October 2, 2022

U.S. Department of Health and Human Services,
Office for Civil Rights
Attention: 1557 NPRM (RIN 0945-AA17),
Hubert H. Humphrey Building, Room 509F,
200 Independence Avenue SW.,
Washington, DC 20201.

Submitted at https://www.regulations.gov

Re: Docket No. RIN 0945-AA17
Nondiscrimination in Health Programs and Activities Proposed Rule Section 1557 of the Affordable Care Act

To the Office for Civil Rights,

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) appreciates the opportunity to comment on the request of the Office for Civil Rights (OCR) for input on its proposed rule, “Nondiscrimination in health programs and activities proposed rule Section 1557 of the Affordable Care Act,” published in the Federal Register. It is a timely and important proposed Rule. We offer these comments in support of the proposed Rule and offer suggestions to strengthen and extend it.

The MRCT Center is a research and policy center that addresses the ethics, conduct, oversight, and regulatory environment of international, multi-site clinical trials. Founded in 2009, it functions as an independent convener to engage diverse stakeholders from industry, academia, patients and patient advocacy groups, non-profit organizations, and global regulatory agencies. The MRCT Center focuses on pre-competitive issues, to identify challenges and to deliver ethical, actionable, and practical solutions for the global clinical trial enterprise. In addition to other initiatives, over the last six years, the MRCT Center has been intimately involved in advancing diversity, equity, and inclusion (DEI) in clinical trials, and more generally, in clinical research. We have worked with multiple international and national agencies, and in the US, including OCR, NIH, FDA, and OHRP, but please note that we have not discussed the comments provided herein with anyone at those agencies. The responsibility for the content of this document rests with the leadership of the MRCT Center, not with its collaborators nor with the institutions with which its authors are affiliated.

Particularly in this time of heightened awareness of structural and systemic prejudices and health inequities, the proposed rule underscores the importance of nondiscrimination and particularly protection from nondiscrimination in access to and benefit from health programs and activities. The proposed Rule clarifies and strengthens the commitment of OCR, HHS, and the administration to nondiscrimination. The MRCT center applauds OCR’s proposed Rule.

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1 Brigham and Women’s Hospital, Harvard Medical School, and Harvard University.
The direct attention to nondiscrimination on the basis of sex, limited English proficient (LEP) individuals, and people with disabilities, and the clarification of the specific measures that are anticipated to comply with Section 1557 are welcome. Specifically, we support the major clarifications in the rule:

- The interpretation of Section 1557 to cover all health programs and activities administered by HHS
- The interpretation that provision of Medicare Part B assistance is federal financial assistance, and that entities receiving Medicare Part B funds must comply with the Rule
- The application to health insurance issuers that receive federal financial assistance
- The clarification that the protections against discrimination on the basis of sex as including sexual orientation and gender identity, and discrimination on the basis of sex stereotypes, and the extension of these protections to CMS regulations
- The expectation that compliance will require implementing programs to develop, maintain, and communicate clear policies, and train on, the provision of language assistance services for limited English proficient (LEP) individuals, and effective communication and reasonable modifications to policies and procedures for people with disabilities.
- The requirement that implementing entities provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states.
- The expectation of nondiscrimination based on clinical algorithms
- The expectation that nondiscrimination extends to telehealth services, and
- The development of clear processes for requesting exceptions from the expectation of compliance.

In the context of strong support for the Rule as proposed by OCR, we offer several additional comments for consideration.

1. **Clarity that Nondiscrimination in Health Programs and Activities includes access to participation in clinical research**

The definition of “Health program or activity” does not currently clarify that access to participation in clinical research is an activity that would be subject to nondiscrimination. The current definition states:

§ 92.4 Definitions.

*Health program or activity* means:

1. Any project, enterprise, venture, or undertaking to…

   (iv) Engage in health research…

   and

2. All of the operations of any entity principally engaged in the provision or administration of any health projects, enterprises, ventures, or undertakings described in paragraph (1) of this definition, including, but not limited to, a State or local health agency, hospital, health clinic, health insurance issuer, physician's practice, pharmacy, community-based health care provider, nursing facility, residential or community-based treatment facility, or other similar entity or combination thereof.

In our opinion, it would be preferable to change the bullet to “Engage in health or *clinical* research” for clarity, and, in the list of entities, to include “clinical trial sites including wherever potential clinical trial participants are screened or recruited,” for absence of doubt. The fact that there is a long list, if
non-exhaustive list, of entities that does not currently include mention of clinical trial sites may imply that these sites are not included and/or that clinical research was not intended to be included.

In the context of advocating for a change in definition, we note that “access to clinical research” does not imply the expectation of enrollment into a research protocol or trial but rather the expectation that the individual is not precluded from consideration for reasons of discrimination.² Practically, this clarification would imply that inclusion or exclusion criteria are justified based on scientific, medical, or ethical considerations; language assistance provided where necessary; removal of architectural, communication, or transportation barriers; and other modifications or accommodations provided, as necessary.

The MRCT Center fully appreciates that the proposed Rule makes clear that reasonable modifications are an expectation, and we applaud the focus on practical action. We think it would be helpful to include examples of reasonable modifications in clinical research, in part to amplify the expectation that non-discrimination applies to access to participation in clinical research and to the conduct of research if people potentially subject to discrimination are enrolled in the research. We suggest that one practical example would be in the explicit mention of supported decision-making.³ Supported decision-making, unlike reliance on a guardian or legally authorized representative, is a process that enables individuals with impaired decision-making ability to retain autonomy and choose designated supporters, such as family members or friends, to help them make informed choices concordant with their values and wishes.⁴

2. Change in the definition of limited English proficient (LEP) individual

The definition of LEP individuals states:

§ 92.4 Definitions.

A limited English proficient individual means an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English. A limited English proficient individual may be competent in English for certain types of communication (e.g., speaking or understanding), but still be limited English proficient for other purposes (e.g., reading or writing).

While the MRCT Center agrees in large part with this definition, we feel strongly that the word “and” in the definition should be revised to read “or.” Specifically, we propose:

A limited English proficient individual means an individual whose primary language for communication is not English or who has a limited ability to read, write, speak, or understand English. A limited English proficient individual may be competent in English for certain types

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⁴ Silverman BC, Ne’eman A, Strauss DH, DeCormier Plosky W, Francis L, Stein MA, Bierer BE. Supported decision-making can advance clinical research participation for people with disabilities. Nature Medicine, in press.
of communication (e.g., speaking or understanding), but still be limited English proficient for other purposes (e.g., reading or writing).

There are many people in the United States whose primary language is English but who have a limited ability to read, write, speak, or understand English, for reasons that may or may not be related to disability, who deserve protection from discrimination. Only by replacing the word “and” with “or” will such protections be ensured.

3. **Change the expected duration for record retention of grievances that have been filed with an entity from calendar years from the date of “filing” to calendar years from the date of “resolution.”**

Section § 92.7 *Designation and responsibilities of a Section 1557 Coordinator, section (c 2) Grievance procedures*, states that:

(2) A covered entity to which this paragraph applies must retain records related to grievances filed with it that allege discrimination on the basis of race, color, national origin, sex, age, or disability for no less than three (3) calendar years from the date of the filing of the grievance.

The MRCT Center strongly advocates that the expectation of record retention be changed to no less than three (3) calendar years from the date of resolution of the grievance. It is entirely too easy for a covered entity to extend investigation and delay resolution such that the suggested record retention period expires, leaving little documentation to review or upon which to rely.

Specifically, we propose that the paragraph reads:

(2) A covered entity to which this paragraph applies must retain records related to grievances filed with it that allege discrimination on the basis of race, color, national origin, sex, age, or disability for no less than three (3) calendar years from the date of the **resolution** of the grievance.

4. **Clarify that Section § 92.11 Notice of availability of language assistance services and auxiliary aids and services, applies to participation in clinical research.**

Specifically, section § 92.11 (c) (5) (vii) should be revised to read:

Consen forms and instructions related to medical procedures or operations, **clinical research participation**, medical power of attorney, or living will (with an option of providing only one notice for all documents bundled together);

Currently, clinical research commonly excludes people with limited English proficiency from clinical trials, without explanation or justification, resulting in discrimination.⁵

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5. **Considerations regarding Accessible medical diagnostic equipment**

The MRCT Center endorses the expectation that covered entities have accessible medical diagnostic equipment available and that it is an enforceable standard. In the absence of such diagnostic equipment, how can appropriate and nondiscriminatory medical care be provided?

We wish to provide three further comments for consideration:

a. It is unclear why the Rule limits the expected standard to diagnostic equipment, rather than the more general expectation of medical equipment, including therapeutic (and preventive) in addition to diagnostic equipment. We suggest deleting the word “diagnostic” and clarifying the intention that accessible medical equipment should be available and an enforceable expectation.

b. As is clear to OCR, there are two meanings of the word accessible. First, that the piece of equipment is in a physical location that is accessible to people with disabilities (see (c) that follows). The second is that the piece of equipment is accessible in its design (e.g., the example of screening mammography scans designed such that they do not require the patient to stand). Clarification that both interpretations of accessibility are embodied by the Rule would be beneficial. For purposes of clarity, additional examples would also be helpful.

c. It is true that many types of highly specialized medical equipment exist, and that it may be an unreasonable expectation that every covered entity be expected to have every piece of equipment on site. We believe it would be sufficient for the covered entity to have such access to specialized medical equipment if and only if the covered entity provides access (e.g., transportation) to the specialized medical equipment and only if the delay in provision would not negatively influence the health outcome.

In guidance that follows the publication of the Rule, we advocate that OCR publish guidelines to help covered entities determine which diagnostic, therapeutic, and other medical equipment be maintained on site, and which can be available through other means (e.g., contracted entities or services). Such considerations might be related to anticipated frequency of use, risk of delay in access, severity of the condition, and other variables. Further, we suggest OCR address when access to medical equipment in the health “network” is sufficient and when local availability is required.

6. The MRCT Center supports the inclusion in Section 1557 of a provision requiring covered entities to comply with accessibility standards for web content, and we advocate that the most recent edition of the selected, published standard is adopted. While we are familiar with Web Content Accessibility Guidelines and the WCAG 2.1 standards (which are the prevailing standards and noted, for example, by the Department of Justice in its guidance), we defer to others that have greater expertise as to the options. Whatever standard is chosen, regardless of whether the standard is set in the Rule or by guidance, OCR should require covered entities comply with the most recent standard available, with the minimum timeline for adoption, and no greater than a year. Shorter timelines might be appropriate depending on the complexity of the updates in the future and can be decided at the time.

We also suggest that the Rule be specific in requiring compliance with accessibility standards for web content for all languages in which the provider is providing language assistance services and auxiliary aids.

We suggest that in addition to accessibility standards for web content, that the Rule require health literacy standards at the 6th grade level or lower (easy read) to help people with intellectual
disability be able to understand the information. This will also assist in translation and interpreter services.

In addition to the specific comments above, we have several additional comments and suggestions.

1. A number of specific expectations of covered entities enumerated in the revised Rule extend to the training, role, and function of “employee[s].” The MRCT Center suggests that the definition of employee be extended to include contractors, service providers, sponsored staff, and other designees of the covered entity. In the absence of this clarification, one that can be accomplished by definition or reference, the covered entity can escape many of its obligations under the Rule.

2. Following issuance of the revised Rule, further guidance is necessary for implementation of nondiscrimination in the use of clinical algorithms in decision-making. The MRCT Center fully supports section § 92.210 Nondiscrimination in the use of clinical algorithms in decision-making, that states:

   A covered entity must not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities through the use of clinical algorithms in its decision-making.

   However, understanding discrimination in the context of the artificial intelligence (AI) and machine learning (ML) that often inform clinical algorithms in decision-making is arcane and complex. Data sources that are used in AI/ML are often not representative of the general population nor of those affected by the condition. In the development of AI/ML algorithms, one dataset is often divided into two: a training dataset and a validation dataset that “validates” functionality, utility, and predictive validity. That practice, however, fails to expose any limitations in the representativeness or inclusion of diverse groups, often subject to discrimination, of the original dataset. In addition to the lack of representation, the data are often impacted by bias (e.g., clinician bias in diagnosis and/or treatment decisions.) The negative consequences have been well documented but the approach to correction has not. We advocate that OCR develop guidance in how to identify and prevent discrimination in the development, testing, and validation of clinical algorithms and to establish standards upon which the regulated community can rely.

3. A specific issue that warrants immediate correction is discrimination relating to the algorithm bias embedded in the crisis standards of care and other accepted algorithms. Specifically, the value assessment of quality-adjusted life-year (QALY), a single measure that combines the quality and quantity of life lived and often used in economic evaluations, discounts for disability, embedding discrimination in this commonly used measure. Payers currently determine cost-effectiveness of a medical intervention based on QALYs (compounded by the lack of data from trials that have not been appropriately inclusive of people with disabilities), thus excluding people with disabilities from appropriate care and treatment. The Rule should prohibit the use of and reliance of QALYs and similar measures that may subjectively discount the value of lives lived with disability.

   A similarly structured argument can be made against the use of disability-adjusted life years (DALYs). The DALY burden for a particular condition is the sum of YLL years of life lost (YLL) due to premature mortality added to the years lost to disability (YLD). The Rule should
prohibit the use of and reliance of DALYs that may subjectively discount the value of lives lived with disability.

4. The MRCT Center suggests that OCR clarify that health benefits should not be compromised by complying with the integration mandate of Title II of the ADA. The same coverage, for example, of home health services should be provided for people cared for in institutions, living in congregate structures, or living in community-based settings.

5. We suggest that either the preamble to the Rule, the Rule, or accompanying guidance give further examples of discrimination on the basis of disability. Specific illustrations will be helpful.

6. The MRCT Center strongly endorses the position that the revised Rule clarifying Section 1557 should establish that one standard of nondiscrimination applies, and that standard is the most protective of those who have been or are subject to discrimination on the bases of race, color, national origin, disability, age, or sex. It should clarify that one standard exists for health care for all categories, and no expectation that one disadvantaged group is afforded preference or rights above another. That disparate impact, beyond and inclusive of disparate treatment, is discrimination should be the single applicable standard. In addition, the Rule should clarify that reasonable accommodations are an expectation and must be provided to demonstrate compliance with the Rule.

Thank you again for the opportunity to comment on these important issues. OCR has taken a strong position in the protections from nondiscrimination, and we welcome the additional clarifications. The guidance and specificity of the Rule represent important advances.

We are available to discuss our comments with you if that would be helpful and would be happy to work with you on any of the aforementioned items. Please feel free to contact us at the MRCT Center at bbierer@bwh.harvard.edu, wdecormierplosky@bwh.harvard.edu, or sawhite@bwh.harvard.edu.

Respectfully submitted,

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