

October 3, 2022



Xavier Becerra
Secretary
Department of Health and Human Services
Office for Civil Rights
Attention: 1557 NPRM (RIN 0945-AA17)
200 Independence Avenue, SW
Washington, DC 20201

Melanie Fontes Rainer
Director
Office for Civil Rights
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Re: RIN: 0945-AA17 – Nondiscrimination in Health Programs and Activities Proposed Rule
87 Fed. Reg. 47824 (August 4, 2022)

Dear Secretary Becerra and Director Fontes Rainer:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the Nondiscrimination in Health Programs and Activities (section 1557) proposed rule. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

Having comprehensive and affordable health insurance coverage is a key determinant for surviving cancer. Research from the American Cancer Society shows that uninsured Americans are less likely to get screened for cancer and thus are more likely to have their cancer diagnosed at an advanced stage when survival is less likely and the cost of care more expensive.¹ This not only impacts the more than 1.9 million Americans who will be diagnosed with cancer this year, but also the 16.9 million Americans living today who have a history of cancer.²

Cancer is a disease that affects everyone, but does not affect everyone equally:

- In 2022, it is estimated that approximately 144,000 new cancer cases will be diagnosed in individuals who identify as LGBTQ.³ The LGBTQ community faces a disproportionate burden of cancer, have distinctive risk factors, and face additional barriers in accessing health care. For example, gay and bisexual men have a higher risk for anal cancer (particularly if they are HIV+) and lesbian and bisexual women may have an increased risk of breast, cervical, and ovarian cancers.
- In 2021, cancer was the leading cause of death in the U.S. Hispanic population.⁴ Compared to non-Hispanic White individuals, Hispanic men and women in the U.S. have lower rates of the most common types of cancer (female breast, colorectal, lung, and prostate), but higher rates of infection-related cancers (stomach, liver, cervical) and gallbladder cancer. Though incidence of these cancers varies greatly by country of origin and nativity. Hispanic men and women are less likely to be diagnosed with cancer at an early stage, when treatment is more likely to be successful and less intensive.

¹ Zhao, J., Han, X., Nogueira, L., Fedewa, S.A., Jemal, A., Halpern, M.T. and Yabroff, K.R. (2022), Health insurance status and cancer stage at diagnosis and survival in the United States. *CA A Cancer J Clin.* <https://doi.org/10.3322/caac.21732>.

² American Cancer Society. *Cancer Facts & Figures 2022*. Atlanta: American Cancer Society; 2022.

³ [Lesbian, Gay, Bisexual, Transgender, Queer \(LGBTQ\) People and Cancer Fact Sheet](#)

⁴ American Cancer Society. *Cancer Facts & Figures for Hispanic/Latino People 2021-2023*. Atlanta: American Cancer Society, Inc. 2021.

- Cancer history among the American Indian or Alaskan Native (AIAN) population is higher than among Whites for lung, colorectal, and kidney cancers and for infection-related cancers (liver, stomach, and cervical).⁵ AIANs generally have their cancer diagnosed at a later stage compared to Whites (with huge disparities in breast and stomach cancers). As a result, the 5-year relative survival is lower for AIANs than for Whites for most cancer types.
- In 2022, more than 224,000 Black men and women are expected to be diagnosed with cancer, and approximately 74,000 Black men and women are expected to die from cancer in 2022.⁶ In the U.S. Black people have the highest death rates and shortest survival rates for any racial or ethnic group for most cancers.

ACS CAN applauds the Department of Health and Human Services (“HHS” or “the Department”) and the Office of Civil Rights (“OCR”) for promulgating updated regulations implementing the Section 1557 nondiscrimination provisions of the Affordable Care Act (ACA). We believe these regulations will help to reduce discrimination in health care. We offer comments on the following specific proposals:

- *Application (§ 92.2)*
- *Notice of nondiscrimination (§ 92.10)*
- *Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (§ 92.11)*
- *Meaningful Access for Limited English Proficient Individuals (§ 92.201)*
- *Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage (§ 92.207)*
- *Use of Clinical Algorithms in Decision-Making (§ 92.210)*

III. NONDISCRIMINATION IN HEALTH PROGRAMS AND ACTIVITIES

Subpart A – General Provisions

Application (§ 92.2)

The Department proposes to amend the application of Section 1557 to apply the rule to every health program or activity that receives Federal financial assistance (either directly or indirectly) from HHS; every program administered by HHS; and every program or activity administered by a Title I entity. The Department also proposes to extend the rule to Medicare Part B.

ACS CAN strongly supports the proposed rule and appreciates the Department including a definition of “health program or activity” which would include any entity that “provides or administers health-related services, health insurance coverage, or other health-related coverage” including those that “provide clinical pharmaceutical, or medical care.” We believe these provisions are in line with the statutory intent of Section 1557 and will help to ensure that the anti-discrimination provisions extend widely throughout the health care system.

Notice of nondiscrimination (§ 92.10)

The Department proposes to require each covered entity to provide a notice of nondiscrimination relating to its health programs and activities to participants, enrollees, beneficiaries and applicants of its health programs and activities, as well as members of the general public.

⁵ [Cancer Facts & Figures 2022 - Special Section: Cancer in the American Indian and Alaska Native Population](#).

⁶ American Cancer Society. *Cancer Facts & Figures for African American/Black People 2022-2024*. Atlanta: American Cancer Society, 2022.

ACS CAN supports this proposal. Section 1557 protections are only valuable if individuals are aware of their existence. Requiring covered entities to provide a notice of nondiscrimination and the ways that an individual could access interpretation services or reasonable access to auxiliary aids and services will help ensure that individuals take advantage of these vital services, if needed, which will help reduce health care disparities. We also urge the Department to consider creating model notices in order to ensure consistency for consumers and mitigate any undue burden on covered entities.

Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (§ 92.11)

The Department proposes to require that a covered entity provide a notice of availability of language assistance services and auxiliary aids and services free of charge. This notice must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant state and in alternative formats for individuals with disabilities.

ACS CAN supports this provision. Issues related to health care are often confusing to individuals, particularly individuals for whom English is not their native tongue. We appreciate the Department requiring the notice of availability of language assistance services be provided in the 15 most spoken languages in the relevant state and not just the most common languages spoken in the United States as a whole. This will better ensure more diversity of languages being offered. We also recommend that this notice be provided in large type (at least 18-point font), which will assist individuals with visual impairment, and that the notice be clearly identifiable on the beginning of any document so as to be clearly identifiable to individuals who may require these services.

Subpart C – Specific Applications to Health Programs and Activities

Meaningful Access for Limited English Proficient Individuals (§ 92.201)

The Department proposes to require that covered entities take reasonable steps to provide meaningful access to each limited English proficient individual eligible or likely to be affected by its health programs and activities. These services must be provided free of charge and must be provided by a qualified interpreter.

We support this proposal. We are also pleased the Department allows for the use of video interpretation services (provided that certain requirements are met). We believe the use of such technology will facilitate discussion between qualified translators and individuals for whom English is not their primary language but will also assist individuals who may have disabilities for which they are aided by the use of such technology. For those individuals with serious illnesses like cancer the ability to effectively communicate with their physicians and other providers is critical.

Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage (§ 92.207)

The proposed rule would prohibit discrimination on the basis of race, color, national origin, sex, age, or disability in the provision or administration of health insurance coverage or other health-related coverage. The proposed rule would reinstate the 2016 rule's requirement that would specifically prohibit covered entities from denying, cancelling, limiting, or refusing to issue or renew health insurance coverage or other health-related coverage, or denying or limiting coverage of a claim, or imposing additional cost-sharing or other limitations or restrictions on coverage on the basis of race, color, national origin, sex, age, or disability. The Department also expresses growing concerns regarding impermissible discrimination in the application of value assessment methodologies, used by payers to set values for goods and services.

We applaud the Department for further articulating discriminatory practices and providing policies to address those practices, as discussed in more detail below. We also share the Department's concern about potential discrimination in the use of value assessment methodologies to value health care goods and services. The

proposed rule doesn't define specific types of value assessment methodologies but cautions that value assessment makes use of methods for calculating value that penalize individuals or groups on the basis of their race, color, national origin, sex, age, or disability (for example, by placing a lower value on life-extension for a group of individuals) they may violate this part. ACS CAN opposes the use of value assessment tools (such as quality-adjusted life years) used by health care payers to determine whether to provide coverage or to set patient cost-sharing for a given treatment because doing so fails to take into account the value an individual may place on the quality of life provided to them for a given treatment. We urge the Department in the final rules implementing Section 1557 to specifically outlaw the use of value assessment methodologies.

Benefit Design

The proposed rule does not define the term "benefit design" but the preamble provides specific examples including coverage exclusions, limitations of benefits, prescription drug formularies, cost-sharing (including copayments, co-insurance and deductibles), utilization management tools (such as step therapy and prior authorization), medical management designs (such as medical necessity standards) and provider network design. The preamble also notes that OCR will determine if there is a legitimate, nondiscriminatory justification for a particular benefit design feature, but that justification cannot be pretext for discrimination.

We applaud the Department's recognition that a health plan's benefit could be designed in a discriminatory manner. We are particularly pleased the preamble notes that health plans are permitted to use utilization management tools to control prescription drug costs as long as the use of the tools is applied in a neutral manner and not discriminatory in nature. The preamble notes that utilization management tools "could raise concerns under this proposed rule if [they] establish more restrictive requirements for certain diseases or conditions without justification." As the Department finalizes the rule, we urge consideration be given to expressly note the limitation on the use of utilization management tools in the text of the regulation itself, and not just the preamble.

Scope of Application and Application to Excepted Benefits and Short-Term Limited Duration Insurance

The proposed rule would apply Section 1557 protections to all of an issuer's health programs and activities when the issuer is principally engaged in providing or administering health insurance coverage or other health-related coverage. Thus, under the proposed rule, an issuer offering a product in the Exchange (thereby receiving Federal financial assistance and thus covered by the Section 1557 requirements) would be bound by Section 1557 requirements both for its Exchange products as well as any non-qualified health plan (QHP) products offered off the Exchange, including excepted benefit plans and short-term limited duration (STLD) health plans.

ACS CAN applauds this interpretation. We believe that Section 1557 was intended to apply broadly to covered entities – not only to individual lines of business. ACS CAN is concerned about the proliferation of short-term limited duration health plans and excepted benefit products that mimic QHP coverage. These products can engage in discriminatory policies. STLD plans fail to provide the kind of comprehensive coverage an individual would need if they were diagnosed with a serious and unplanned disease such as cancer.⁷ We believe these practices to be discriminatory in nature and strongly support Section 1557 requirements to be extended to cover these plans.

⁷ American Cancer Society Cancer Action Network. Inadequate coverage: An ACS CAN examination of short-term health plans. May 13, 2019. Available at <https://www.fightcancer.org/sites/default/files/ACS%20CAN%20Short%20Term%20Paper%20FINAL.pdf>.

At the same time, we recognize that Section 1557 requirements alone will not address all issues with STLD insurance. We supported the 2016 STLD rules, which limited these policies and objected to the 2020 rule which allowed for the proliferation of these plans. We urge the Department to work with the Treasury Department to promulgate new rules curtailing the availability of STLD plans as quickly as possible.

Application to Third Party Administrators

The Department notes that some third-party administrators (TPAs) are responsible for the development of the group health plan or other documents that are ultimately adopted by the self-insured plan. The proposed rule makes clear that in cases where the discriminatory terms of the group health plan originated with the TPA (rather than the plan sponsor) the TPA could be liable for a discriminatory design feature under Section 1557.

ACS CAN agrees with this interpretation. We appreciate the Department recognizing the role that TPAs – including pharmacy benefit managers – play in the design and administration of health services. To the extent that a TPA's actions create a discriminatory benefit design or result in discriminatory practices, the TPA should be held liable for any and all Section 1557 actions it creates.

Network Adequacy

Other federal and state laws may govern network adequacy requirements that are outside the scope of Section 1557. However, the proposed rule notes that plan networks – particularly narrow networks – can limit access to care for individuals, particularly individuals with limited English proficiency, disabilities, and those who may face discrimination that is protected by Section 1557. HHS is soliciting input on how Section 1557 may apply to provider networks.

ACS CAN appreciates the opportunity to provide feedback on this topic. We have a long history of working at the state and federal levels to ensure that individuals who may not yet have cancer, those who are in active treatment, and cancer survivors have access to the providers (including physicians and facilities) they need. While we recognize that other state and federal entities promulgate network adequacy standards, we nonetheless believe that Section 1557 protections are needed to ensure that plan networks are not designed in a manner that would result in discrimination and that these protections be consistent across all plan designs.

Use of Clinical Algorithms in Decision-Making (§ 92.210)

The Department proposes to make clear that a covered entity may not discriminate against any individual on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision-making. Under the proposal, covered entities would not be liable for clinical guidelines and algorithms they did not develop, but they may be liable for decisions that were made in reliance on clinical algorithms.

ACS CAN supports this proposal. As the Department noted, clinical algorithms are used to guide health care decision making such as screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning and allocation of resources. The Department cites a number of studies demonstrating that the use of health care tools that rely on clinical algorithms are designed based on biased data. We agree that covered entities should be responsible for ensuring compliance with all nondiscrimination provisions, including decisions that are made in reliance on clinical algorithms. If a covered entity is made aware that a clinical algorithmic tool is resulting in discriminatory action, that entity may face liability under Section 1557 rules. We also urge the Department to include in the final rule a definition of the term “clinical algorithms” which would include any automated decision-making system on which the covered entity relies.

CONCLUSION

Thank you for the opportunity to comment on the Section 1557 proposed rule. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa A. Lacasse". The signature is fluid and cursive, with the first name "Lisa" being the most prominent.

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network