We appreciate the opportunity to comment on this landmark proposed rule and thank HHS for its continued efforts to enhance communication and prevent discrimination against individuals with disabilities in health care. This proposed rule has the potential to make significant strides toward achieving this goal. Should you have any further questions regarding this letter, please contact DRRC Co-Coordinator at Peter.Thomas@PowersLaw.com or Natalie.Keller@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of DRRC

American Academy of Physical Medicine & Rehabilitation*

American Association on Health and Disability

American Music Therapy Association

American Congress of Rehabilitation Medicine

American Occupational Therapy Association*

American Physical Therapy Association*

American Therapeutic Recreation Association

Amputee Coalition

Association of Academic Physiatrists*

Association of University Centers on Disabilities

Brain Injury Association of America*

National Neurotrauma Society

Rehabilitation Engineering and Assistive Technology Society of North America

Spina Bifida Association

United Spinal Association

Indicates DRRC Coalition Steering Committee Member*