September 28, 2022

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

Re: (RIN Number 0945-AA17) Nondiscrimination in Health Programs and Activities; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing more than 41,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists—appreciates the opportunity to comment on the notice of proposed rulemaking (NPRM) from the Centers for Medicare and Medicaid Services (CMS) and the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) regarding "Nondiscrimination in Health Programs and Activities" in accordance with Section 1557 of the Affordable Care Act (ACA). The ACR is the convener of the Radiology Health Equity Coalition to improve access to equitable radiological care (https://www.radhealthequity.org/).

The following ACR comments focus exclusively on the newly proposed 45 CFR 92.210, "Use of Clinical Algorithms in Decision-Making," which states the following:

> "*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*." (§92.210; 87 FR 47824)

The ACR is aware of the potential for clinical algorithms to inadvertently create or contribute to unintended discrimination on the bases protected by ACA Section 1557 and in the manner broadly described in the proposed §92.210. This is among the reasons why it is always important for clinical algorithms to be medically used exclusively by relevant human experts who are qualified to review the input data without algorithmic assistance, and to disagree with the outputs from the algorithm if necessary. However, the issue is more complex than is reflected by the explanatory language in the NPRM.

Health care artificial intelligence (AI) is in a relatively nascent phase, with researchers and early clinical adopters still learning its benefits and limitations, and with a continuously evolving manufacturing and regulatory oversight paradigm. There are concerns with the unspecified and unlimited notion in the proposed §92.210 that providers "*may be held liable under this provision for their decisions made in reliance on clinical algorithms*." To preserve the potential public health benefits of AI while ensuring that algorithms do not inadvertently contribute to discrimination, ACR urges information sharing and coordination among HHS agencies with regulatory oversight over AI-enabled clinical algorithms.

AI Generalizability Concerns

With respect to information sharing between HHS agencies, the ACR recommends that OCR and CMS engage with the Food and Drug Administration (FDA) to understand limitations designed into certain clinical algorithms

that meet the statutory "medical device" definition and that have been cleared or otherwise authorized for the U.S. market. Specifically, we are concerned that unintended discrimination could result from use of certain AI-enabled software as a medical device (SaMD). Development and/or regulatory decisions outside the direct control of the clinical end-user may result in algorithms not trained, tested, and validated with patient datasets representative of the diverse populations encountered across the many clinical practices in which the algorithm may be used. Many currently marketed AI SaMD are, by inherent development design, not necessarily generalizable across all bases protected by ACA Section 1557.

We illustrate this concern with a specific example in which there is an obvious characteristic of the population that may be different from the training population used to create the algorithm: patient age. Many interpretative radiology AI SaMD—including algorithms for detection, diagnoses, or triage— are not intended for use on pediatric patient populations. Algorithm design choices effectively necessitate downstream differences in patient care workflows and processes for pediatric patients compared to adult patients by clinical end-users of such products. If used on pediatric patients, the provider would risk using the AI SaMD off-label in a manner for which it was not designed by the developer nor reviewed for safety and effectiveness by FDA. Yet, exclusive use of the adult-designed AI SaMD on adult patients could be viewed by OCR as discrimination based on age per the unspecified language in the proposed §92.210.

We can envision similar problems for multisite imaging providers, as populations served across the enterprise may differ by locale, and furthermore, real-world clinical algorithm performance can vary depending on image acquisition devices and models used within a site or across different locations. Consequently, using or not using a clinical algorithm with input data from a particular location and/or acquisition device could result in unintended discrimination under the proposed §92.210 despite the provider's intent being to ensure algorithm accuracy and to provide patients with safe and optimal radiology care.

AI Transparency Concerns

We believe the proposed §92.210 is well-intentioned, but there is an urgent need for enhanced public transparency for AI SaMD and other AI-enabled clinical algorithms before practices can reasonably achieve compliance. In many cases a particular algorithm's limitations are unlikely to be readily apparent to clinical end-users prior to tool acquisition. HHS agencies such as FDA should continue to make progress with manufacturers to improve the public accessibility and usability of information about the development, testing, and validation datasets and processes to sufficiently inform algorithm purchase, implementation, and medical use decision-making. Rather than reiterate continued specific AI transparency needs in this comment submission, we urge OCR and CMS to reference ACR's November 2021 letter to FDA linked in the footnote.[1]

The ACR Data Science Institute (DSI) provides an online library of all FDA-cleared radiology AI SaMD. We are working to continuously increase transparent posting of available information, describing context in which algorithms were trained, tested and can be expected to be used. The FDA similarly provides a centralized online database of AI SaMD from the various device specialty domains. To date, these libraries demonstrate an unfortunate sparsity of public domain details regarding datasets, input devices, and methodologies used to design and test commercially available algorithms.

[1] ACR's recommendations to FDA for enhanced AI transparency. https://www.acr.org/-/media/ACR/Files/Advocacy/Regulatory-Issues/acr-comments_fda-ai-transparency.pdf. Nov. 15, 2021.

The American College of Radiology welcomes further dialog with OCR and CMS regarding the proposed §92.210. For additional information on ACR's AI-related programs and resources, please visit the ACR DSI website at https://www.acrdsi.org/. For questions about this comment submission, please contact Gloria Romanelli, JD, ACR Senior Director of Government Relations, at gromanelli@acr.org; or Michael Peters, ACR Senior Government Affairs Director, Regulatory Policy, at mpeters@acr.org.

Sincerely,

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Chair, Board of Chancellors
American College of Radiology