October 3, 2022

U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue Southwest
Washington, District of Columbia 20201

Dear Ms. De Kervor:

We represent a diverse coalition of stakeholders that span the healthcare and technology sectors, all of whom support the expanded use of connected health technologies in healthcare. Evidence demonstrates that digital health improves patient care, reduces hospitalizations, helps avoid complications, and improves patient engagement. We write in response to the Department of Health and Human Services' (HHS) proposed rule on Section 1557 of the Affordable Care Act (ACA), and specifically its proposal to update § 92.210 to "make explicit that covered entities are prohibited from discriminating through the use of clinical algorithms on the basis of race, color, national origin, sex, age, or disability under Section 1557."[1]

Leveraging the wide range of datasets, including patient-generated health data, with artificial intelligence (AI) tools holds incredible promise for equitably advancing value-based care in research, health administration and operations, population health, practice delivery improvement, and direct clinical care. To achieve this potential, government policies must be put in place to support building infrastructure and preparing and training personnel, as well as developing, testing, validating, and maintaining AI systems to ensure value. AI tools are also critical in meeting the Administration's priorities, such as reducing disparities.

We appreciate HHS' efforts to date to responsibly bring the benefits of AI to patients in a way that will advance health equities and benefit all providers and patients. For example, the Centers for Medicare and Medicaid Services has taken a number of important steps to make AI's benefits available to more caregivers and patients, including updating its Medicare Physician Fee Schedule rules to provide national payment rates for AI's responsible use in addressing specific use cases, such as in diabetic retinopathy; and integrating AI into value-based care, specifically in various Quality Payment Program Merit-based Incentive Payment System quality measures.

In its proposed rule, HHS proposes to make explicit that covered entities are prohibited from discriminating through the use of clinical algorithms on the basis of race, color, national origin, sex, age, or disability under Section 1557, and requests input on the appropriate scope and specificity of such a requirement. While we share HHS' goal of advancing the use of beneficial algorithms by covered entities, share concerns with potential discriminatory outcomes resulting from the use of health AI tools and services, and further support the intent of the 1557 rule as a whole, HHS' proposal target AI in its rules raises numerous concerns:

- HHS' evaluation of various use cases demonstrating its concerns with health AI-related discriminatory outcomes does not adequately differentiate root causes for the outcomes it then seeks to avoid.

[1] 87 FR 47884.

- HHS' proposal to explicitly address an emerging technology area (AI) raises the risk of technology terms and capabilities evolving more quickly than regulations can be updated.
- Our community is working to develop a consensus standard on how to validate that biases are being identified and appropriately mitigated, and to establish an adequate infrastructure of test beds for making such standards operational. For example, providers, technology developers, governments, and others continue to address how to make AI data sets appropriately representative of the populations/communities AI tools are intended to serve and benefit.
- HHS' proposal appears to omit that providers rely on a health AI manufacturer's intended uses, whether the AI meets the definition of a medical device or not, and that its proposal would force covered entities to police their own supply chains for AI tools and services, despite realities that would make such efforts impracticable (for example, it is often infeasible to require a covered entity to audit AI and/or the datasets used to train AI they purchase). Further, the additional steps that covered entities would need to take to comply with HHS' proposed requirement are very likely to contribute to providers' already strained workload and further contribute to burnout.
- HHS' proposed rule does not account for the fact that some algorithms are specifically designed to identify and/or consider specific patient characteristics when assisting decision-making (*e.g.*, an algorithm intended to identify certain groups of patients susceptible to a condition or that may benefit from a particular therapy).
- HHS' proposals impacting the use of AI do not adequately consider the role of transparent communication of intended uses and related risks, and of patient consent, with respect to the appropriate use of AI tools and services by covered entities.
- Under HHS' proposal, covered entities could face liability for discriminatory outcomes realized after using an AI tool for some time, presenting a significant incentive to avoid using AI tools altogether, which may not align with health AI-related liability distributions for other risks (*e.g.*, patient safety).
- Machine translation tools are widely relied upon by providers, and serve as a critical tool in providing timely and efficacious care (particularly in the real-time communication context), and continue to be improved upon. HHS proposes to require a covered entity that uses machine translation to have translated materials reviewed by a qualified human translator when the underlying text is critical to the rights, benefits, or meaningful access of an LEP individual; when accuracy is essential; or when the source documents or materials contain complex, non-literal, or technical language. HHS' rationale for such a proposal lacks a sufficient evidence base of machine translation tools being blanket categorized as not fit for purpose and could effectively force any covered entity using machine translation tools to have to further provide for a human translator's review in all circumstances.
- Implementing the proposed 1557 regulations for AI will require significant efforts to build capacity within HHS to appropriately conduct fact-specific analyses of allegations of discrimination, and to work with the covered entity to achieve compliance.

To be clear, we share HHS' concerns about health AI and the impact of harmful biases and are committed to advancing solutions to ensure that such harms are identified and mitigated. Providers, technology developers and vendors, health systems, insurers, and other stakeholders all benefit from understanding the distribution of risk and liability in building, testing, and using healthcare AI tools. We urge HHS to collaborate with all stakeholders to develop and operationalize frameworks that utilize risk-based approaches to align healthcare AI uses with consensus benchmarks for safety, efficacy, and equity, and to ensure the appropriate distribution and mitigation of risk and liability by supporting that those in the value

chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so. HHS' proposed 1557 regulatory updates for AI bias, as drafted, would derail the progress made through public-private partnerships and standardization activities, and significantly disincentivize covered entities use of AI, ultimately robbing patients of the benefits of AI.

As a result, we strongly urge HHS to withdraw its proposal that make explicit that covered entities are prohibited from discriminating through the use of clinical algorithms on the basis of race, color, national origin, sex, age, or disability under Section 1557 at this time. Instead, we urge HHS to:

- Initially, clearly scope and identify its concerns, and categorize root causes and appropriate tests.
- Explore how general 1557 regulatory language already in existence may be relied upon to address its concerns with health AI and discriminatory outcomes in a technology neutral manner.
- Partner with our community to advance standardization and testing efforts that will mitigate AI bias harms, and in contributing to the appropriate distribution and mitigation of risk and liability (*i.e.*, that those in the value chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so).
- Account for communication of use/risk and the role of patients to consent to the use of AI based on those communications.
- Consider the impact of its AI-related proposals on covered entities' practical ability to use AI tools and services, particularly for frontline safety net covered entities with limited resources, as well as the need to reduce provider burnout.
- Conduct further consultation with and outreach to the FDA, NIH, and our community to (1) gain understanding of the state of health AI technologies and deployments, including technical and legal realities of health technology supply chains, (2) ensure that its proposals impacting health AI and liability for discriminatory outcomes do not disincentivize the development and use of beneficial AI tools in healthcare, and (3) avoid misaligning liabilities for health AI-related discriminatory outcomes with the distribution of risks and liabilities related to other risks.
- With respect to machine translation, HHS should recognize that its proposed requirements could result in the widespread abandonment of machine translation tools across covered entities, ultimately harming patient care, increasing healthcare costs, and adding to provider burdens. We strongly urge HHS to consider the wide benefits that machine translation tools provide today across healthcare contexts, particularly in real-time communications, and to clarify that a mandate for review by a human interpreter does not apply to real-time communications (whether in-person or via video); and that compliance analyses will weigh the net impacts of removing machine translation tools from the care continuum entirely in assessing the reasonableness of a covered entity's activities in using such machine translation tools under its proposed factors.
- Examine ways to build HHS' capacity to address AI-related concerns (*e.g.*, training and staffing, enhanced public-private partnership activities, etc.).

We appreciate HHS' consideration of our input on its proposals and encourage thoughtful consideration of our input. As a community, we stand ready to assist further in any way that we can.

Sincerely,

American Board of Quality Assurance and Utilization Review Physicians

American Medical Association

College of Healthcare Information Management Executives

Connected Health Initiative

Digital Therapeutics Alliance

Videra Health