Oct. 3, 2022

Secretary Xavier Becerra

U.S. Department of Health and Human Services

Office for Civil Rights

Attention: 1557 NPRM (RIN 0945-AA17)

Hubert H. Humphrey Building

Room 509F

200 Independence Avenue, S.W.

Washington, D.C. 20201

**RIN Number 0945-AA17**

Dear Secretary Becerra,

I write to you on behalf of the American Thoracic Society (ATS) regarding the Notice of Proposed Rulemaking (NPRM) (HHS-OS-2022-0012-0001) for protections prohibiting discrimination in U.S. Department of Health and Human Services funded health care programs, services, and activities on the basis of race, color, national origin, sex, age, or disability pursuant to Affordable Care Act Section 1557, 42 U.S. Code § 18116 and other applicable federal law.

The ATS is the world's leading medical society dedicated to accelerating the advancement of global respiratory health through multidisciplinary collaboration, education, and advocacy. Core activities of the Society’s more than 16,000 members are focused on leading scientific discoveries, advancing professional development, impacting global health, and transforming patient care.

The ATS is pleased to provide comments in response to the NPRM.

General Comments – Race, Racism and Medicine

The ATS recognizes that systemic racism continues to be a pervasive problem in the U.S., creating significant barriers for many Americans to fully enjoy the benefits and freedoms offered in our society. We further recognize that medicine is not immune from the racist practices that have shaped our society. We agree with the recent scrutiny that “race-adjusted algorithms” used in medicine has received. We want to emphasize that the ATS recognizes that race is a social construct and not a clinical or scientific construct. The ATS believes that the use of race-adjustment in medical clinical algorithms should be rare, used only to address an identified disparity, evidence-based and demonstrably-designed to improve health for minority populations. Given the increasing reliance on clinical algorithms to inform decision-making in health care, the use of any race-adjustment in a clinical algorithm must be closely scrutinized to ensure its inclusion meets an identified need, is evidence-based, and serves to benefit the health of minority patients.

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

Race and Pulmonary Function Tests

The ATS has set rigorous standards for the performance of lung function testing. Lung function testing provides airflow, lung size, and gas exchange measurements. These measurements are directly made, and the techniques are not influenced by race or ethnicity.

Race and ethnicity have been included in the interpretation of the measured lung function values, along with an individual's age, sex, and height. The rationale for this has been based on observed differences in the lung function of healthy individuals that vary according to race and ethnicity. The ATS, and other leading organizations, have questioned this practice due to the potential to perpetuate race-based medicine.

In response to emerging evidence, the ATS is now examining whether the interpretation of lung function should be race and ethnicity blind. Multiple discussions are being held to reach consensus to produce a statement that addresses concerns and provides appropriate recommendations for a worldwide audience.

The ATS recognizes the appropriate scrutiny that the inclusion of race in the interpretation of pulmonary function tests interpretation has received and in response has recently convened a panel of experts to review current pulmonary function testing interpretation guidelines. The ATS expects the panel of experts to offer guidance in the near future.

Race and Pulse Oximetry

Another test in the pulmonary world receiving scrutiny for how it incorporates race is the pulse oximeter. A pulse oximeter is a device that uses light beams to estimate the oxygen saturation of the blood and the pulse rate.[[1]](#footnote-1) Pulse oximeters are widely used to guide the administration of supplemental oxygen in patients with hypoxia. However, pulse oximeters give different readings on individuals with dark skin pigmentation due to overlapping absorption of red light by oxyhemoglobin and the skin pigment melanin, leading to an overestimation of oxygen saturation for those with darker skin pigmentation. Without adjusting for skin pigmentation, many Black or other non-white populations may receive falsely higher blood oxygenation readings, potentially masking hypoxemia in people of color.[[2]](#footnote-2) [[3]](#footnote-3)Studies found that Black patients had nearly three times the frequency of occult hypoxemia compared to white patients[[4]](#footnote-4) and increased incidence of occult hypoxemia in Black infants[[5]](#footnote-5) when using pulse oximeters.[[6]](#footnote-6)

The COVID-19 pandemic brought the issue into sharp relief for the public. During the pandemic, many clinicians relied predominately on pulse oximeter readings to adjust oxygen flow for COVID-19 patients who required supplemental oxygen. For patients with darker skin pigmentation, this may have resulted in patients receiving less supplemental oxygen than they needed, potentially leading to adverse clinical outcomes.

Both the physician community and the medical device industry recognize the need to address this problem in pulse oximeter interpretation. The Food and Drug Administration - Anesthesiology Devices Panel of the Medical Devices Advisory Committee – is holding a meeting in November to discuss challenges with accurate interpretation of pulse oximeters and what steps need to be taken by the medical device industry, the medical community, and regulatory agencies. The ATS will be presenting at this meeting and is committed to working with industry and the FDA to revise current medical practices to ensure appropriate use and interpretation of this valuable medical monitoring technology. We look forward to the findings and recommendations that will flow from the FDA discussion.

**Nondiscrimination in the Delivery of Health Programs and Activities Through Telehealth Services (§ 92.211)**

Proposed § 92.211 provides that a covered entity must not, in delivery of its health programs and activities through telehealth services, discriminate on the basis of race, color, national origin, sex, age or disability. During the COVID-19 pandemic, telehealth use expanded exponentially because of the need for social distancing, and was enabled by changes that were made to telehealth reimbursement regulations and to the Health Insurance Portability and Accountability Act (HIPAA) of 1996—specifically, the Privacy, Security and Breach Notification Rules—governing telehealth.[[7]](#footnote-7) [[8]](#footnote-8) In 2020, virtual health visits increased from just 840,000 in 2019 to 52.7 million —a 63-fold increase from 2019, according to a U.S. Department of Health and Human Services report.[[9]](#footnote-9) The increased telehealth use, while potentially beneficial, must also be viewed in the context of potential discrimination and health care disparities. For example, as HHS notes in the NPRM, studies indicate the presence of “disparities in access based on race and disability. One study found “significant” racial disparities in telehealth use during the COVID-19 pandemic, which the authors believe may lead to the worsening of pre-existing health disparities.”[[10]](#footnote-10)

Meaningful Access for LEP Individuals and Individuals with Disabilities

Barriers to telehealth must be removed, including, most poignantly, those barriers that affect the information provided to patients without regard to whether the patients are limited English proficient or have communication disabilities. Such barriers inexorably result in significant health care inequity and are ineluctable components of the social determinants of health, as HHS noted in the NPRM’s preamble.

According to a March 2021 Health Affairs article entitled, “*Disparities in Telehealth Use Among California Patients with Limited English Proficiency,*” the authors undertook a study to highlight the impact of language barriers on telehealth use. The study evaluated the impact of telehealth use on health care access and use among patients with limited English proficiency.[[11]](#footnote-11) The study concluded that policy makers and clinicians must focus on limited English proficiency as an important dimension to promote telehealth equity and decrease digital divides.[[12]](#footnote-12)

The ATS recommends that, to improve the access of telehealth for limited English proficient patients and patients with communication disabilities, the Department consider national and local policy initiatives identified in the Health Affairs study[[13]](#footnote-13):

* “Collaborate with health organizations to apply a comprehensive approach that promotes digital equity, including broad-band access, device access, telehealth infrastructure, and community-based digital literacy programs.
* Programs supporting telehealth at community health centers that disproportionately serve patients with limited English proficiency, such as the FCC’s COVID-19 telehealth program, should be bolstered. This program has allowed organizations to build their telehealth infrastructure, provide patients with technology, and engage community health workers in promoting digital literacy.
* Health care organizations can partner with community organizations (for example, libraries) to provide digital literacy training, similar to efforts supporting patient portal use.
* A commitment from payers, including the Centers for Medicare and Medicaid Services (CMS) and commercial payers, to payment parity across visit modalities (video, telephone, and in-person) will help maintain telehealth as a health care option. Further, payers, such as CMS, should expand reimbursement for interpreters, thus encouraging their use across all visit modalities.”

At the institutional level:

* “Seamlessly integrating interpreters, including ASL interpreters, into telehealth workflows will help with both patient and provider satisfaction.
* Institutions should monitor telehealth use across patient demographics, including language and disability, to quantify the magnitude of disparities as they are likely to persist.”

The ATS recommends that the Department reinforce the principals of the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards) concerning telehealth services and all communications by HHS-funded providers with non-English speaking people. These standards are intended to advance health equity, improve quality, and help eliminate health care disparities by providing a blueprint for individuals and health care organizations to implement culturally and linguistically appropriate services. See: <https://thinkculturalhealth.hhs.gov/clas> Indeed, the CLAS standards are based upon the landmark civil rights laws that are the foundation of Section 1557, such as Title VI of the 1964 Civil Rights Act.

As proposed in the NPRM, the ATS commends the Department for requiring thorough training by covered entities about the nondiscriminatory policy, grievance procedures, and processes by which to obtain language assistance services for LEP individuals and to ensure effective communication with and provide reasonable modifications for individuals with disabilities. The ATS agrees with the U.S. Department of Justice (DOJ) that the importance of mandatory, effective training and education cannot be gainsaid. The DOJ and Department both place much emphasis on the importance of training and education in health care. For example, Americans with Disabilities Act training is incorporated in federal regulations, such as training for the compliant use of Video Remote Interpreting (VRI). (Effective Communication: 28 Code of Federal Regulations § 36.303 (f)). Furthermore, it has long also been recognized by health care providers, researchers, and scientists that effective training is an essential part of health care legal compliance.[[14]](#footnote-14)

**CMS Provision of Supplemental Oxygen – the Home Oxygen Benefit**

The ATS notes with interest, that if finalized as drafted, the proposed 1557 rule would expand HHS OCR scope of authority to address policies and practices that inhibit patients from fully engaging in their community. The ATS would encourage OCR to use this new authority to closely review CMS’s coverage policy for supplemental oxygen for Medicare beneficiaries. In regulatory text, CMS defines the supplemental oxygen as a “home oxygen benefit” and has constructed coverage and payment policies to ensure patients have supplemental oxygen in the home only. Focusing on coverage of supplemental oxygen in the home only effectively inhibits the use of currently available oxygen systems that enable Medicare beneficiaries to use supplemental oxygen outside the home for work, medical appointments, travel and other normal community activities. As the agency moves forward with finalizing the proposed rule, we encourage HHS OCR to consider using its new scope of authority to review CMS’s coverage and payment policies for supplemental oxygen.

The ATS looks forward to working with the Department as Section 1557’s regulatory protections from discrimination are finalized.

Sincerely,

Text

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Gregory Downey, MD, ATSF

President, American Thoracic Society

1. Deloitte Insights. “Rethinking when and how to use race appropriately in care delivery.” A report from the Deloitte Health Equity Institute, 19 May 2022. [↑](#footnote-ref-1)
2. Ibid. [↑](#footnote-ref-2)
3. The source of bias in measurement is overlapping absorption of light in the red region (660 nm) for both oxyhemoglobin and the skin pigment melanin. Prior studies have shown bias in measurement based on skin tone, and that this bias may increase with worsening hypoxemia. Of note, Jubran and Tobin (Chest 1990) prospectively studied a cohort of ICU patients to determine if SpO2 measurements could be used to titrate oxygen to maintain a PaO2 > 60. Those authors identified a greater bias in SpO2 measurements in patients with dark skin tones and recommended that a threshold of 95% be used for oxygen titration versus 92% for White patients. However, this was not adopted, and this knowledge not well known within the field in the current era until the Michigan study. See: Jubran A, Tobin MJ. Reliability of pulse oximetry in titrating supplemental oxygen therapy in ventilator-dependent patients. Chest. 1990; 97:1420–1425. [↑](#footnote-ref-3)
4. The New England Journal of Medicine, “Racial bias in pulse oximetry measurement,” December 17, 2020. [↑](#footnote-ref-4)
5. Zachary Vesoulis et al., “Racial discrepancy in pulse oximeter accuracy in preterm infants,” Journal of Perinatology (2022): pp. 79-85. [↑](#footnote-ref-5)
6. Deloitte Insights. “Rethinking when and how to use race appropriately in care delivery.” A report from the Deloitte Health Equity Institute. 19 May 2022. [↑](#footnote-ref-6)
7. Centers for Medicare and Medicaid Services [Internet]. Baltimore (MD):CMS. Press release, Trump Admin-istration makes sweeping regulatory changes to help U.S. healthcare system address COVID-19 patient surge; 2020 Mar 30 [cited 2021 Jan 13]. Available from: https://www.cms.gov/newsroom/press-releases/trump-administration-makes-sweeping-regulatory-changes-help-us-healthcare-system-address-covid-1916. [↑](#footnote-ref-7)
8. Schwamm LH, Erskine A, Licurse A. A digital embrace to blunt the curve of COVID19 pandemic. NPJ DigitMed. 2020; 3(1):64. [↑](#footnote-ref-8)
9. New HHS study shows 63-fold increase in Medicare telehealth utilization during the pandemic, HHS press release, December 3, 2021. [↑](#footnote-ref-9)
10. Robert P. Pierce and James J. Stevermer, *Disparities in the Use of Telehealth at the Onset of the COVID-19 Public Health Emergency*, J. Telemed and Telecare, Oct. 21, 2020, at p. 5, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7578842/pdf/10.1177_1357633X20963893.pdf>,

    Ole-Petter R. Hamnvik et al., *Telemedicine and Inequities in Health Care Access: The Example of Transgender Health*, Transgender Health (pre-print) (2022), <https://www.liebertpub.com/doi/epdf/10.1089/trgh.2020.0122> and

    Carli Friedman and Laura VanPuymbrouck, *Telehealth Use by Persons with Disabilities During the COVID-19 Pandemic*, 13 Int’l J. Telerehabilitation 2 (2021), https://doi.org/10.5195/ijt.2021.6402. [↑](#footnote-ref-10)
11. [Disparities In Telehealth Use Among California Patients With Limited English Proficiency](https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2020.00823), Jorge A. Rodriguez, Altaf Saadi, Lee H. Schwamm, David W. Bates, and Lipika Samal, Health Affairs 2021 40:3, 487-495. [↑](#footnote-ref-11)
12. Ibid. [↑](#footnote-ref-12)
13. Ibid. [↑](#footnote-ref-13)
14. Recent Civil Rights Resolution Agreements and Compliance Reviews, U.S. Department of Health and Human Services, Office for Civil Rights, <https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/agreements/index.html>; [US Physicians’ Knowledge About The Americans With Disabilities Act And Accommodation Of Patients With Disability](https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2021.01136), Lisa I. Iezzoni, Sowmya R. Rao, Julie Ressalam, Dragana Bolcic-Jankovic, Nicole D. Agaronnik, Tara Lagu, Elizabeth Pendo, and Eric G. Campbell, Health Affairs 2022 41:1, 96-104; [Physicians’ Perceptions Of People With Disability And Their Health Care](https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2020.01452); Lisa I. Iezzoni, Sowmya R. Rao, Julie Ressalam, Dragana Bolcic-Jankovic, Nicole D. Agaronnik, Karen Donelan, Tara Lagu, and Eric G. Campbell, Health Affairs 2021 40:2, 297-306. [↑](#footnote-ref-14)