October 3, 2022

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

Melanie Fontes Rainer
Director, Office for Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Nondiscrimination in Health Programs and Activities Proposed Rule [HHS-OS-2022-0012; RIN 0945-AA17]

Dear Director Fontes Rainer:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition appreciate the opportunity to provide comments on the Office of Civil Rights' (OCR) proposed rule on Section 1557 of the Affordable Care Act (ACA) regarding nondiscrimination in health programs and activities. The ITEM Coalition is a national consumer- and clinician-led coalition advocating for access to and coverage of assistive devices and technologies for persons with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including such conditions as paralysis, spinal cord injury, ALS, multiple sclerosis, hearing and speech impairments, visual impairments, cerebral palsy, stroke, brain injury, spina bifida, limb loss, and other life-altering conditions.

Given the ITEM Coalition's scope, these comments are limited to the provisions in the proposed rule regarding devices used in the health care setting by individuals with disabilities. However, we strongly support the overarching goal of ensuring nondiscrimination in the provision of health programs and activities, and many of the undersigned members also plan to offer comments either individually or through other coalitions in response to the full scope of the proposed rule. We urge OCR to finalize this rule quickly to continue to protect the ability of all individuals to access the health care services they need without fear of discrimination.

Ensuring the Availability of Accessible Medical Diagnostic Equipment

OCR briefly notes a request for comment regarding accessibility of medical diagnostic equipment (MDE). Specifically, OCR seeks comment on whether existing standards developed by the U.S. Access Board on accessible MDE should be incorporated as an enforceable standard for covered entities under Section 1557, and whether lack of access to accessible MDE constitutes discriminatory benefit design or network inadequacy.

Accessibility of medical equipment has been a longstanding priority of the ITEM Coalition, and we thank OCR for including this issue in the proposed rule. In previous communications with the

Department, the ITEM Coalition and other stakeholders, including the National Council on Disability, have noted that millions of Americans with disabilities encounter serious barriers to accessing medical care when equipment, especially diagnostic equipment, is not accessible to them. In particular, items such as examination tables and chairs, weight scales, mammography machines, MRI machines, imaging equipment, and more are often unusable by people with certain disabilities. Oftentimes, patients with disabilities are refused treatment or are unable to undergo necessary parts of their examination due to inaccessibility and the failure to provide reasonable accommodations, such as a safe transfer or the concurrent use of a ventilator, to ensure these patients can access the care they need.

This can result in undiagnosed and untreated conditions, not to mention inconvenience, burden, and humiliation when people cannot receive care in a provider's office or other health care setting. Further, the increased use of at-home diagnostic tools, such as blood pressure monitors, thermometers, pulse oximeters, glucose monitors, and others has underscored the need for such equipment to be accessible to and usable by people with disabilities. As one example, blind individuals or persons with learning disabilities cannot be expected to read the solely visible output of such devices during a telehealth visit.

As obliquely referenced in the proposed rule, the Affordable Care Act[1] directed the United States Access Board (the Access Board) to develop formal technical standards for accessible medical diagnostic equipment, which were issued after a thorough consensus development process in 2017.[2] However, these standards were not further adopted into regulation by an enforcement authority such as OCR or the Department of Justice (DOJ), and thus have had little impact on providers. Individuals frequently continue to encounter inaccessible MDE when they seek medical care, striking examples of which can be found in the NCD report citied in the proposed rule.[3] Accessible medical equipment is available; reasonable accommodations can be made in instances where providing accessible equipment would present an undue burden. However, the proliferation of inaccessible equipment persists, resulting in a clear discriminatory impact on individuals with disabilities.

DOJ had considered rulemaking on this topic itself in 2010, prior to the issuance of the Access Board standards, but these efforts did not progress and were in fact withdrawn entirely in 2017. In 2016, when OCR issued the first iteration of the Section 1557 regulations, OCR deferred proposing accessibility standards specifically because the Access Board standards were still under development. As the NCD has noted, meaningful systemic improvements in the availability of accessible MDE will not be achieved without specific enforceable standards. Such standards already exist for people with physical disabilities. ***We strongly encourage OCR to incorporate these standards as a requirement for entities covered under Section 1557, and to standardize these requirements across other areas of the Department's regulatory scope (in particular, the forthcoming update to regulations implementing Section 504 of the Rehabilitation Act).***

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[1] Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 510 (codified at 29 U.S.C. 794f).
[2] Standards for Accessible Medical Diagnostics Equipment, 82 Fed. Reg. 2810 (January 9, 2017).
[3] Nat'l Council on Disability, Enforceable Accessible Medical Equipment Standards: A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities (2021), https://ncd.gov/sites/default/files/Documents/NCD_Medical_Equipment_Report_508.pdf.

The adoption of these already developed standards is a key first step to ensuring that covered entities do not discriminate in the provision of their health programs and activities with regards to medical equipment. Making these standards enforceable would meaningfully decrease barriers to access for individuals with mobility, balance, strength, and respiratory impairments. However, to truly ensure nondiscrimination, equipment must be made accessible across the disability population. We urge OCR to consider additional medical equipment accessibility standards to account for the needs of individuals with visual, sensory, and other functional limitations. Finally, we note that the Access Board standards are limited (by legislative design) to a relatively narrow category of diagnostic equipment used primarily in physician's offices or hospitals.

We urge OCR to ensure that the Section 1557 regulations (as well as other similar regulations currently under review) consider the full range of medical equipment that must be made accessible, including at-home diagnostic tools, telehealth equipment, and other equipment frequently used in the health care setting. The development of such additional standards should not delay the adoption of the existing Access Board standards, which have been widely available for years and now must be made enforceable to ensure meaningful access to health programs and activities covered under Section 1557.

Accessibility of Information and Communication Technology for Individuals with Disabilities

OCR also seeks comment on several proposals relating to accessibility of information and communication technology (ICT) for people with disabilities. The current iteration of the Section 1557 regulations require covered entities to ensure that "their health programs and activities provided through ICT are accessible to individuals with disabilities," a requirement that OCR proposes to maintain with redesignation. Covered entities under Section 1557 are thus already required to provide accessible ICT unless such provision would result in undue burden or a fundamental alteration of their programs (in such cases, covered entities must then provide reasonable accommodations to ensure that individuals with disabilities can receive the benefits of the program or activity to the maximum extent possible). OCR also proposes to apply these existing requirements applicable to websites to mobile applications as well.

As noted in the prior section, the health care sector is facing an increasing reliance on ICT to provide critical health services. The COVID-19 pandemic led to a dramatic increase in the use of telehealth services, as well as other remote patient monitoring systems that may require input or operation by the patient in their home. Further, the patient experience in health care settings now involves the use of a wide range of ICT, such as electronic forms, check-in and billing kiosks, patient portals, and other tools that are frequently inaccessible to individuals with a wide range of disabilities. Despite the requirements to ensure that ICT is accessible, many covered entities fail to offer accessible health care ICT, resulting in significant harm to individuals who are unable to utilize the health care services to which they are entitled.

One of the major drivers of this inaccessibility is the lack of clarity as to what accessibility actually entails. The existing Section 1557 regulations (as well as broader accessibility mandates such as the Americans with Disabilities Act, its implementing regulations, and those governing Section 504 of the Rehabilitation Act) ***do not*** currently include specific technical standards for accessibility. OCR notes in the proposed rule that some covered entities "are currently relying on

Section 508 standards promulgated by the Access Board or Web Content Accessibility Guidelines (WCAG) to ensure that their ICT is accessible," but this is by no means uniform across covered entities. OCR now seeks comment on whether the Section 1557 rule should include a requirement to comply with specific technical standards.

The inaccessibility of ICT used in the health care setting provides as much of a barrier to equal access to health care services as does a doctor's office without a wheelchair ramp, an exam table that cannot accommodate individuals with mobility impairments or providing medical information without access to American Sign Language or braille. When a blind individual is handed an electronic tablet to check in for their appointment, detail any symptoms, or submit billing information, for example, they are prevented from equally benefiting from health care services. Requiring covered entities to comply with specific standards for ICT accessibility would help ensure that individuals do not face such discriminatory barriers.

We urge OCR to include specific, clear, and enforceable ICT accessibility and usability standards in the Section 1557 regulations that align with widely accepted standards that already exist for other entities, such as the Access Board's Section 508 standards and the international Web Content Accessibility Guidelines (WCAG) 2.1 Levels A and AA. As the proposed rule references, these standards, developed by the international standards body the Worldwide Web Consortium (W3C), are regularly evolving through an expert stakeholder development and consensus process. We encourage OCR to develop regulatory language clarifying that compliance should relate to the currently accepted version of WCAG as well as successor standards as they are finalized and published. Further, we encourage OCR to ensure that the regulations continue to make clear that ICT encompasses not only websites, but mobile applications, online systems, and other forms of ICT – all of which should be made accessible to individuals with disabilities. Lastly, if and when OCR finalizes these regulations, we urge OCR to establish and communicate to covered entities clear consequences for failures to comply with and implement these accessibility requirements.

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We appreciate your consideration of these comments. Should you have any further questions regarding this letter, please contact the ITEM Coalition coordinators at Peter.Thomas@PowersLaw.com and Joseph.Nahra@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready
The ALS Association *
American Association for Homecare
American Association on Health and Disability
American Cochlear Implant Alliance
American Congress of Rehabilitation Medicine

American Council of the Blind
American Medical Rehabilitation Providers Association
American Music Therapy Association
American Occupational Therapy Association
American Physical Therapy Association
American Speech-Language-Hearing Association
American Therapeutic Recreation Association
Amputee Coalition *
Association of Rehabilitation Nurses
Blinded Veterans Association
Christopher & Dana Reeve Foundation *
Cure SMA
Easterseals
Epilepsy Foundation
Hearing Loss Association of America
Lakeshore Foundation
Long Island Center for Independent Living
Miami Project to Cure Paralysis
Muscular Dystrophy Association
National Association for the Advancement of Orthotics and Prosthetics
National Association of Councils on Developmental Disabilities
National Association of Rehabilitation Providers and Agencies
National Association of Rehabilitation Research and Training Centers
National Coalition for Assistive and Rehab Technology
National Disability Rights Network (NDRN)
National Registry of Rehabilitation Technology Suppliers
National Respite Coalition
Paralyzed Veterans of America *
Prevent Blindness
Rehabilitation Engineering and Assistive Technology Society of North America
The Simon Foundation for Continence
Spina Bifida Association *
Team Gleason *
United Spinal Association *

**** ITEM Coalition Steering Committee Member***