American Lung Association.

October 3, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

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

Dear Secretary Becerra:

Thank you for the opportunity to submit comments on the proposed rule regarding Section 1557 of the Affordable Care Act.

The American Lung Association is the oldest voluntary public health association in the United States, representing the more than 34 million individuals living with lung disease. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy.

Supporting investments and policies that eliminate health disparities caused by systemic racism and building health equity across all policy areas are core priorities in the Lung Association's Public Policy Agenda.[1] Section 1557 of the Affordable Care Act (ACA) prohibits discrimination across a range of health programs and activities. We strongly support this proposed rule from the Department of Health and Human Services (HHS or the Department) to realign Section 1557 nondiscrimination regulations with the statute and federal nondiscrimination law. We urge that the proposed rule be promptly finalized and fully enforced.

In addition to the robust comments we submitted with other patient advocacy organizations,[2] the Lung Association offers the following comments on the proposed rule:

Application of the Rule and Related Definitions

It is critical that patients with lung disease are able to access the care they need without discrimination on basis of race, color, national origin, sex, age or disability. We therefore support provisions in the proposed rule that restore the application of Section 1557 to all health programs and activities of the Department; reinstate regulatory definitions, including for "health program and activity" to reestablish regulatory authority over entities principally engaged in providing or administering health insurance coverage or other health-related coverage; and require covered entities to comply with Section 1557's nondiscrimination requirements across all of their operations. Previous rulemaking on Section 1557 finalized in 2020 (the 2020 rule) limited the application of Section 1557, clearly contradicting the statute and impermissibly limiting nondiscrimination protections for the patients we represent. We strongly support these revisions in the proposed rule. We also appreciate the clarification that short-term limited duration plans and excepted benefit plans must comply with Section 1557 if the issuer receives federal financial assistance.

The Lung Association also supports the proposal to include Medicare Part B funds within the definition of federal financial assistance. The prevalence of certain lung diseases increases with

age, and 10% of Medicare enrollees have COPD.[3] Recognizing that Medicare Part B funds constitute federal financial assistance is consistent with the text and purpose of Section 1557. Bringing the recipients of those funds within the scope of Section 1557's nondiscrimination requirements will expand protections to additional patients with COPD and other lung diseases and is likely to reduce confusion among Medicare beneficiaries. We urge the Department to finalize the change as proposed.

Prohibited Forms of Discrimination

The proposed rule codifies a general prohibition of discrimination on the basis of race, color, national origin, sex, age or disability by any covered entity and supplements this protection by providing a non-exhaustive series of more specific examples of prohibited conduct. We are gratified by the strong restatement of nondiscrimination protections contained in these provisions and believe the additional clarity offered by the examples will help promote compliance by covered entities and a greater understanding by patients of the nondiscrimination protections to which they are entitled. We strongly support this approach.

We strongly support the Department's proposal to clarify that Section 1557's prohibition on sex discrimination includes discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity. This proposal advances the purpose of the statute by making clear that a range of forms of discrimination affecting LGBTQI+ individuals is unlawful and that prohibiting such misconduct is fully within the Department's authority. These protections are a key component of eliminating lung health disparities in the LGBTQI+ community. For example, lesbian, gay and bisexual adults and youth smoke at substantially higher rates than the general population, putting them at higher risk for lung cancer and other tobacco-related diseases.[4] As documented at length in the proposed rule, discrimination in healthcare contributes to disparities in health status and outcomes. By reducing discrimination against LGBTQI+ individuals in healthcare, the proposed rule will help to improve access to services to prevent, diagnosis and treat lung disease, including tobacco cessation.

Discriminatory Benefit Design or Marketing Practices

The Lung Association supports the application of Section 1557 to health insurance coverage, especially health benefit designs. Without the prohibition on discriminatory marketing or benefit design, insurers will be able to use marketing and benefit design to try to avoid enrolling people with disabilities, including patients with lung diseases and other chronic conditions, in order to maximize their profits. For example, a health insurance plan may put therapies or medications for severe asthma in the highest cost-sharing tier, while not doing so for other conditions, in order to discourage enrollment of people with severe asthma. A plan might also arbitrarily limit pulmonary rehabilitation services in order to reduce the services used by someone who is diagnosed with a chronic lung disease like COPD or pulmonary fibrosis during the plan year. Application of Section 1557 to marketing and benefit design is essential to protecting people with disabilities, including individuals with lung diseases and other chronic conditions, and other protected classes from insurers who will find roundabout ways to discourage their enrollment and undermine the protections for people with pre-existing conditions under the ACA.

Language Assistance and Meaningful Access for LEP Individuals

Appropriate language assistance for individuals with limited English proficiency (LEP) is important to ensure people with lung diseases and their caregivers fully understand how to manage their conditions and avoid negative health outcomes. For example, children with

asthma with LEP caregivers are less likely to use an asthma action plan, an important component of asthma management, than children with caregivers who are proficient in English.[5] Additionally, research has shown that children with asthma in Hispanic and Asian/Pacific Islander families for whom English is not their primary language are more likely to be hospitalized due to their asthma, another sign of poor asthma control.[6]

The Lung Association supports provisions in the proposed rule regarding the notice of the availability of language assistance and the requirements for when this notice must be made available. We recommend that if a covered entity operates across multiple states, that the covered entity has to provide the notice in not merely the top 15 languages in the aggregate (that is, across all the states) but rather a total of the top 15 languages in each state. We also recommend that the Office of Civil Rights (OCR) require covered entities to provide the notice in large print (at least 18-point font), at the beginning or on the first page of any document and in plain language. As was done previously, we suggest that the Department develop and provide covered entities with model notices and translated information in the relevant languages that will be needed across the country.

We also support provisions in the proposed rule related to meaningful access, including the requirements related to machine translation and the restoration of requirements related to video interpreting. Regarding the section on "evaluation of compliance," we have concerns about the lack of a requirement to develop a language access plan, as it is important for covered entities to gather information about the needs of LEP individuals in its service area prior to developing policies and procedures. Additionally, we support the clarification in the proposed rule related to the restricted use of certain persons to interpret or facilitate communication, and we recommend that the Department add a requirement that a "companion" of an LEP individual who needs language services must also be provided meaningful access, including access to qualified interpreters and translated materials.

Integration Mandate

The Lung Association supports the explicit requirement that health insurance coverage and health-related coverage include the provision or administration of that coverage in the most integrated setting appropriate to the needs of covered individuals with disabilities, including individuals with lung diseases and other chronic conditions. This provision acknowledges a fundamental tenet of disability rights law and the pivotal 1999 Supreme Court decision in Olmstead v. Zimring. This provision can help patients with lung diseases access the care they need to manage their conditions in community settings.

We appreciate the proposal's specific mention of "utilization management practices, provider reimbursement, contracting out to third party-contractors such as PBMs, and quality measurement and incentive systems" as areas where covered entities should pay careful attention. We also agree with the Department's examples of plans requiring prior authorization or step therapy or other utilization management when individuals are accessing a medication in the community, but not using these tools when individuals are institutions would count as discrimination.

In response to the Department's question about scope and nature of this protection, we encourage the Department to consider the impact of policies for people who require oxygen. At present, people with lung diseases who require supplemental oxygen at continuous or high flow rates are often restrained from leaving their homes due to the inability to obtain portable liquid

oxygen. This lack of portable liquid oxygen impacts these individuals' ability to follow physician-ordered exercise regimens, do simple errands such as grocery shopping, as well as attend church and other community activities. We urge OCR to investigate these issues and other aspects of health coverage that may result in more isolation and segregation of individuals with lung disease.

Nondiscrimination in the Use of Clinical Algorithms in Decision-Making
The preamble to the proposed rule provides numerous documented examples of bias from clinical algorithms. Many clinical algorithms, including those that assess risk of disease, dictate that Black patients, in particular, must be more ill than white patients before they can receive treatment for a range of life-threatening conditions. For example, race-based correction factors are used in spirometry for individuals who are identified as Black or Asian, leading to concerns that disease severity is underestimated in these groups and patients may not receive needed treatment.[7] One recent study found that removing the race correction for Black individuals led to a 20.8% increase in patients diagnosed with a pulmonary defect and concluded that "the use of race correction in clinical algorithms may mask and, thus, reinforce the effects of structural racism, including known disparities in care processes and outcomes for Black patients with lung diseases."[8] Professional societies including the American Thoracic Society are currently evaluating the evidence and guidance on this issue.[9] The Lung Association supports the new provision on the discriminatory impact of clinical algorithms in the proposed rule, which will help protect patients with lung diseases from adverse coverage decisions based on these types of algorithms.

Additionally, we request that the Department include in the final rule a broad definition of clinical algorithms that encompasses any form of automated or algorithmic decision-making system for care or healthcare enrollment. There are numerous examples of bias, discrimination, and harm by covered entities by automated decision-making tools and models that may fall outside the term "clinical algorithm,"[10] such as eligibility systems for Medicaid, CHIP, or Marketplace coverage that wrongfully deny or terminate coverage.[11] The preamble to the rule recognizes this broader definition, noting that clinical algorithms can range in form from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions and models. Yet in the absence of a definition, the term "clinical algorithms" may be too narrowly construed and may allow some to consider excluding, for example, the Crisis Standard of Care Plans cited in the preamble as not "clinical algorithms" under a narrow definition because many were policies or ranking systems rather than automated decisions. Including a clear, comprehensive definition in the final rule will reduce confusion and decrease the risk that patients face discrimination from any automated or algorithmic decision-making system related to healthcare.

Conclusion
The proposed rule takes important steps to address discrimination on the basis of race, color, national origin, sex, age and disability in healthcare and will help to improve access to care for patients with lung diseases. We look forward to working with the Department to ensure this rule is finalized quickly and fully implemented. Thank you for the opportunity to provide comments.

Sincerely,

Harold Wimmer
President and CEO

[1] American Lung Association Public Policy Agenda, 117th Congress (2021-2022). Available at https://www.lung.org/policy-advocacy/public-policy-agenda.
[2] Letter to Secretary Becerra re: Proposed Rule on Section 1557, Nondiscrimination in Health Programs and Activities. October 3, 2022. Available at w https://www.lung.org/policy-advocacy/advocacy-archive.
[3] Centers for Disease Control and Prevention. National Center for Health Statistics. National Health Interview Survey, 2020. Analysis performed by the American Lung Association Epidemiology and Statistics Unit using SPSS software.
[4] Centers for Disease Control and Prevention. (2022, June 27). *LGBTQ+ people experience a health burden from commercial tobacco*. Centers for Disease Control and Prevention. Retrieved September 27, 2022, from https://www.cdc.gov/tobacco/health-equity/lgbtq/health-burden.html.
[5] Antonio Riera, Aledie Navas-Nazario, Veronika Shabanova & Federico E. Vaca (2014) The impact of limited English proficiency on asthma action plan use, Journal of Asthma, 51:2, 178-184, DOI: 10.3109/02770903.2013.858266
[6] Aratani Y, Nguyen HA, Sharma V. Asthma-Related Emergency Department Visits Among Low-Income Families With Young Children by Race/Ethnicity and Primary Language. Pediatric Emergency Care. 2020 Nov: 36(11), DOI: 10.1097/PEC.0000000000001430.
[7] Vyas, D. A., Eisenstein, L. G., & Jones, D. S. (2020). Hidden in plain sight — reconsidering the use of race correction in clinical algorithms. *New England Journal of Medicine*, *383*(9), 874–882. https://doi.org/10.1056/nejmms2004740
[8] Moffett, A. T., Eneanya, N. D., Halpern, S. D., & Weissman, G. E. (2021). The impact of race correction on the interpretation of pulmonary function testing among Black Patients. A7. A007. *Impact of Race, Ethnicity, and Social Determinants on Individuals with Lung Diseases.* https://doi.org/10.1164/ajrccm-conference.2021.203.1_meetingabstracts.a1030
[9] American Thoracic Society. *Health equity and pulmonary function testing*. Pulmonary Function Testing. Retrieved September 27, 2022, from https://www.thoracic.org/professionals/pulmonary-function-testing/health-equity-and-pulmonary-function-testing.php
[10] Edwards, E., Machledt, D., Rosellini, S., & Taylor, L. M. C. (2021, September 15). *NHELP AHRQ comments*. National Health Law Program. Retrieved September 27, 2022, from https://healthlaw.org/resource/nhelp-ahrq-comments/
[11] Edwards, E. (2021, October 14). *Preventing harm from Automated Decision-making systems in Medicaid*. National Health Law Program. Retrieved September 27, 2022, from https://healthlaw.org/preventing-harm-from-automated-decision-making-systems-in-medicaid/