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November 13, 2023

Melanie Fontes Rainer, Director
Office of Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: HHS Proposed Rule Updating Section 504 Regulations: *Discrimination on the Basis of Disability in Health and Human Service Programs or Activities*. Docket No: 2023-19149, RIN: 0945-AA15

Dear Director Fontes Rainer:

The ALS Association appreciates the opportunity to comment on the U.S. Department of Health and Human Services (HHS or Department) Office of Civil Rights' (OCR) proposed rule, *Discrimination on the Basis of Disability in Health and Human Service Programs or Activities*¹ updating Section 504 of the Rehabilitation Act of 1973 ("Section 504").

We strongly support the proposed rule and the updated definition of "disability" and terminology to ensure consistency with the Rehabilitation Act, the Americans with Disabilities Act ("ADA"), the Americans with Disabilities Act Amendments Act of 2008 ("ADAAA"), the Affordable Care Act ("ACA"), and the U.S. Supreme Court's 1999 *Olmstead* decision. We also support the broad application of Section 504 updates to cover all entities that receive federal financial assistance including, Medicare, Medicare Advantage, Medicaid, and advocate for the rule's application for all third-party insurance such as Medicare supplemental insurance (Medigap) plans.

The ALS Association joined and supported comments from several patient focused coalitions such as the Partnership to Improve Patient Care (PIPC), Independence Through Enhancement of Medicare and Medicaid Coalition (ITEM), Coalition to Preserve Rehabilitation (CPR), and the Alliance for Aging Research. We individually and collectively support HHS's objectives to update and clarify existing nondiscrimination requirements, effectively prohibiting discrimination in important federal programs to protect equality in health care including medical treatment, value assessments, medical equipment, and digital domains.

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

Sections of the proposed rule of interest to the ALS community:

- Definition of Disability for Section 504 and that of ALS Disability Status
- Prohibition of Discrimination in Medical Treatment Decisions
- Prohibition of the Discriminatory Use of Value Assessments
- Enforcement of Section 504
- Alignment of Section 1557 with Section 504

Definition of Disability for Section 504 and that of ALS Disability Status:

The ALS Association is fully supportive of HHS's statement in the proposed rule and that of the definition of "disability" be broadly constructed and applied. The updated definition of disability and terminology identifying people with disabilities ensures consistency with current ADA and ADAAA and is meant to ensure a "broad scope of protection" under the Rehabilitation Act. Upon diagnosis of Amyotrophic Lateral Sclerosis (ALS), individuals qualify for Social Security Disability Insurance (SSDI), Medicare, and State Medicaid (if applicable) and should be afforded protections under the law for health care services and access medical equipment and therapies throughout the course of their disease.

We support the Department's goal to ensure the broadest coverage allowable under Section 504 and HHS's phrase within Section 84.68(a) of the proposed rule which states, "No qualified individual with a disability shall, solely on the basis of disability, be excluded from participation in or be denied the benefits of the programs or activities of a recipient or be subject to discrimination by any recipient."²

Prohibition of Discrimination in Medical Treatment Decisions:

The ALS Association fully supports the proposed rule's intent to eliminate discriminatory practices in medical treatment and believe that these changes, once broadly implemented, will significantly improve medical care for individuals with disabilities and provided them with added protections under the law so that they are not deprived of health services or treatments based on prejudice and or lack of provider knowledge. We support the underlying tenet of the proposed Section 84.56(b)(1), that stipulates that medical treatment should not be denied or limited based on misconceptions, stereotypes, or biases about disabilities.

Discriminatory decision-making in health care can also be grounded in implicit or unconscious bias, which is more difficult to detect and can be hidden behind professional judgement. This propose rule and its prohibition of discriminatory treatment decisions is critical to ensuring equal access to medical care for people with disabilities. We appreciate the broad application of this proposed rule to clarify that denying any medical treatment on the basis of disability if the treatment would be provided to a similarly situated patient without a disability constitutes discrimination on the basis of disability. The proposed rule makes significant strides towards achieving protections on the basis of disability and we appreciate the Department's focus in this important area.

² See 88:177 Fed. Reg. at 63505

Prohibition of the Discriminatory Use of Value Assessments:

We fully support the proposed rule's intentions to address discrimination on the basis of disability in the use of value assessments that have been well documented to limit access to treatments for people living with disabilities. We agree with the position of the National Council on Disabilities' (NCD) which determined that the use of Quality-Adjusted Life Year (QALY) measures in cost effective analysis is discriminatory for people with disabilities.³ We agree the use of QALYs and similar metrics violate protections afforded by Section 504 by placing a lower value on the life of an individual living with ALS.

We emphatically disagree with the use of QALYs in public programs and disagree with the findings of reports by the Institute for Clinical and Economic Review (ICER) because of their use of QALY value assessment methods that discriminate based on disability and fail to accurately reflect cost and quality of life factors that matter to patients and their families. We are supportive of the effort to expand the Affordable Care Act's (ACA) ban on the use of quality adjusted life year and similarly flawed Equal Value of Life-Years Gained (evLYG) to discriminate against people with disabilities by placing a lower value on their lives.

There are consequences beyond ensuring health and wellbeing since the use of discriminatory value assessments in health care also has economic consequences such as passing on the high out-of-pocket costs to vulnerable patient populations. Therefore, we are highly supportive of the proposed rule's broad application to focus on any measure, assessment, or tool that discounts the value of life or quality of life based on disability.

We advocate that HHS establish an ongoing process to review clinical quality measures for bias against people with disabilities and ensure that there are opportunities for engagement with patient advocate organizations when considering a patient-defined definition of value. We consider it important for HHS to document and provide examples of incidents of the discriminatory use of value assessment methods to illustrate the inappropriate use and application of measures so that both providers and payers are notified of biased practices (e.g., placing a lower value on life-extension for a group of individuals is an inappropriate use of a clinical quality measure).

Although the proposed rule stipulates that not all value assessments or their use are discriminatory, we challenge the Department to continue to question whether value assessment or the calculation value of life years is discriminatory to individuals with disabilities. We are especially concerned if the use of these methodologies undermines access to treatments, services, and durable medical equipment that is critical to providing high quality care and maintaining quality of life.

We recommend OCR use its full authority under Section 504 to prohibit discrimination in any use of value assessment methodologies. We also recommend that HHS utilize its oversight and authorities to broadly advance policies to promote health equity and prohibit discrimination based on disability in utilization management, such as in formulary design, therapy price negotiations, alternative payment models, and other coverage for evidence development decisions involving access to health care. Lastly,

³ National Council on Disability, Quality-Adjusted Life Years and the Devaluation of Life with Disability (Nov. 6, 2019), https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.

we recommend timely and comprehensive patient-centered data collection methods and patient preferences in value-based measures.

Enforcement of Section 504:

We strongly support the Department's proposition in the proposed rule that standards for civil rights apply to all situations where people with disabilities receive or are eligible for health care and that Section 504 applies broadly to Medicare, Medicare Advantage, Medicaid, and any other federal or state program or activity receiving federal financial assistance for health care. We recommend that the Department clarify the full spectrum of entities that receive federal funding in health care so that patients are well informed of the entities that should be compliant with Section 504's nondiscrimination provisions.

While enforcement of Section 504 is complaint driven, we caution against the reliance on complaints alone to enforce these important civil rights protections. To adequately enforce civil rights protections, we advocated that OCR work to reduce the burden of filing complaints and improve communication with people with disabilities. We recommend the prioritization and strengthening of enforcement mechanisms, that legal resources to file complaints are made broadly available to individuals with disabilities, and that the Department track evidence of the reduction of incidents of health discrimination of people with disabilities. We also recommend that OCR be adequately funded and staffed to fully implement and enforce Section 504's civil rights protections.

Alignment of Section 1557 with Section 504:

In conjunction with the stated goal to align Section 504 with ACA disability laws, we recommend the Department publish the updated final rules pertaining to Section 1557 of the Affordable Care Act (ACA) forthwith. Since the currently proposed rule is intended to update and clarify the operation of Section 504 considering key legislation, case law, and regulations, we urge OCR to clarify in this proposed rule how Section 504 and Section 1557 would work in unison to protect people with disabilities from health disparities.

The ALS Association:

Established in 1985, The ALS Association is the only national nonprofit organization fighting ALS on every front. By leading the way in global research, coordinating multidisciplinary care through certified clinical care centers, and fostering government partnerships, our mission is to build hope and enhance quality of life while aggressively searching for new treatments and a cure for ALS. The ALS Association is committed to ensuring all people with ALS have equitable access to health care services to enhance their health and wellbeing and improve the quality of their life. Until ALS is cured, our goal is to make ALS a livable disease for all.

Delivering effective treatments and a cure to people affected by ALS will take the commitment and compassion of all people and federal and state government partners collaborating with urgency across geographic, socio-economic, cultural, and ideological boundaries. Therefore, The ALS Association is dedicated to cultivating an inclusive environment in which patient and caregiver voices are raised and heard as we serve, engage, advocate for, and empower people with ALS to live full and active lives. We are committed to maintaining a community that resolves inequities that impede progress in the fight

against ALS and ensures that our mission-driven work is informed by multiple perspectives and experiences.

About ALS:

Amyotrophic Lateral Sclerosis is a neurodegenerative disease that can affect anyone, at any time. ALS destroys nerve cells in the brain and spinal cord, causing the loss of muscle control throughout the body in which people with ALS become prisoners within their own bodies, unable to eat, breathe, or move on their own. Their minds, however, often remain sharp so they are aware of what is happening to them. There is no cure for ALS, and most people with the disease die within 2 – 5 years of diagnosis. Although the disease can strike at any age, symptoms most commonly develop between the ages of 55 and 75.

ALS often commences with muscle twitching and weakness. The weakness slowly spreads to both arms and both legs as the motor neurons slowly die and stop sending signals to the muscles which results in the loss of the use of a limb and slurred speech. Eventually, ALS affects major muscles essential to move, speak, eat, and breathe.

As the disease progresses, a person with ALS requires more support for activities of daily living. In addition to multidisciplinary specialty services provided by physicians and clinicians, people living with ALS require skilled (nursing and allied health professional) and non-skilled (activities of daily living) care services provided by paid providers and family caregivers. A person living with ALS often requires access to durable medical equipment to manage their conditions such as complex power wheelchair systems, ventilators, speech generating devices, and other assistive communication technologies to assist people with ALS and their family member or caregiver to communicate.

Conclusion:

The ALS Association appreciates HHS's proposal to provide uniform protections for people with disabilities in the American health care system. We urge the Department and OCR to finalize the proposed rule quickly to protect access to care and alleviate the fear of discrimination for people living with ALS. Our community stands ready to assist HHS in any way possible to secure equitable access to health care services, therapies, and medical equipment the enhance quality of life and make ALS a livable disease.

Please contact Rich Brennan, Vice President of Federal Affairs, rich.brennan@als.org with any questions.

Sincerely,

A handwritten signature in black ink that reads "Melanie Lendnal". The signature is written in a cursive, flowing style.

Melanie Lendnal, Esq.
Senior Vice President, Policy & Advocacy
The ALS Association