MPL | MEDICAL PROFESSIONAL LIABILITY ASSOCIATION

December 20, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: *Nondiscrimination in Health Programs and Activities, (RIN 0945-AA17)*

Dear Secretary Becerra:

On behalf of the Medical Professional Liability (MPL) Association and its more than 50 medical professional liability insurer members, I am writing to express our concerns about the Department of Health & Human Services' (hereinafter, the Department) recent Proposed Rule regarding Nondiscrimination in Health Programs and Activities.

The MPL Association is the leading trade association representing insurance companies, risk retention groups, captives, trusts, and other entities owned and/or operated by their policy holders, as well as other insurance carriers with a substantial commitment to the MPL line. MPL Association members insure more than 2.5 million healthcare professionals around the world— doctors, dentists, oral surgeons, nurses and nurse practitioners, podiatrists, and other healthcare providers. MPL Association members also insure more than 3,000 hospitals and 50,000 medical facilities and group practices globally.

We share the Administration's desire to prevent discrimination in the delivery of healthcare services, however, we have strong concerns about the reinterpretation of Section 1557 of the Affordable Care Act. Most notable is the proposed new section entitled *Nondiscrimination in the use of clinical algorithms in decision-making* (45 CFR 92.210). As proposed, this section could have far-reaching consequences which would be detrimental to the very people it aims to protect, in addition to the broader community of patients and potential patients.

The proposed language for §92.210 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." As described in the accompanying narrative, however, the Department does not intend to apply liability for violating this section solely against intentional or even negligent acts of discrimination, but also against acts of alleged discrimination in which the discriminatory nature of the clinical algorithm was unknown at the time of the act and which may not have even come to light for years after the fact.

Throughout the notice of proposed rulemaking, the Department acknowledges the lack of certainty which surrounds the use of clinical algorithms. In this regard, the notice appropriately states, "The Department strongly cautions covered entities against overly relying upon a clinical algorithm." Such warning is helpful in encouraging the healthcare community to take adequate precautions to prevent inadvertent discrimination which could result from overreliance on these new tools. Furthermore, the notice says, "We encourage covered entities to use updated tools that have removed or do not have known biases..." Again, such cautioning is more than appropriate to alert health professionals and facilities that bias may exist within some tools, and that they should take steps to minimize that risk to the greatest extent practicable.

As further correctly noted in the notice of proposed rulemaking, "Clinical algorithmic tools are pervasive, and a covered entity may be unaware of any discrimination that may result from their reliance on such a tool." In such circumstances, it is wholly inappropriate to suggest that the threat of liability is the appropriate mechanism for reducing discrimination. Education about tools with known biases will greatly assist the medical community in reducing discrimination, and assistance in identifying and correcting those biases will benefit both healthcare providers and their patients. Threats of liability for utilizing related tools which may only subsequently be revealed to contain biases will only serve to hinder the use of all clinical algorithms.

In its notice of proposed rulemaking, the Department states, "The intent of proposed §92.210 is not to prohibit or hinder the use of clinical algorithms," yet that is the exact result the rule, as proposed, will have. As partners with the medical community in the areas of risk management and patient safety, medical professional liability insurers actively seek ways to help reduce all manner of liability risk. The vagueness surrounding implementation of the proposed rule, and the seemingly unlimited liability threat that is poses, would leave little option for insurers other than to recommend that clinical algorithmic tools never be used since the rule leaves no avenue for using them that does not contain an unacceptable level of liability risk.

As such, the MPL Association strongly recommends that the Department withdraw proposed §92.210 and engages in substantive discussions with the broad array of stakeholders, including medical professional liability insurers, who may be affected by this proposal. Only after such discussions develop a consensus among those stakeholders should a liability proposal regarding the use of clinical algorithms be considered.

If the Department insists on moving forward with §92.210, however, at the very least it should modify the section so that it applies only to the use of such algorithms with discriminatory biases that were known to the health professional or facility at the time of use that resulted in the alleged discrimination. Without factoring in the knowledge of the user of the algorithm, §92.210 will merely serve to deter the use of all clinical algorithmic tools altogether, including those which benefit the very patients that the proposed rule intends to protect.

We appreciate this opportunity to comment on the Department of Health & Human Services' notice of proposed rulemaking regarding Nondiscrimination in Health Programs and Activities.

Should you have any questions or need further information, please do not hesitate to contact me at batchinson@MPLassociation.org or 240.813.6128 or my colleague Mike Stinson, Vice-President, Public Policy and Legal Affairs, at 240.813.6139 or via email at mstinson@MPLassociation.org.

Thank you.

Sincerely,

Brian K. Atchinson
President & CEO