

September 22, 2023

The Honorable Cathy McMorris Rodgers  
Chair  
Committee on Energy and Commerce  
United States House of Representatives  
Washington, District of Columbia 20515

The Honorable Frank Pallone  
Ranking Member  
Committee on Energy and Commerce  
United States House of Representatives  
Washington, District of Columbia 20515

The Honorable Bernie Sanders  
Chairman  
Committee on Health, Education, Labor, and  
Pensions  
Washington, District of Columbia 20510

The Honorable Bill Cassidy  
Ranking Member  
Committee on Health, Education, Labor, and  
Pensions  
Washington, District of Columbia 20510

Dear Chair McMorris Rodgers, Ranking Member Pallone, Chairman Sanders, and Ranking Member Cassidy:

Thank you for your leadership on digital health and telehealth issues in the 118th Congress. Your focus on healthcare innovation has helped ensure that federal law and policy enables the use of digital health tools to provide higher-quality, more cost-effective care. There is much more work to do on this front, and we call your attention to one issue in particular involving the development and use of healthcare tools involving artificial or augmented intelligence (AI) and how the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) is proposing to regulate these technologies.

We represent a diverse coalition of stakeholders that span the healthcare and technology sectors, all of whom support the expanded use of digital health technologies in healthcare. Evidence demonstrates that these innovative digital health tools and services improve patient care, reduce hospitalizations, help avoid complications, and improve patient engagement. We write to share views on the OCR proposed rule under Section 1557 of the Affordable Care Act (ACA), and specifically its proposal to add artificial intelligence-specific provisions to the Section 1557 regulations.<sup>1</sup>

AI tools hold 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 in delivery of and access to healthcare services.

To be clear, we share OCR's 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.

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<sup>1</sup> 87 Fed. Reg. 47884.

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.

While we share OCR's 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 support the intent of the 1557 rule as a whole. However, HHS' proposals targeting AI raise a number of issues relating to scope, the relationship of OCR's proposed AI-specific requirements to the goals of Section 1557, misalignment with the U.S. government's broad priority for scaled approaches to risk mitigation, and, ultimately, the practical impact on existing and developing pro-patient uses of AI across a range of contexts. Accordingly, we have asked OCR to withdraw its technology-specific proposal addressing covered entities' use of algorithms in its 1557 nondiscrimination rules.

To address its concerns, we note that OCR can already address instances of bias and related discriminatory outcomes through the application of its 1557 rules across use cases that may involve new technology capabilities and means, including AI, in a technology-neutral manner to providers' activities that are in scope. Before advancing AI-specific requirements in its 1557 rules, at a minimum, OCR should undertake further consultations and an evaluation of existing and ongoing research and best practices, in collaboration with the broader healthcare 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 disincent 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 issues. As part of this process, OCR should build on and defer to the leading work of other federal actors with deep expertise in AI and bias risk mitigation, such as the Food and Drug Administration, and to leverage these agencies' expertise to build its capacity to address AI-related concerns (*e.g.*, training and staffing, enhanced public-private partnership activities, etc.).

Such a process would enable OCR to partner with our community to advance standardization and testing efforts that will mitigate AI bias harms and contribute to the appropriate distribution and mitigation of risk and liability (*i.e.*, ensuring that those in the value chain with the knowledge and ability to mitigate risks should have the appropriate incentives to do so). Such a consultation would also enable OCR and others to fully understand the effect of its AI-related proposals on covered entities' practical ability to use AI tools and services, particularly those with limited resources, and other priorities such as the need to reduce provider burnout.

We appreciate your consideration of our input on HHS' proposals and encourage thoughtful consideration of these views as the oversight committees with jurisdiction over HHS' 1557 rule. As a community, we stand ready to assist further in any way that we can.

Sincerely,

Accuhealth  
AMC Health  
Cardiac RMS  
CarePICS.com  
College of Healthcare Information Management Executives (CHIME)  
Connected Health Initiative  
Diasyst  
Digital Therapeutics Alliance  
HealthFlow LLC  
Helplinknow.com  
Medical Society of Northern Virginia  
MiCare Path  
Nova Insights  
Otsuka America Pharmaceutical Inc  
Patient Premier, Inc.  
Puretalk.AI  
Quantify Remote Care  
Rockridge Mobile Health, Inc  
TracPatch Health LLC  
VeeOne Health, Inc.