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October 3, 2022

Melanie Fontes Rainer, Director
Office for Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, D.C. 20201

Submitted Electronically

Attention: Nondiscrimination in Health Programs and Activities (Section 1557 NPRM), RIN 0945-AA17

Dear Director Fontes Rainer:

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the Nondiscrimination in Health Programs and Activities proposed rule published in the Federal Register on August 4, 2022.

ASCO is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

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The Department of Health and Human Services (HHS) is issuing this proposed rule on Section 1557 of the Affordable Care Act (ACA), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities; Section 1557(c) of the ACA authorizes the Secretary of the Department to promulgate regulations to implement the nondiscrimination requirements of Section 1557.

ASCO supports the explicit recognition in the current proposed rule that Section 1557's prohibition on sex discrimination includes discrimination on the basis of sex stereotypes, sexual orientation, gender identity and sex characteristics, including intersex traits.

HHS first finalized the Section 1557 regulation on May 18, 2016 (2016 Rule). In 2019, HHS issued a proposed rule removing protections against sexual orientation and gender identity discrimination from a number of regulations governing programs run by the Centers for Medicare and Medicaid Services (CMS). At the time, our affiliate organization, the American Society of Clinical

Oncology (the Society) expressed concern that implementation of the proposed rule would substantially curtail the rights and protections of SGM patients and reduce the anti-discrimination requirements on health insurers and medical providers. Specifically, the Society was concerned that the new limited definitions and scope described in the 2019 proposed interpretation of Section 1557, as described in the proposed rule, would inhibit access to equitable cancer care, and adequate insurance coverage to meet the needs of SGM individuals affected by cancer.

In formal comments to HHS at the time, ASCO explained that the SGM population bears a disproportionate cancer burden, and that transgender individuals already experience limitations in insurance coverage for transition-related care and cancer screening, given that the individual's anatomy may not be compatible with the gender listed in his or her policy. Eliminating the protections from discrimination based on gender identity, and those specifically for transgender individuals, could allow insurers to require higher cost-sharing for treatments related to a specific condition. Additionally, without the protections afforded under Sec. 1557 of the ACA, providers could refuse to treat people who are transgender or otherwise do not conform to traditional gender identities.

ASCO encouraged HHS to maintain the definition defined in the 2016 Section 1557 regulation which redefined discrimination "on the basis of sex" to include gender identity, as doing so would preserve the protections afforded to patients and healthcare consumers under the Affordable Care Act and prohibit discrimination on the basis of sexual orientation and gender identity. However, the final 2020 version of the regulations implementing section 1557 removed protections against sexual orientation and gender identity discrimination from a number of regulations governing programs run by the Centers for Medicare and Medicaid Services (CMS).

The current proposed rule recognizes that Section 1557's prohibition on sex discrimination includes discrimination on the basis of sex stereotypes, sexual orientation, gender identity and sex characteristics, including intersex traits. We are pleased to see that those are being restored in this rule and also expanded into additional CMS programs.

Clinical Algorithms

HHS is also proposing a new provision explicitly prohibiting discrimination in the use of clinical algorithms to support decision-making in covered health programs and activities. The intent of this provision is not to prohibit or hinder the use of clinical algorithms but rather to make clear that discrimination that occurs through their use is prohibited. The proposed rule offers a broad definition of clinical algorithms, specifically: "Clinical algorithms are tools used to guide health care decision-making and can range in form from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models. End-users, such as hospitals, providers, and payers (e.g., health insurance issuers) use these systems to assist with decision-making for various purposes. Clinical algorithms are used for screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning, health care operations, and allocation of resources, all of which affect the care that individuals receive."

HHS also highlights that recent studies have found that health care tools using clinical algorithms may create or contribute to discrimination on the bases protected by Section 1557, and as a result of their use by covered entities in their health care decision-making may lead to poorer health outcomes among members of historically marginalized communities.

In the proposed rule, HHS strongly cautions covered entities against overly relying upon a clinical algorithm, for example, by replacing or substituting the individual clinical judgment of providers with clinical algorithms, stating that the individual clinical judgment of a provider should always be based on the specific needs and medical history of the patient being treated. HHS states that covered entities that overly rely upon clinical algorithms run the risk of noncompliance with Section 1557 because such overreliance may result in discrimination.

HHS also notes that a covered entity may be unaware of any discrimination that may result from their reliance on such a tool, and that individual providers are not likely to have designed the clinical algorithms that augment their clinical decision-making. However, covered entities are responsible for ensuring that any action they take based on a clinical algorithm does not result in discrimination prohibited by this part, irrespective of whether they played a role in designing the algorithm. HHS states that, "The fact that a covered entity did not design the algorithm or does not have knowledge about how the tool works does not alleviate their responsibility to ensure that they do not take actions that result in discrimination. In sum, this part does not hold covered entities liable for clinical algorithms that they did not develop but holds entities liable under this proposed section for the decisions they make in reliance on such algorithms."

We share here general observations on clinical practice guidelines and raise specific issues with the assessment of other types of clinical algorithms. As a developer of clinical practice guidelines, ASCO agrees that clinical algorithms should not replace or substitute the individual clinical judgment of providers. ASCO guidelines specifically state that, "[T]he information is not intended to substitute for the independent professional judgment of the treating provider, as the information does not account for individual variation among patients… In all cases, the selected course of action should be considered by the treating provider in the context of treating the individual patient."

We believe an important underlying, unaddressed issue in this provision is the lack of diversity in clinical trials. ASCO has long advocated for increased diversity in clinical trials, as evidenced by our work with both the National Cancer Institute and the Food and Drug Administration on this topic, and our tireless advocacy for passage of the *CLINICAL TREATMENT Act,* which requires coverage of routine care costs for Medicaid beneficiaries enrolled in clinical trials. Many clinical trials lack adequate diversity in the trial population; increased diversity in the trial population renders the trial more reflective of the demographics of the population as a whole and better informs the development of various types of clinical algorithms.

As HHS considers moving forward with this proposal, it is important for HHS to understand what information clinicians may or may not have access to, especially in the setting of highly complex and/or automated algorithms. In a very practical sense, clinicians will often not have access to the data and/or methodology underlying some algorithm development. ASCO supports the intent of this proposal but cautions that OCR should first continue with information gathering to inform its thinking; it is critical that OCR has a clear understanding of the creation and real-world use of clinical algorithms, and then work with stakeholders to agree on principles that can guide improved algorithm development. OCR should also work, where possible, with its partners across federal agencies to encourage and support diverse clinical trial enrollment.

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We appreciate the opportunity to comment on the Nondiscrimination in Health Programs and Activities proposed rule. Please contact Gina Hoxie (gina.baxter@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,

Lori Pierce, MD, FASTRO, FASCO
Chair of the Board
Association for Clinical Oncology