



October 3, 2022

VIA ELECTRONIC SUBMISSION

Secretary Xavier Becerra
U.S. Department of Health and Human Services
Herbert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

RE: RIN 0945-AA17, Nondiscrimination in Health and Health Education Programs or Activities

Dear Secretary Becerra:

The Center for Health Law and Policy Innovation at Harvard Law School and the Disability Law Center submit these comments on behalf of the undersigned organizations and individuals, in response to the Department of Health and Human Services' (HHS or the Department) Notice of Proposed Rulemaking (Proposed Rule) entitled "Nondiscrimination in Health and Health Education Programs or Activities," published in the Federal Register on August 4, 2022. We urge the Department to further strengthen these protections in its final version. Our comments are primarily, but not exclusively, directed to proposed regulation **§ 92.210 Nondiscrimination in the use of clinical algorithms in decision-making**, governing use of clinical decision support tools (CDSTs) and "race corrections" used in tests administered in health programs or activities.

INTRODUCTION

Discriminatory health care systems and policies play an outsized role in creating an uneven playing field for access to quality health care in the United States.¹ Given the deep legacy of racism and other forms of discrimination in health systems and health policy, Section 1557 of the Affordable Care Act (42 U.S.C. §18116) is a significant step toward rectifying centuries of policies and practices that have created worse health outcomes for communities of color, individuals with disabilities, women of color, LGBTQI+ people, Limited English Proficient (LEP) individuals, older adults, and other systemically marginalized communities.²

¹ For additional background, see LINDA VILLAROSA, UNDER THE SKIN: THE HIDDEN TOLL OF RACISM ON AMERICAN LIVES AND ON THE HEALTH OF OUR NATION (2022).

² See, e.g., DANYA BOWEN MATTHEW, JUST MEDICINE: A CURE FOR RACIAL INEQUALITY IN AMERICAN HEALTH CARE 9-32 (2015) (reviewing the effects of systemic racism on health disparities over the course of American history).

Although a number of federal laws prohibit forms of discrimination, Section 1557 extends nondiscrimination protections to any health program or activity that receives federal funding, any health program or activity that HHS administers, the Health Insurance Marketplace, and all plans offered by insurers that participate in those marketplaces. The Proposed Rule not only clarifies the broad civil rights protections extended in Section 1557, but also provides tools to combat racism and other forms of discrimination in health care. First, the Proposed Rule addresses various forms of discrimination that disproportionately affect communities of color, including on the basis of disability status, national origin, and sex. Second, the Proposed Rule addresses systemic discrimination, including policies and practices that harm people of color. Finally, the Proposed Rule calls for vast enforcement authority across all segments of the health care system and related activities — ensuring Section 1557’s prohibition against race discrimination is adhered to across the United States.

Ultimately, we urge the Department to grasp this landmark opportunity to establish a Final Rule that addresses discrimination and racism in health care. We urge the Department to finalize the Proposed Rule with strengthened protections, as explained further below.

I. We support the Department’s proposal to explicitly prohibit discrimination through the use of clinical algorithms and urge the adoption of changes that would strengthen and clarify the prohibition.

Federal law has prohibited race discrimination in health care since the passage of Title VI of the Civil Rights Act of 1964. However, Title VI does not apply to all health programs and activities, nor does it apply to all forms of discrimination. Section 1557 therefore fills in a critical gap by extending nondiscrimination protections to people at the intersection of multiple identities and to people throughout the health care landscape.

Proposed Sec. 92.210 would make explicit that covered entities are prohibited from discriminating through the use of clinical algorithms on the basis of race, color, national origin, sex, age, or disability under Section 1557. Many clinical algorithms 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, including for kidney disease, heart failure, and pregnancy-related complications. Similarly, Crisis Standards of Care, which are also driven by clinical algorithms, have often reflected a bias against people living with disabilities, people of color, and older adults.³ The standards typically prioritize care toward patients who are younger and do not have disabilities, excluding or de-prioritizing those who have certain health conditions, those who are presumed unlikely to survive in the intermediate or long term, and those presumed to require greater resources to survive the acute episode of illness. This provision in the Proposed Rule is critical in addressing a prevalent form of systemic discrimination in health care today and should be finalized with changes that would strengthen and clarify the law.

³ See, e.g., Elisabeth Riviello et al., *Assessment of a Crisis Standards of Care Scoring System for Resource Prioritization and Estimated Excess Mortality by Race, Ethnicity, and Socially Vulnerable Area During a Regional Surge in COVID-19*, JAMA NETWORK OPEN (March 15, 2022), <https://perma.cc/J4LN-9D6Y>.

A. The Proposed Rule’s prohibition of discrimination is a necessary step toward preventing racism and other discriminatory conduct in health programs and activities.

The Department properly notes that racial health disparities in the United States are directly attributable to “persistent bias and racism” in the health care system. Both intentional and unintentional race discrimination serve as barriers to care, lead to lower quality care, and drive worse health outcomes for communities of color. Discrimination in health care is often systemic — deeply embedded within the policies, procedures, and practices of covered entities. The Proposed Rule addresses several major drivers of systemic racism, including inadequate antidiscrimination policies and procedures, algorithmic discrimination, and discriminatory health insurance networks. Each of these are a critical step toward addressing the ways in which racism manifests systemically in health care.

As the Proposed Rule notes, for patients of color, trust in their health care providers would increase if these patients could voice their concerns directly to their health care providers, which would in turn improve these patients’ overall health care experiences. However, existing Section 1557 policy and procedure requirements are disjointed, confusing, and ineffective. The Proposed Rule, more broadly, would streamline these requirements by requiring covered entities to adopt and implement nondiscrimination policies against all forms of discrimination, including language and disability access procedures (which can exacerbate the impact of discriminatory health care decision-making as a result of clinical algorithms). The proposed Section 1557 regulations aim to prevent discrimination from occurring in the first place by ensuring covered entities have greater knowledge of and accountability for their obligations under Section 1557.

B. The Proposed Rule addresses racial health disparities by improving disability access.

Improving health care access for people living with disabilities is critical to reducing racial health disparities.⁴ Black people are more likely to have a disability relative to White people in every age group, and according to the CDC, three in 10 American Indian/Alaskan Native people and one in four Black people live with disabilities.⁵

⁴ Improving health care access for people living with disabilities will require close monitoring of value-based assessments and purchasing methodologies that rely on the premise that the benefits or life extension that a treatment brings to the lives of people living with disabilities is worth less than the benefits or life extension for people without disabilities. For example, the Quality Adjusted Life Year (QALY) is a measure that focuses on evaluating how a drug or therapy extends or improves the quality of a person’s life as a way to determine the economic worth of any given treatment. The QALY bases its assessment of quality-of-life improvements and life values on subjective general public assessments, which are deeply influenced by implicit bias and stereotypes about living with disabilities. QALY-based approaches can also fail to consider differences in patient experience that result from “access disparities, structural racism . . . and other social determinants of health” and can reinforce “existing racial bias and . . . unequal access to capital.” KIRSTEN AXELSEN & RAJINI JAYASURIYA, CHARLES RIVER ASSOCIATES, ASSESSING THE VALUE OF MEDICINE FOR DIVERSE PATIENTS: IMPLICATIONS OF A QALY APPROACH FOR HEALTH DISPARITIES 2, 3 (2021), <https://perma.cc/FYT5-N68H>.

⁵ Ctrs for Disease Control and Prevention, *Adults with Disabilities: Ethnicity and Race* (Sept. 16, 2020), <https://perma.cc/ZFT8-A6BE>.

The Americans with Disabilities Act and Rehabilitation Act both prohibit discrimination against people living with disabilities, though Section 1557 strengthens these antidiscrimination protections. First, the Proposed Rule proactively requires covered entities to ensure patients living with disabilities are provided with reasonable accommodations. For example, the Department clarifies that a covered entity must provide modifications in the absence of a request when it had knowledge of an individual's disability or when the individual's disability is obvious. Next, in addition to a number of technical requirements that improve access, Sec. 92.205 of the Proposed Rule requires covered entities to develop written procedures for making reasonable accommodations. This is critical where people of color routinely report feeling unable to convey their medical needs to physicians or having those needs dismissed.

C. The Final Rule should clarify its scope as broadly applying to a range of clinical algorithms.

We support the inclusion of multiple examples cited in the preamble to the Proposed Rule regarding bias from clinical algorithms. The indiscriminate use of race-based clinical algorithms has no place in health care.

In medicine, clinical decision support tools (CDSTs) are intended to help providers 1) keep track of medical research and information and 2) diagnose patients, predict prognoses, and decide on treatment options. However, many aspects of measurements used in clinical medicine are rooted in structural and historical racism. A striking example is that many CDSTs adjust test scores and risk levels based on race, thus exacerbating racial disparities and leaving people of color, especially Black people, unqualified for certain treatments and interventions.⁶ This is a practice known as “race correction.”⁷

There is little to no evidence of biological health differences between races. In fact, according to the American Society of Human Genetics, more genetic differences exist within racial groups as opposed to between racial groups.⁸ While some mutations responsible for conditions tend to affect one particular racial group more frequently, the conditions themselves affect each race the same. Still, patients of color, usually Black patients, are scored differently in many areas related to medical care.

i. Different Types of CDSTs and Algorithms

We support a Final Rule that includes a definition of “clinical algorithm” that appropriately reflects the wide variety and ubiquity of CDSTs and algorithms, including those that produce discriminatory results due to inaccurate and racialized scientific theory and those that produce

⁶ For general background, see MAJORITY STAFF OF H. COMM. ON WAYS AND MEANS, 117TH CONG., FACT VERSUS FICTION: CLINICAL DECISION SUPPORT TOOLS AND THE (MIS)USE OF RACE (2021), <https://perma.cc/25NR-YBY7>.

⁷ In this comment, we have used the terms “race correction” or “race adjustment” since they commonly appear in the literature. However, we urge the Department to adopt alternative language in issuing a final rule, as this vocabulary suggests a white norm to which non-conforming Black people must be “adjusted.”

⁸ American Society of Human Genetics, *ASHG Denounces Attempts to Link Genetics and Racial Supremacy*, 103 ASHG PERSPECTIVE 636 (Nov. 2018), <https://perma.cc/SW92-PKYQ>.

discriminatory results due to using inappropriate proxies for health. Examples of these have been helpfully cataloged in existing scientific literature.⁹

In the Final Rule, the Department should point to the numerous examples of bias, discrimination, and harm caused by covered entities that use or rely on automated decision-making systems (ADS) that may fall outside of what many consider to be traditional clinical algorithms.¹⁰ This would include assessment tools for home and community-based services for both level of care determinations and services allocation that discriminate against groups or deny services needed to maintain community integration, eligibility systems for Medicaid, CHIP, or Marketplace coverage that wrongfully deny or terminate coverage, utilization review practices that are based on financial motives rather than generally accepted standards of care and deny necessary behavioral health services, and service utilization control methods and payment rates that violate mental health parity.¹¹

Discrimination may also result from using technology simply employing a known, faulty design which provides unequal medical benefits on the basis of race or color even in the absence of an intent to discriminate. For example, the pulse oximeter, widely used in medical settings during the COVID-19 pandemic, does not accurately measure oxygen levels of darker-skinned patients and could negatively impact their health care decision-making. As the Boston Globe reported,

A University of Michigan study that captured widespread attention in December 2020 showed that Black patients were three times more likely than white patients to have “hidden hypoxia” — dangerously low oxygen levels that pulse oximeters did not detect. Subsequent studies showed that patients with darker skin receive less supplemental oxygen during stays in the intensive care unit and that hidden hypoxia is a problem in patients with darker skin even when they are not in the ICU. Another study showed darker-skinned patients were less likely to receive cutting-edge COVID-19 treatments.¹²

ii. Different Impacts of CDSTs and Algorithms

⁹ See Darshali A. Vyas, Leo G. Eisenstein, & David S. Jones, *Hidden in Plain Sight — Reconsidering the Use of Race Correction in Clinical Algorithms*, 383 N ENGL J MED 874 (Aug. 2020), <https://perma.cc/P5UP-AVSG>, included as Attachment A.

¹⁰ See National Health Law Program, Comment Letter on Request for Information on the Use of Clinical Algorithms that have the Potential to Introduce Racial/Ethnic Bias into Healthcare (May 4, 2021), <https://perma.cc/M3P4-JX8H>; LYDIA X.Z. BROWN ET AL, CENTER FOR DEMOCRACY AND TECHNOLOGY, CHALLENGING THE USE OF ALGORITHM- DRIVEN DECISION-MAKING IN BENEFITS DETERMINATIONS (Oct. 2020), <https://perma.cc/3QG2-659P>.

¹¹ Elizabeth Edwards, *Preventing Harm from Automated Decision-Making Systems in Medicaid*, National Health Law Program (June 2021), <https://perma.cc/5YWU-SYFJ>; The Kennedy Forum, *A Breakdown of UnitedHealthcare’s Recent Parity Settlements* (Aug. 2021), <https://perma.cc/2WL6-NXLG>.

¹² Usha Lee McFarling, *Fixing a Health Care Device with a Long-Ignored Bias*, BOSTON GLOBE, Sept. 22, 2022, at D1; Usha Lee McFarling, ‘A poster child’ for diversity in science: Black engineers work to fix long-ignored bias in oxygen readings, STAT, Aug. 19, 2022, <https://perma.cc/TQ49-U9FV>.

Racially biased programming of technology or biased use of CDSTs can result in different negative impacts on the health and wellness of vulnerable communities. We share examples below and encourage the Department to finalize and enforce Section 1557 regulations such that all examples would be addressable through Sec. 92.210. Additional information regarding these clinical algorithms may be found in the chart included in Attachment A.

Under-Diagnosis or Underestimation of Illness or Disease Progression & a Failure to Intervene

Lung Function and Spirometry: Historically, doctors held racist assumptions that because Black people have historically displayed lower lung function than white people, their lung function must naturally be lower.¹³ As a result, most spirometry tests adjust for race, either by applying a scaling factor for all people of color or by using population-specific standards. To enable the spirometer, the operator must input the race of the individual.¹⁴ However, applying race correction often results in treatment options for Black patients being reduced or delayed, leading to worse outcomes. While several studies have reported that other racial groups tend to have lower lung capacities than white people, the reasons are likely unrelated to genetics and attributable instead to socioeconomic and environmental factors.¹⁵

¹³ For general background, see LUNDY BRAUN, BREATHING RACE INTO THE MACHINE (2014).

¹⁴ Differential racial classification is programmed into the software of the spirometer. The origins of race correction date prior to the early 19th century. Thomas Jefferson first proposed the idea of lung differences between Black and white people to justify slavery, though he had no empirical evidence. In the 1840s, after the spirometer had been invented, anti-abolitionist Samuel Cartwright built his own spirometer to study difference in lung capacity between enslaved people and white people, in part to further his arguments in favor of slavery. According to Cartwright, Black people had 20% less lung capacity than white people. See generally research authored by Cartwright published in The New Orleans Medical and Surgical Journal in 1851. During the Civil War, Benjamin Apthorp Gould conducted a study that found lung capacity, measured using a spirometer, was lower in Black people than in white people, though he never accounted for height, age, or working and living conditions. By the 1920s, innate differences between the lung function of Black and white people had been assumed to be factually-based.

¹⁵ Spirometry tests commonly assume a reduced lung capacity of Blacks without a corresponding loss of function, and employ a 6-15% correction. There may be support for assuming reduced lung function (Forced Vital Capacity or FVC) comparing Black to white Americans of the same age, height and sex. However, this does not establish a basis in genetics, and may be caused by socio-economic factors and environmental exposures, including exposures during childhood, asthma and incidence of pulmonary infections. Lung growth continues until a person is in their mid-20s, when a slow natural decline begins (possibly influenced by environmental factors, crowded and proper living conditions, exposure to tobacco smoke, etc.). Some have also hypothesized anthropomorphic differences (relative leg length); however, differences in data between races do not reflect different prognostic implications and should not be clinically normalized. In other words, Black people who have lesser lung function (for whatever reason) do not face less risk than white people with similarly impaired lung function. See generally Adam W. Gaffney et al, *Prognostic Implications of Differences in Forced Vital Capacity in Black and Whites US Adults: Findings from NHANES III with Long Term Mortality Follow-Up*, 29 ECLINICAL MEDICINE 1 (2021), <https://perma.cc/BBA9-3VW8>; Meredith C. McCormack et al, *Race, Lung Function and Long Term Mortality in the National Health and Nutrition Examination Survey III*, 205 AM. J. RESPIRATORY & CRITICAL CARE MED 723 (Oct. 2021), <https://perma.cc/Z63J-YCXH>. To the extent this subject continues to be debated, the burden should fall upon proponents of race discrimination to establish, through a

eGFR Scoring to Measure Kidney Function: Historically, doctors held racist assumptions that Black people naturally have greater muscle mass, which means that they have elevated serum creatinine that does not necessarily relate to decreased kidney function.¹⁶ Since elevated creatinine leads to lower eGFR scores, the algorithm was changed to artificially elevate eGFR scores for Black people, which masks the real level of kidney dysfunction in Black people. (Higher eGFR scores indicate lesser impairment of kidney function). However, eGFRs are integral to deciding who is referred to nephrology, administered treatment and medication, and in what dosage, and who is referred for dialysis or placed on transplant lists.¹⁷ This means that race correction causes Black people to become ineligible for, or be delayed in receiving, the care that they need. This is especially disconcerting because according to the National Institute of Diabetes and Digestive and Kidney Diseases, Black people are four times as likely as white people to develop kidney failure. (Again, this is for reasons unrelated to genetics and due more to socioeconomic and environmental factors, and prevalence of hypertension and diabetes, food insecurity and poorer access to medical care, medication and health insurance. Race correction in eGFR testing limiting Black people from receiving proper care on time may also be a factor.)¹⁸

medical consensus, a compelling interest supporting its use, with the use of the discriminatory criteria narrowly tailored to support this compelling interest. See Section II (B) ii, *infra*.

¹⁶ A 1999 study concluded that on average Black people have greater muscle mass, which could account for higher creatinine without a corresponding loss in kidney function. That study was based on three “flawed, small, poor quality studies” published between the 1970s and 1990s; one involved 240 Black and white children, one looked at 40 adults, and one looked at 60 healthy hospital workers. Allison Inserro, *Flawed Racial Assumptions in eGFR Have Care Implications in CKD*, AMERICAN JOURNAL OF MANAGED CARE (October 25, 2020), <https://perma.cc/NFE9-QEWT>. The flawed research justifying racial differentiation in eGFRs continued unquestioned for decades until medical students at the University of Washington questioned this assumption and ignited a long overdue national dialogue. The long delay in questioning the underlying data may derive from “automation bias” and “black box decision making” in which inscrutable predictions mask underlying error and bias but are nonetheless trusted. Gordon J. Apple et. al., *Understanding the Impact of ‘Artificial Intelligence’ on the Future Practice of Law and Medicine*, in HEALTH LAW HANDBOOK 566-603 (2021). CDSTs which promote racial distinctions may both reflect and propagate implicit racial bias and health care disparities. This includes the belief that “you are less at risk because we treat you less often.” For example, Black women have a lower likelihood of being tested for high-risk germline mutations in breast cancer, although their actual risk of those mutations remains similar to other groups. *Id.* at 5. When the data pool is skewed by implicit bias or health care disparities, artificial intelligence constructed around that data will likely also be flawed.

¹⁷ It is important to note that the eGFR is itself an imperfect estimate adopted in lieu of a more accurate measurement, the GFR. Without use of clinical algorithms, the eGFR may vary from the GFR in many instances, according to one study 42% of cases reviewed. Natasha Persaud, *Substantial Discrepancies Found in Estimated vs. Measured GFR in Individuals*, RENAL AND UROLOGY NEWS (July 19, 2022), <https://perma.cc/W49L-QZUM>. Combined with a clinical algorithm, this has the potential to distort even further an actual loss in kidney function.

¹⁸ ESRD rates are 5,855 per million Black Americans compared to 1,704 cases per million whites. Black people represent 13% of the U.S. population but 35% of people on dialysis. Since 2020, eGFR race corrections have begun to be phased out (replaced with CKD-EPI 2021), in many larger hospital networks, Social Security, and professional associations (including the National Kidney Foundation and American Association of Nephrology). This past June, the Organ Procurement and Transplantation Network required network hospitals to use race free eGFR measurements. Hospitals “may” update

Studies have now quantified the harm inflicted upon Black patients by race corrections used in eGFR measurements. One study found that when race correction is removed, one-third of Black patients became reclassified to a more advanced stage of CKD. Of those one-fourth were moved from stage 3 to stage 4. 64 people were moved to an eGFR of less than 20 which is the common threshold for going on a transplant list, but none had had a referral.¹⁹ An assessment of national data between 2015 and 2018 (from NHANES info) showed without a race correction 3.3 million (10.4%) Black Americans would reach a diagnostic threshold for Stage 3 CKD; 300,000 more people would get referrals to nephrologists and 31,000 would become eligible for transplant evaluation and waitlist inclusion.²⁰

False Assumptions of a Higher Risk or Poorer Outcome for the Patient

Some CDSTs and algorithms produce false assumptions of a higher risk or poorer outcome for a patient. For example, the Society for Thoracic Surgeons' Cardiology Guidelines for operative mortality and complications, referenced in Attachment A, adds risk factors which may deter medical intervention. The Vaginal Birth After Cesarean Calculator (VBAC) calculates a lower chance of success of vaginal births after a previous cesarean birth for Black or Hispanic patients.

False Assumptions of a Shorter Survival Period

Some CDSTs and algorithms produce false assumptions about a person's survival period. For example, the Rectal Cancer Survival Calculator, described in Attachment A, assumes a shorter survival period for Black patients with rectal cancer.

False Assumptions of a Lower Risk to the Patient, which discourages or results in lesser testing and screening

Some CDSTs and algorithms produce false assumptions of a lower risk to a patient, which can discourage or result in lesser testing and screening. For example, the American Heart Association Guidelines add three risk points to non-Black patients, further explained in Attachment A. The STONE score assumes a lower risk for ureteral stones among Black patients²¹ and the Urinary

waiting list placement based on past use but presumably are not required to do so. Tenya Clayton & Melodie Hengerer, *Advancing Health Equity in Transplantation: New Waitlist Policies Require Race-Neutral Data*, JDSUPRA (August 4, 2022), <https://perma.cc/B8FZ-PNDB>. The status of other laboratory and medical settings remains unclear, in part because of the lack of transparency surrounding the use of CDSTs.

¹⁹ *Examining Impact of Race in Staging Chronic Kidney Disease*, BRIGHAM AND WOMEN'S HOSPITAL, <https://perma.cc/GX5W-3ZUL> (Accessed Oct. 2, 2022).

²⁰ Jennifer W. Tsai et al, *Evaluating the Impact and Rationale of Race-Specific Estimations of Kidney Function: Estimation from US NHANES, 2015-1018*, 42 ECLINICAL MEDICINE 101197 (Nov. 2021), <https://perma.cc/YHP3-DGPY>. For general background, see Nwamaka D. Eneanya et al., *Health Inequities and the Inappropriate Use of Race in Nephrology*, 18 NATURE REVIEWS NEPHROLOGY 84 (Nov. 2021), <https://perma.cc/74G4-32JZ>. For a concrete example of alleged harm from racially biased clinical algorithms in the life of one kidney patient, see Complaint, Crowley v. Strong Memorial Hospital of the University of Rochester et. al., 2021 WL 4506871 (W.D. N.Y., 2021).

²¹ One commentator notes that neither the AHA nor the STONE score provide any medical rationale for differentiation on the basis of race. Apple et al., *supra* note 16 at 5-6.

Tract Infection (UTI) calculator assumes a lower risk of urinary infections among Black children. The National Cancer Institute Breast Cancer Risk Assessment Tool and the Breast Cancer Surveillance Consortium Risk Calculator both assume a lower risk for breast cancer among Black, Latinx and Asian women. In addition, the Osteoporosis Risk Score calculator and the Fracture Risk Assessment Tool assume a lower risk of osteoporosis and fractures, respectively, among Black women.

D. The Proposed Rule's prohibition of discrimination through the use of clinical algorithms reflects changes that many organizations, researchers, and health care providers have started to adopt already.

Several leading organizations, researchers, and health care providers have voluntarily taken steps to address the use of discriminatory clinical algorithms. For example, the Organ Procurement & Transplantation Network's Board of Directors approved a requirement that "transplant hospitals [] use a race neutral calculation when estimating a patient's level of kidney function."²² This reflects moves that major hospital systems have taken as well.²³ The Organ Procurement & Transplantation Network has taken the additional step to propose a policy that would allow, but not require, waiting time modifications for Black kidney transplant candidates whose placement on the waiting list was affected by race-adjusted eGFR calculations.²⁴

Similar steps can be taken to update the clinical algorithms at question. For example, a popular calculator used to predict the chance of vaginal birth after cesarean was recently updated to remove questions about race and ethnicity.²⁵ However, many note that such corrections don't happen quickly enough²⁶ and that algorithms can be difficult to change since they are often incorporated in widely-used commercial electronic medical systems or remain endorsed by major

²² OPTN Board approves elimination of race-based calculation for transplant candidate listing, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK (June 28, 2022), <https://perma.cc/5EPV-KMCR>.

²³ See, e.g., Jyoti Madhusoodanan, *A Troubled Calculus*, 373 SCIENCE 380 (July 23, 2021), <https://www.science.org/doi/epdf/10.1126/science.373.6553.380> (reporting that University of Washington, Massachusetts General Hospital, and Brigham and Women's Hospital have "dropped race from their eGFR calculations."). This has also been reflective in government policies. See, e.g., Social Security, Program Operations Manual System: Using Laboratory Testing to Evaluate Genitourinary Impairments (Aug. 2022), <https://perma.cc/QNC9-85XL>.

²⁴ Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK (2022), <https://perma.cc/WAK9-MBYG>.

²⁵ Eunice Kennedy Shriver National Institute of Child Health and Human Development, *Maternal-Fetal Medicine Units Network*, <https://perma.cc/NQ2M-5YSE>; William Grobman et al., *Prediction of vaginal birth after cesarean delivery in term gestations: a calculator without race and ethnicity*, 225 AM. J. OBSTETRICS & GYNECOLOGY 664.e1 (Dec. 2021), <https://perma.cc/LA2N-XW3H>; Kaveh Waddell, *Taking Race Out of an Equation for Childbirth*, CONSUMER REPORTS (May 17, 2021), <https://perma.cc/KZ57-CTZ6>.

²⁶ Waddell, *supra* note 25 ("This is a powerful example of what equity work looks like in this space,' says Vyas. 'It shows that tools can remain scientifically rigorous and accurate without race-correcting.' But it didn't need to take this long, she says. 'We had evidence for several years that this tool did not need to use race,' she points out.")

medical societies in their race-adjusted form.²⁷ This highlights a role that the Department should take in ensuring clinical algorithms do not negatively impact people's health care treatment. We support the Department's recognition that it "shares a responsibility in working with recipients, Department components, and Title I entities to identify and prevent discrimination based upon the use of clinical decision tools and technological innovation in health care."²⁸ The Department should proactively work with algorithm developers and users to examine and modify tools that inappropriately adjust results based on reported race or ethnicity. Best practices should be shared widely and publicly to encourage community input and adoption by other covered entities.

E. The Final Rule should include transparency requirements for covered entities using race-conscious clinical algorithms.

The use of clinical algorithms that adjust for race, while widely reported on, remains a mystery to many patients directly impacted by these practices. For example, a reporter sat down with a patient to reconstruct a consultation she had years prior with her obstetrician about vaginal birth after cesarean delivery.²⁹ The patient was surprised to find out that her predicted chance of a successful vaginal birth after cesarean, according to a clinical algorithm, changed 16 percentage points if she indicated her race as Black. Similarly, attendees at a metropolitan-area dialysis support group were surprised to learn that eGFR calculations can adjust for race. Some attendees recalled having seen two eGFR scores reported on their past lab results, but noted more recent labs only reported one. They were unaware that the hospital systems they received care at, as a matter of policy, only recently stopped using race-adjusted eGFRs.

Given the historical backdrop of the health care and public health system failing to protect patients of color, the Department should ensure that patients are informed when their race or ethnicity are used in clinical algorithms that impact their treatment plans. System-wide policies (and changes in policies) should be disclosed to impacted patients as soon as possible so they can work with providers to correct any negative impacts and move their care to a different provider if they wish. Covered entities should be expected to inform patients about underlying adjustments behind algorithms both in person during visits and in writing, using plain, accessible language. Providers of covered entities must share with patients the information they need to better understand how the algorithms in question can impact immediate and future health care decisions within and outside of the covered entity.

This type of disclosure to patients can also ensure that where race and ethnicity *is* collected and used for a permissible reason, that patients are consulted and information is recorded through self-identification.³⁰

²⁷ Madhusoodanan, *supra* note 23.

²⁸ Nondiscrimination in Health Programs and Activities, 87 Fed Reg 47824, 47883 (Aug. 4, 2022).

²⁹ Waddell, *supra* note 25.

³⁰ One retrospective pulmonary testing study revealed that 40% of subjects were classified under the wrong racial or ethnic groupings. R. Dhawan et al., *Impact of Stated Race and Ethnicity on Evaluation of*

F. The Final Rule should allow considerations for demographic variables when they have medical significance, but such tools should be subjected to strict scrutiny.

Race is a social construct, a fabricated social category. As Professor Dorothy Roberts explained, “The very idea that human beings are divided into races is a made-up idea.”³¹ While ancestry can have biological meanings related to DNA, race and skin color, for example, can be a poor proxies for these indicators and instead result in inappropriate assumptions that perpetuate and exacerbate existing health disparities. CDSTs tend to use pseudoscientific notions of biological race to conflate race with biology and/or genetics.³²

As noted above, we generally believe that race is not an appropriate variable to be employed in CDSTs and algorithms. More often than not, efforts to adjust for race can be tied to concerns about variables that can be evaluated individually and not categorically. For example, corrections for skin color may be appropriate for devices such as pulse oximeters whose measurements do not accurately capture health measure due to the amount of melanin in the skin. As another example, it may be appropriate to adjust for on an individualized basis for skin color in tools that assess risk of melanoma, given the protective effects certain levels of melanin can have.³³

Where the proponent of a medical test seeks to use a race classification based upon belief that there are clinical differences which track racialized differences, five important threshold questions should be answered. In each of these instances, a reviewing authority considering the use of such tools under Section 1557 should ask the questions listed below as a part of strict scrutiny analysis, as explained below in Section II (B).

- 1) Does the distinction, however framed, identify a racial/ethnic group which has clinical measurements indicating a higher level of impairment, *but no greater symptoms or more adverse health care outcomes?* If the distinction falling along racial lines only demonstrates that a group overall tests worse because there is more significant illness within that group, then no “adjustment” should be utilized. As described above, this is the problem with the use of race adjustments in spirometry.³⁴

Pulmonary Function Testing, 205 AM. J. RESPIR CRIT CARE MED A2064, <https://perma.cc/Q3BZ-GNL3>. See also Pam Brick, *Spirometry Reference Equations and Children of Mixed Race/Ethnicity*, PULMONOLOGY ADVISOR, Feb. 15, 2022, <https://perma.cc/7KQ6-X7DN>.

³¹ Jacque Smith & Cassie Spodak, *Black or ‘Other’? Doctors may be relying on race to make decisions about your health*, CNN (June 7, 2021) <https://www.cnn.com/2021/04/25/health/race-correction-in-medicine-history-refocused/index.html>.

³² See Nicolle K. Strand, *Racial Myths and Regulatory Responsibility*, 49 J.L. MED. & ETHICS 231, 232, 239 (Summer 2021), <https://perma.cc/27LA-44WC>.

³³ MaryBeth Culp & Natasha Buchanan Lunsford, *Melanoma Among Non-Hispanic Black Americans*, 16 PREVENTING CHRONIC DISEASE 1 (June 2019), <https://perma.cc/WUP6-N9SM>. Even here, the use of a race or color correction would need to be narrowly tailored to a compelling interest. While Blacks are less frequently diagnosed with melanoma, they face a poorer rate of survival. *Id.*

³⁴ Instead of biomedicalizing adversity, omitting the use of race in PFT (pulmonary function tests) is motivating researchers to creatively search for a better understanding of the etiologies of health care

- 2) Can the conclusions as to a group having clinical measurements of illness, with no corresponding symptoms or outcomes of illness, be *reconciled with public health data* regarding illness within that racial/ethnic group? As described above, this is one problem with race adjustment to eGFR scores, where Blacks are treated as able to tolerate higher creatinine and lower eGFR scores without corresponding loss of kidney function, at the same time that it is well established that Blacks are four times more likely to experience chronic kidney disease (largely for socio-economic and environmental reasons and other factors related to health disparities).
- 3) Is race *the best measurement* of the underlying biological cause of any purported health distinction being framed along racial/ethnic lines? Here again eGFR tells the story of a measurement gone wrong. The underlying medical claim (which has now been reputed and understood to be based on small, flawed studies) is that Blacks overall have more muscle mass resulting in the excretion of more creatinine without corresponding loss of kidney function, and therefore a race correction is necessary. Even if this were true (and it is not), race is being used as a crude proxy for muscle mass. The white bodybuilder would have an inaccurately high measurement of loss of kidney function and a thin, frail Black person would have an inaccurately low measurement (by as much as a 20% undercount) of loss of kidney function. Even a crude self-reported clinical measurement of muscle mass (e.g., on a three point scale) would seem to be more accurate.
- 4) Is the proponent of the distinction using race *able to carry the burden of strict scrutiny by setting forth a compelling interest established using a consensus of objective medical evidence*? In addition, is the use of the race distinction *narrowly tailored to support the stated compelling interest*?
- 5) If a racially differentiated CDST may be justified based on all of the above, *is the provider employing the most accurate means of determining race/ethnicity*, taking into account genetic diversity that is greater within racial groupings than between them? (Please see discussion below).

Only if all five of these factors are able to be established by the proponent, should a racially differentiated CDST be permitted. In that scenario, *the covered provider using the CDST should also be required to provide notice to the patient* that a racially differentiated CDST has been used. This notice must be included in any lab report or related correspondence sent by the provider, must include the percentage by which any measurement has been altered because of race/ethnicity and a short description of the reason for the racially differentiated CDST, and must explain that the provider is available to answer further questions upon request.³⁵

disparities. Joseph L. Wright et al., *Eliminating Race-Based Medicine*, 150 PEDIATRICS 1 (June 2022), <https://perma.cc/96P6-W2QG>.

³⁵ This list shares components with suggestions offered in Vyas et al, *supra* note 9 at 874 (“When developing or applying clinical algorithms, physicians should ask three questions: Is the need for race

G. The Final Rule should allow for considerations of race that address health disparities.

We support the Administration’s prioritization of addressing health disparities. Our objections to race correction should not be misunderstood as any limitation on the importance of health providers collecting information about health outcome disparities on a community level and attempting to eliminate gaps in availability of services or quality of care. Providers should regularly track voluntary information about sex, gender, race, ethnic origin, disability,³⁶ income, among others, to ensure that services are reaching historically underserved people. Efforts to rebalance existing health care disparities in staffing and resources should not be considered discrimination in violation of Section 1557. Providers should also be free to exercise clinical judgment and adjust a clinical score if doing so would more accurately represent the patient’s health or risk of illness (including but not limited to socio-economic factors, environmental exposures, occupational hazards, chronic stress, or past or present health disparities).

H. The Final Rule should explicitly prohibit covered entities from employing algorithms that categorically deny or restrict access to gender-affirming care.

We urge the Department to make clear that covered entities are not permitted to employ algorithms that use demographic variables to add barriers to or deny access to gender-affirming care. Such algorithms would include coding used by insurers that rely on a person’s recorded sex to automatically deny or otherwise stall claims for gender-affirming care (such as hormone therapy) or other care typically provided to individuals with a different sex marker (such as birth control).³⁷ This would also include clinical guidelines or prior authorization criteria that exclude the coverage of certain procedures due to an individual’s recorded sex, gender identity, or gender dysphoria.³⁸ While such discrimination might also be prohibited in proposed Sec. 92.206 and 92.207, given the ubiquity of such discrimination to this day, we believe it appropriate to clarify in Sec. 92.210 as well.

II. We support the Department’s proposal to ensure compliance across all segments of the health care system and related activities, consistent with law, and call for agency commitments that support and enable robust enforcement.

correction based on robust evidence and statistical analyses (e.g., with consideration of internal and external validity, potential confounders, and bias)? Is there a plausible causal mechanism for the racial difference that justifies the race correction? And would implementing this race correction relieve or exacerbate health inequities?”).

³⁶ As one clinician explained, “If you look at a population level, what you’re looking for is not for the evidence of race as a biological construct. You’re looking for the impact of racism on populations and that’s the difference: It’s racism not race.” Lisa Gillespie, *How Racist is Your Algorithm?*, MEDSCAPE (July 4, 2022), <https://perma.cc/WDH8-PU3X> (quoting Nathan Chomilo).

³⁷ See, e.g., New York State Department of Financial Services, Insurance Circular Letter No. 13 (June 28, 2020) (“Issuers are prohibited from automatically denying claims for transgender individuals because the gender or sex with which the individual identifies does not match the gender or sex of someone to whom those services are typically provided.”) <https://perma.cc/Y28D-YKAS>.

³⁸ *Id.*

Given the enormity of discriminatory conduct in health care, Section 1557 requires rigorous enforcement in order to ensure communities of color and other marginalized groups can access quality health care. We therefore support a Final Rule that properly identifies the scope of covered entities and strengthens private enforcement of the law. We also urge the Department to commit the resources necessary for proactive and effective leadership that will be necessary to prohibit such discrimination.

A. The Final Rule should identify the proper scope of Section 1557 necessary for anti-discrimination enforcement across health care programs and activities.

The 2020 Final Rule offers inaccurate and restrictive interpretations of the law and the types of activities and entities that must comply with Section 1557, limiting the Department's enforcement efforts in preventing discrimination. We offer strong support for the Department's clarification in the Proposed Rule that Section 1557 both provides an "independent basis for regulation of discrimination in covered health programs and activities" and is applicable to an expansive range of "health programs and activities," including those administered by the Department itself, as well as any health insurance products offered by corporate entities, any part of which receives federal financial assistance.

We also commend the Department's important clarification that Section 1557 applies to Medicare Part B. For decades, the Department erred in determining that Medicare Part B payments were not "federal financial assistance." As noted in one article, "[a]s a result, a hospital could pass Title VI certification and, through the racially exclusionary admission practices of its medical staff, remain segregated." Moreover, many patients have been unable to sue their doctors for discrimination on the basis of race, color, or national origin under Title VI. The Proposed Rule addresses this problem by applying a reasonable interpretation of "federal financial assistance" and clarifying that Medicare Part B providers are covered entities under Section 1557.

All of these clarifications in the Proposed Rule are an important step in addressing racism and other forms of discrimination in all health care settings by ensuring the Department has broad enforcement authority.

B. The Final Rule should clarify the legal standards to be applied in the context of discrimination "through the use of" clinical algorithms.

The Final Rule should clarify the legal standards to be applied in the context of discrimination "through the use of" clinical algorithms. At least three distinct questions of legal interpretation warrant regulatory clarification. First, the Final Rule should clarify the principles to determine if a given covered entity's decision-making practice falls within the scope of this rule. Second, the Final Rule should address what constitutes impermissible discrimination where a covered entity employs an algorithm that it knows (or should know) to use variables overtly taking a protected status (race, race, color, national origin, sex, age, or disability) into account. Last, the Final Rule should address what constitutes impermissible discrimination where a covered entity employs an algorithm that has a disparate impact on a group with protected status. With respect to each of these questions, the Final Rule should clarify that the covered entity has the burden of

proving that its use of a given clinical algorithm did not result in a discriminatory health care decision.

i. Responsible Entity

The first question of legal interpretation warranting clarification in the final rulemaking focuses on the connection between the covered entity and the problematic clinical algorithm. Modern clinical practice encompasses a vast array of decision-making tools, some of which are purposefully acquired and used by providers in their everyday work, and some of which may be more passively incorporated into diagnostic processes considered to be the standard of care by individual providers. The Final Rule should establish a broad scope of responsibility for all algorithmic tools within this spectrum. Such an interpretation will spur providers, provider associations, guideline-making groups, researchers, quality assurance and certification agencies, insurers, insurer groups and other large organizations connected to medical decision-making to undertake considered scrutiny of their tools and methodologies intended to root out systemic discrimination embedded in the status quo.

The preamble to the Proposed Rule describes the principle connecting covered entities to the tools they employ as follows:

While covered entities are not liable for clinical algorithms that they did not develop, they may be held liable under this provision for their decisions made in reliance on clinical algorithms. . . . By over-relying on a clinical algorithm in their decision-making, such as by replacing or substituting their own clinical judgment with a clinical algorithm, a covered entity may risk violating Section 1557 if their decision rests upon or results in discrimination.³⁹

Liability in this description appropriately aligns the locus of responsibility with the party responsible for the medical decision itself, regardless of the tools employed to reach it. To the extent that an individual patient is compromised as a result of a given decision of care, the covered entity should be held responsible if a discriminatory tool was a causal part of the decision-making process. This remains true whether the covered entity is responsible for the origin of the problematic tool or not. The determining factor is that a covered entity has control over the means by which it reaches health care decisions.⁴⁰

Such a standard appropriately encourages covered entities to take responsibility for the component parts of their decision-making methodologies, and incentivizes self-audits at both the provider level and field level that will be the most efficient path to preventing systemic discriminatory decision-making in the age of ever more automated medicine. It also appropriately

³⁹ Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. at 47880.

⁴⁰ Conversely, the author of a discriminatory tool would not be subject to Section 1557 liability to the extent that it is not proximately responsible for an individual health care decision made in reliance on such a tool. This control principle will incentivize upstream scrutiny by those entities and individuals who are directly responsible for individual health care decisions.

tracks the standard set forth in the Proposed Rule with respect to third party administrators. That standard makes covered entities responsible for decisions that they have control over. “We also newly address that a third party administrator may be liable under this part when it is responsible for the underlying discriminatory plan design feature that is adopted by a group health plan.”⁴¹ Just as a covered third party administrator may be liable for insurance plan design for which it exercises control, so too should a covered entity be held responsible for component parts of health care decision-making that it has the ability to incorporate or exclude from its own methodology as it sees fit.

ii. Clinical Algorithms that Directly Employ Protected Class Characteristics Require Use of Strict Scrutiny

The second question of legal interpretation presented by the proposed Section 92.210 arises where the target clinical algorithm directly employs protected class characteristics as an input used for analysis. Many such instances are described above and cited in the Proposed Rule and its footnotes. For example, footnote 547 of the Proposed Rule, 87 Fed. Reg. at 47880, cites to a 2020 New England Journal of Medicine article that compiles 13 widely used clinical tools that expressly consider race.⁴² Stated more broadly, the question in such circumstances is when the use of such tools constitutes “discrimination.” This question, in turn, raises issues of both harm and intent.

The Final Rule should acknowledge that not every use of protected class characteristics in health care decision-making constitutes discrimination. For example, the Proposed Rule cites evidence that understanding differences in health and health care by race and ethnicity remains important for understanding and addressing disparities that stem from systemic racism and inequities.⁴³ By contrast, health care decision-making that directly employs protected class characteristics can cause great harm to patients. For example, some state Medicaid programs continue to employ a prior authorization protocol that excludes individuals with active substance use disorder from coverage for direct-acting antiviral treatment for hepatitis C.⁴⁴ Where an individual who is disabled by substance use disorder is prevented from accessing treatment by a covered entity acting pursuant to such a policy, Section 1557 liability should lie. The difference between these two scenarios is in the injury that is effected by the clinical tool.⁴⁵

⁴¹ Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. at 47876.

⁴² Vyas et al., *supra* at note 9 at Table 1.

⁴³ Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. at 47881 n. 557 (citing Michelle Tong & Samantha Artiga, Kaiser Family Foundation, Issue Brief: Use of Race in Clinical Diagnosis and Decision Making: Overview and Implications (Dec. 9, 2021)).

⁴⁴ See Robert Greenwald, Phil Waters, & Sarah Cayer, *Enforcement of Legal Remedies to Secure Hepatitis C Virus Treatment With Direct-Acting Antiviral Therapies in Correctional Facilities and Medicaid Programs*, 135 PUBLIC HEALTH REPORTS 44S (2020), <https://perma.cc/NSH6-5CSZ>.

⁴⁵ Similarly, the DOJ’s Title VI Manual acknowledges that considerations of race may be permissible in order to “remedy the effect of prior discrimination.” Therefore, the finalized rule should clarify that it would be permissible for entities to use race in decisions about how to provide appropriate treatment to those previously denied treatment due to biased tests and algorithms. For example, this might include

Where such harm is present, the inquiry naturally turns to the question of intent. The Final Rule should make clear that a finding of liability in such instances should not turn on whether the covered entity “intended” to discriminate; where such tools are used, the covered entity has a duty to understand the nature of its own decision-making. Stated differently, a covered entity either knows or should know that it is employing an algorithm in its own decision-making that directly takes into account a protected class characteristic. For that reason, intentional use of such clinical tools justifies the application of disparate treatment analysis. In such circumstances, the Office of Civil Rights should make clear that the rubric governing race-based motives applies. “The Supreme Court has held that strict judicial scrutiny applies to a governmental entity’s intentional use of race . . . race may be used when the government has a compelling interest supporting its use, and that use is narrowly tailored to support the stated compelling interest.”⁴⁶ Similar standards should apply when a covered entity uses a clinical algorithm directly using other protected characteristics as well. The proper inquiry is not whether a covered entity intended to discriminate; rather, *liability lies where the covered entity cannot carry its burden of showing that its use of clinical tools directly employing protected characteristics is narrowly tailored to achieve a compelling interest that it cannot otherwise reach.* A list of relevant considerations to be employed in such an inquiry is set forth above in Section I (F).

The Proposed Rule also requests comment on what possible defenses a covered entity may have when using a clinical algorithm in its decision-making that results in discrimination. 87 Fed. Reg. at 47884. The Final Rule should account for efforts by covered entities to defend themselves by analogizing the standard applicable to Section 1557 to civil rights doctrines articulating the highest burdens of proof. For example, in various contexts courts have required a showing of discriminatory animus in order to make out a claim of discrimination using methods of proof such as the *Arlington Heights*⁴⁷ or the *McDonnell Douglas* burden-shifting framework.⁴⁸ Such standards are a mismatch where the protected class characteristic is expressly built into the challenged policy or practice. Where the protected characteristic is explicitly stated, intent is proven as a matter of law and is thus not at issue.⁴⁹ The final rule should clarify that the appropriate standard for evaluating these policies is strict scrutiny, rather than *Arlington Heights* or *McDonnell Douglas* burden-shifting. This means that the burden should fall upon the proponents of race discrimination

readjusting the placement on a transplant waiting list for kidney patients whose eGFR scores had been erroneously elevated by 16-20% based solely on race.

⁴⁶ U.S. Department of Justice, Civil Rights Division, TITLE VI LEGAL MANUAL 25 (citing *Parents Involved in Cmtv. Schs. v. Seattle Sch. Dist. No. 1*, 551 U.S. 701, 720 (2007)), <https://perma.cc/8APK-YMT7> [hereinafter TITLE VI LEGAL MANUAL].

⁴⁷ *Vill. of Arlington Heights v. Metro. Housing Dev. Corp.*, 429 U.S. 252, 266-68 (1977).

⁴⁸ *McDonnell Douglas Corp. v. Green*, 411 U.S. 792 (1973); *Guardians Ass'n v. Civil Serv. Comm'n of New York City*, 463 U.S. 582, 584 (1983) (White, J.) (“I conclude that ... in the absence of proof of discriminatory animus, compensatory relief should not be awarded to private Title VI plaintiffs”).

⁴⁹ TITLE VI MANUAL at 25 (“A recipient’s express or admitted use of a classification based on race, color, or national origin establishes intent without regard to the decision-makers’ animus or ultimate objective.”)

to establish a compelling interest supporting its use, through a consensus established in clinical literature.⁵⁰

The rule should further clarify that, under strict scrutiny, entities must show that the use of the protected class characteristic is narrowly tailored to serve a compelling government interest.⁵¹ This means that race should not be used in an imprecise or speculative manner as a poor proxy for an underlying variable which could be readily determined, such as muscle mass or torso or leg measurements.

Instances where a covered entity knows or should know that its health care decision-making tools employ protected class characteristics are appropriately analogized to circumstances where a third-party creates a hostile work environment. In such cases, a defendant is found liable where it knows or should know of the harassing behavior, and fails to take prompt and effective steps reasonably calculated to end the harassment, eliminate the hostile environment, prevent its recurrence, and address its effects.⁵² When entities employ algorithms and decision-making tools that use protected class characteristics, the entities know, or reasonably should know, that they are engaging in this practice. Thus, just as is required when a hostile work environment is created, entities should take prompt and effective steps reasonably calculated to end the policy, prevent its recurrence, and address its effects. Whatever standard employed by the Final Rule, it should hold covered entities responsible for the tools and methodologies that they choose to use by requiring it to carry the burden of proof to justify any clinical algorithm that directly employs protected class characteristics.

iii. Clinical Algorithms that have an Adverse Effect on Protected Classes

Scholars note that “[p]rivate parties play a more important role in enforcing regulatory law in the U.S. legal system than in other advanced economies,” and that private parties “bring significant additional resources to the task of enforcing public law . . . [as] state and federal agencies are chronically under-resourced and overworked.”⁵³ Indeed, since Fiscal Year 2016, civil rights case receipts have increased by 252%, leaving the Department’s Office for Civil Rights with a backlog of complaints.⁵⁴ We therefore offer strong support for the Proposed Rule’s clarification

⁵⁰ See Patrolment’s Benevolent Ass’n of New York v. City of New York, 310 F. 3d 43, 53 (2nd Cir. 2002) (requiring that the reason for the racial classification must be “substantiated by objective evidence” and rejecting conjecture or speculation) (citations omitted).

⁵¹ See TITLE VI LEGAL MANUAL at 25 (citing Parents Involved in Cmty. Schs. v. Seattle Sch. Dist. No. 1, 551 U.S. 701, 720 (2007)).

⁵² Davis Next Friend LaShonda D. v. Monroe Cnty. Bd. of Educ., 526 U.S. 629, 629–30 (1999).

⁵³ Michael Sant’Ambrogio, *Private Enforcement in Administrative Courts*, 72 Vanderbilt Law Review 425 (2019), <https://perma.cc/KPS7-NJ2F>.

⁵⁴ DEPT. OF HEALTH AND HUMAN SERVICES, FISCAL YEAR 2023: BUDGET IN BRIEF 154 (2022), <https://perma.cc/DYT9-HQUL>.

that a private right of action exists for all claims of discrimination under Section 1557, as judicial enforcement is necessary to protect patients and other beneficiaries from discriminatory conduct.⁵⁵

However, we are concerned that the Proposed Rule suggests private litigants are unable to bring disparate impact claims in court. Race discrimination in health care may not manifest as public signs barring people of color or doctors who openly refuse to treat patients of color. Without a disparate impact theory of liability, a private right of action will ring hollow for people of color and other systemically marginalized groups. Additionally, in an era where artificial intelligence and automated decision-making are increasingly responsible for resource allocation, recognition of disparate impact liability is critical. The 2019 Obermeyer study cited in the Proposed Rule examined UnitedHealth's use of a complex algorithm to target enhanced resources to those patients predicted to be at greater health risk.⁵⁶ By reviewing data associated with the algorithm's inputs, outputs, and outcomes, the researchers concluded that eligibility for high risk care management was infected with racial bias.⁵⁷ Importantly, race was not explicitly taken into account by the algorithm. Eligibility was based on a prediction of health care costs rather than illness.⁵⁸ However, systemic, pre-existing inequality in access to care means that less money was generally spent caring for Black patients than their white counterparts. As a result, Black patients at a given risk score were considerably sicker than white patients, and white patients were disproportionately deemed eligible for enhanced care management and resources. This is just one example of a discriminatory effect resulting from a protocol that does not expressly invoke any protected class characteristic. The algorithm examined in this study is not unique. "Rather, it is emblematic of a generalized approach to risk prediction in the health sector, widely adopted by a range of for- and non-profit medical centers and governmental agencies."⁵⁹ In recognition of the increasing use of such tools, the Final Rule should expressly reach instances of discrimination that do not employ protected class characteristics, yet yield discriminatory effects.

The Proposed Rule seeks comment on its proposed approach "to preserve—and not expand—the longstanding treatment of disparate impact in the referenced statutes' implementing regulations."⁶⁰ Because of the dramatic expansion of algorithmic decision-making in health care, it is critical that the Final Rule expressly reaffirm the interpretation established by the 2016 Final Rule recognizing claims for disparate impact discrimination on the basis of any of the criteria enumerated in the legislation.⁶¹ Government actors and covered entities alike have an interest in

⁵⁵ Recently, the Supreme Court recognized in *Cummings v. Premier Rehab Keller, P.L.L.C.* that it is "beyond dispute that private individuals may sue to enforce" Section 1557.

⁵⁶ Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. at 47880 n. 547 (citing Ziad Obermeyer et al., *Dissecting racial bias in an algorithm used to manage the health of populations*, 366 SCIENCE 447 (2019), <https://doi.org/10.1126/science.aax2342>).

⁵⁷ Obermeyer et al., at 1.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. at 47860.

⁶¹ Such an interpretation would allow for coherent treatment of intersectional discrimination. Such discrimination occurs where more than one protected class is implicated. "[W]here two bases of discrimination exist, the two grounds cannot be neatly reduced to distinct components." *Gorzynski v. JetBlue Airways Corp.*, 596 F.3d 93, 110 (2d Cir. 2010). "[T]he attempt to bisect a person's identity at the intersection of race and gender often distorts or ignores the particular nature of their experiences"

uniformity of civil rights enforcement.⁶² Amending each of the constituent statutes referred to in Section 1557, Congress passed the Civil Rights Restoration Act in 1988. In so doing, Congress intended that Title VI and its progeny “be given the broadest possible interpretation” so that federal agencies may “assist in the struggle to eliminate discrimination from our society by ending federal subsidies of such discrimination.”⁶³ The statute here at issue states that “[t]he enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.”⁶⁴ The statutory term “available under” is particularly pertinent to encompass regulatory interpretations associated with each of the four preexisting statutes. Various courts have assumed that federal agencies may proscribe some conduct that has a disparate impact on a protected class in the case of each of the pre-existing civil rights statutes referenced in Section 1557.⁶⁵

including a specific set of stereotypes and assumptions not shared by all persons of that race or gender.” *Id.* (quoting *Lam v. Univ. of Haw.*, 40 F.3d 1551, 1562 (9th Cir.1994)).

⁶² By way of example, Executive Order 12250 directs the Attorney General to “coordinate the implementation and enforcement by Executive agencies” of *Title VI, Title IX, and Section 504* as well as “any other provision of Federal statutory law which provides, in whole or in part, that no person in the United States shall, *on the ground of race, color, national origin, handicap, religion, or sex*, be excluded from participation in, be denied the benefits of, or be subject to discrimination under any program or activity receiving Federal financial assistance.” Exec. Order No. 12250, 45 Fed. Reg. 72995 (Nov. 4, 1980) (emphasis added).

⁶³ S. REP. NO. 100-64 at 7 (1987), *as reprinted in* 1988 U.S.C.C.A.N. at 9.

⁶⁴ 42 U.S.C. § 18116(a).

⁶⁵ See *Alexander v. Sandoval*, 532 U.S. 275, 281 (2001) (Title VI) (“[W]e must assume for purposes of deciding this case that regulations promulgated under § 602 of Title VI may validly proscribe activities that have a disparate impact on racial groups. . . .”); *Horner v. Ky. High Sch. Athletic Ass'n*, 206 F.3d 685, 692 (6th Cir. 2020); *Roberts v. Colorado State Bd. of Agric.*, 998 F.2d 824, 833 (10th Cir. 1993) (Title IX) (“the district court did not err here in failing to require proof of discriminatory intent”); 34 C.F.R. § 106.21(b)(2) (Title IX regulation prohibiting admission policies with a “disproportionately adverse effect on persons on the basis of sex unless the use of such test or criterion is shown to predict validly success in the education program or activity in question and alternative tests or criteria which do not have such a disproportionately adverse effect are shown to be unavailable.”); *Katz v. Regents of the Univ. of California*, 229 F.3d 831, 835 (9th Cir. 2000) (interpreting the sister statute to the Age Discrimination Act) (“in this circuit, disparate impact claims are cognizable under the ADEA.”); *Alexander v. Choate*, 469 U.S. 287, 301 (1985) (Section 504) (“To determine which disparate impacts § 504 might make actionable, the proper starting point is *Southeastern Community College v. Davis*, 442 U.S. 397 (1979) . . . The balance struck in *Davis* requires that an otherwise qualified handicapped individual must be provided with meaningful access to the benefit that the grantee offers.”); *Robinson v. Kansas*, 295 F.3d 1183, 1186-87 (10th Cir. 2002) abrogated on other grounds as recognized by *Arbogast v. Kansas, Dept. of Lab.*, 789 F.3d 1174 (10th Cir. 2015) (continuing to recognize disparate impact liability under Section 504 based on the differing aim and context of the Rehabilitation Act). Of course, countervailing judicial authority exists on this question as well, especially with regard to private enforcement based on disparate impact theory. *Kamps v. Baylor Univ.*, 592 F. App'x 282 (5th Cir. 2014) (“The [Age Discrimination Act] does not prohibit policies that have a disparate impact.”); *see also Doe v. BlueCross BlueShield of Tennessee, Inc.*, 926 F.3d 235, 240–42 (6th Cir. 2019).

For these reasons, there is ample justification to interpret Section 1557 broadly and uniformly proscribe clinical algorithms that yield a disparate impact, regardless of the grounds of discrimination at issue.

C. The Final Rule must be supported by a commitment of resources dedicated to proactively identifying discriminatory algorithms and other CDSTs.

It will be imperative for the federal government to dedicate robust financial and staff resources to identify clinical algorithms that are discriminatory. The United States health care system – in delivery, research, and financing, among others – has a troublesome history and relationship with vulnerable communities and the enforcement of such civil rights protections cannot fall primarily on patients filing complaints with the Office of Civil Rights. Patients may not be aware of when or how algorithms may affect their course of care, and may not be privy to an algorithm’s underlying design and development. Without this knowledge, they may be unable to file a complaint or unaware that they can or should.

Furthermore, discriminatory algorithms are often used in time-sensitive situations and may not be adequately addressed by the Office of Civil Rights’ current complaint process. Historically, complaints filed with the Office of Civil Rights can take months of investigation, with some complaints closed without decision after over 2 years.⁶⁶ Many of the algorithms already identified in the Notice of Proposed Rulemaking have direct and immediate implications for people living with chronic and emergent health conditions (e.g., positions on transplant waiting lists), leaving a lengthy complaint process unsuited to addressing this type of discrimination.

CONCLUSION

The Proposed Rule holds promise as a significant step toward addressing discrimination against people of color and persons with disabilities, and should be finalized with serious consideration given to the issues raised above.

Thank you for the opportunity to comment. Our comments include numerous citations to supporting research, in many cases including direct links for HHS’ benefit in reviewing our comments. We direct HHS to each of the sources cited and we request that the full text of each source, along with the full text of our comments be considered part of the administrative record in this matter for purposes of the Administrative Procedure Act.

⁶⁶ For example, in 2016 CHLPI, along with partners in seven states, filed fourteen formal administrative complaints with HHS’ Office of Civil Rights. See *CHLPI Launches Groundbreaking Campaign to Enforce Health Care Rights for People Living With HIV In Seven States*, CHLPI BLOG (2016), <https://perma.cc/ZP5K-MRBR>. Complainants received minimal information about the status of complaints until 2019, when at least nine were closed without conclusion because the insurer ceased offering QHPs on the Marketplace. Efforts to obtain information through the Freedom of Information Act relevant to community-led enforcement have been ineffective.

Please contact Maryanne Tomazic at mtomazic@law.harvard.edu and Richard Glassman at rglassman@dlc-ma.org if we can be of assistance.

This letter is submitted by the undersigned individuals, groups, and organizations:

Center for Health Law and Policy Innovation (<https://chlpi.org>)

The Center for Health Law and Policy Innovation (CHLPI) is a clinical teaching program of Harvard Law School. CHLPI advocates for legal, regulatory, and policy reforms in health and food systems, with a focus on improving the health of people with lower income, people of color, LGBTQ+ communities, and people living with chronic health conditions. CHLPI works at all levels of government to monitor, analyze, and respond to regulations, laws, and policies that impact access to health care and social services. We also work to ensure stakeholders have the tools, research, and recommendations they need to support health care reform and progressive policy proposals.

Disability Law Center (<https://www.dlc-ma.org>)

The Disability Law Center (DLC) is a 501(c)(3) nonprofit corporation, functioning as a public interest law organization, and as the Protection and Advocacy (P&A) system for the Commonwealth of Massachusetts. Our mission is to provide advocacy on disability issues that promote the fundamental rights of all people with disabilities to participate fully and equally in social and economic life of the Commonwealth. This includes representing individuals with disabilities in civil rights matters arising in the health care sector and addressing related systemic issues. We have a particular interest in intersectional issues of disability and race and assisting clients who are persons with disabilities who are multiply marginalized through their identification with other protected classes. One aspect of our role as the P&A is the authority to engage with policymakers on issues of concern to our constituents.

Disability Policy Consortium (<https://www.dpcma.org/>)

Disability Policy Consortium is a disability rights advocacy and research organization based in Boston, MA. Our mission is to bring the voice of people with disabilities to the table on key issues, to support the health of our community through participatory research and expert policy analysis, and to empower grassroots disability leaders to transform their communities. Our credo is "About Us, By Us"--the belief that when decisions are made about people with disabilities, people with disabilities should be the ones making them.

RDMH Dialysis Patient Support Group - Barbara Gibbs, RN Founder/President

Roxbury, Dorchester, Mattapan, and Hyde Park are in the inner city of Boston, Massachusetts. There are high percentages of people of color in these neighborhoods.

Center for Public Representation (<https://www.centerforpublicrep.org/>)

The Center for Public Representation (CPR) is a public interest law firm that has assisted people with disabilities for more than 40 years. CPR uses legal strategies, systemic reform initiatives, and

policy advocacy to enforce civil rights, expand opportunities for inclusion and full community participation, and empower people with disabilities to exercise choice in all aspects of their lives. CPR is both a statewide and a national legal backup center that provides assistance and support to public and private attorneys representing people with disabilities in Massachusetts and to the federally funded protection and advocacy programs in each of the States. CPR has litigated systemic cases on behalf of persons with disabilities in more than 20 states and submitted amici briefs to the United States Supreme Court and many courts of appeals in order to enforce the constitutional and statutory rights of persons with disabilities, including the right to be free from discrimination under the Americans with Disabilities Act, Section 504 of the Rehabilitation Act, and other laws.

Attachment A

MEDICINE AND SOCIETY

Debra Malina, Ph.D., *Editor***Hidden in Plain Sight — Reconsidering the Use of Race Correction in Clinical Algorithms**

Darshali A. Vyas, M.D., Leo G. Eisenstein, M.D., and David S. Jones, M.D., Ph.D.

Physicians still lack consensus on the meaning of race. When the *Journal* took up the topic in 2003 with a debate about the role of race in medicine, one side argued that racial and ethnic categories reflected underlying population genetics and could be clinically useful.¹ Others held that any small benefit was outweighed by potential harms that arose from the long, rotten history of racism in medicine.² Weighing the two sides, the accompanying Perspective article concluded that though the concept of race was “fraught with sensitivities and fueled by past abuses and the potential for future abuses,” race-based medicine still had potential: “it seems unwise to abandon the practice of recording race when we have barely begun to understand the architecture of the human genome.”³

The next year, a randomized trial showed that a combination of hydralazine and isosorbide dinitrate reduced mortality due to heart failure among patients who identified themselves as black. The Food and Drug Administration granted a race-specific indication for that product, BiDil, in 2005.⁴ Even though BiDil’s ultimate commercial failure cast doubt on race-based medicine, it did not lay the approach to rest. Prominent geneticists have repeatedly called on physicians to take race seriously,^{5,6} while distinguished social scientists vehemently contest these calls.^{7,8}

Our understanding of race and human genetics has advanced considerably since 2003, yet these insights have not led to clear guidelines on the use of race in medicine. The result is ongoing conflict between the latest insights from population genetics and the clinical implementation of race. For example, despite mounting evidence that race is not a reliable proxy for genetic difference, the belief that it has become embedded, sometimes insidiously, within medical practice. One

subtle insertion of race into medicine involves diagnostic algorithms and practice guidelines that adjust or “correct” their outputs on the basis of a patient’s race or ethnicity. Physicians use these algorithms to individualize risk assessment and guide clinical decisions. By embedding race into the basic data and decisions of health care, these algorithms propagate race-based medicine. Many of these race-adjusted algorithms guide decisions in ways that may direct more attention or resources to white patients than to members of racial and ethnic minorities.

To illustrate the potential dangers of such practices, we have compiled a partial list of race-adjusted algorithms (Table 1). We explore several of them in detail here. Given their potential to perpetuate or even amplify race-based health inequities, they merit thorough scrutiny.

CARDIOLOGY

The American Heart Association (AHA) Get with the Guidelines—Heart Failure Risk Score predicts the risk of death in patients admitted to the hospital.⁹ It assigns three additional points to any patient identified as “nonblack,” thereby categorizing all black patients as being at lower risk. The AHA does not provide a rationale for this adjustment. Clinicians are advised to use this risk score to guide decisions about referral to cardiology and allocation of health care resources. Since “black” is equated with lower risk, following the guidelines could direct care away from black patients. A 2019 study found that race may influence decisions in heart-failure management, with measurable consequences: black and Latinx patients who presented to a Boston emergency department with heart failure were less likely than white patients to be admitted to the cardiology service.²⁴

Cardiac surgeons also consider race. The Society of Thoracic Surgeons produces elaborate calculators to estimate the risk of death and other complications during surgery.¹⁰ The calculators include race and ethnicity because of observed differences in surgical outcomes among racial and ethnic groups; the authors acknowledge that the mechanism underlying these differences is not known. An isolated coronary artery bypass in a low-risk white patient carries an estimated risk of death of 0.492%. Changing the race to “black/African American” increases the risk by nearly 20%, to 0.586%. Changing to any other race or ethnicity does not increase the estimated risk of death as compared with a white patient, but it does change the risk of renal failure, stroke, or prolonged ventilation. When used preoperatively to assess risk, these calculations could steer minority patients, deemed to be at higher risk, away from surgery.

NEPHROLOGY

Since it is cumbersome to measure kidney function directly, researchers have developed equations that determine the estimated glomerular filtration rate (eGFR) from an accessible measure, the serum creatinine level. These algorithms result in higher reported eGFR values (which suggest better kidney function) for anyone identified as black.^{11,25} The algorithm developers justified these outcomes with evidence of higher average serum creatinine concentrations among black people than among white people. Explanations that have been given for this finding include the notion that black people release more creatinine into their blood at baseline, in part because they are reportedly more muscular.^{11,25} Analyses have cast doubt on this claim,²⁶ but the “race-corrected” eGFR remains the standard. Proponents of the equations have acknowledged that race adjustment “is problematic because race is a social rather than a biological construct” but warn that ending race adjustment of eGFR might lead to overdiagnosis and overtreatment of black patients.²⁷ Conversely, race adjustments that yield higher estimates of kidney function in black patients might delay their referral for specialist care or transplantation and lead to worse outcomes, while black people already have higher rates of end-stage kidney disease and death due to kidney failure than the overall population.²⁵

As long as uncertainty persists about the cause of racial differences in serum creatinine levels, we should favor practices that may alleviate health inequities over those that may exacerbate them.

Similar adjustment practices affect kidney transplantation. The Kidney Donor Risk Index (KDRI), implemented by the national Kidney Allocation System in 2014, uses donor characteristics, including race, to predict the risk that a kidney graft will fail.¹² The race adjustment is based on an empirical finding that black donors’ kidneys perform worse than nonblack donors’ kidneys, regardless of the recipient’s race.²⁸ The developers of the KDRI do not provide possible explanations for this difference.¹² If the potential donor is identified as black, the KDRI returns a higher risk of graft failure, marking the candidate as a less suitable donor. Meanwhile, black patients in the United States still have longer wait times for kidney transplants than nonblack patients.²⁹ Since black patients are more likely to receive kidneys from black donors, anything that reduces the likelihood of donation from black people could contribute to the wait-time disparity.²⁹ Use of the KDRI may do just that. Mindful of this limitation of the KDRI, some observers have proposed replacing “the vagaries associated with inclusion of a variable termed ‘race’” with a more specific, ancestry-associated risk factor, such as *APOL1* genotype.²⁸

OBSTETRICS

The Vaginal Birth after Cesarean (VBAC) algorithm predicts the risk posed by a trial of labor for someone who has previously undergone cesarean section. It predicts a lower likelihood of success for anyone identified as African American or Hispanic.¹³ The study used to produce the algorithm found that other variables, such as marital status and insurance type, also correlated with VBAC success.¹⁴ Those variables, however, were not incorporated into the algorithm. The health benefits of successful vaginal deliveries are well known, including lower rates of surgical complications, faster recovery time, and fewer complications during subsequent pregnancies. Nonwhite U.S. women continue to have higher rates of cesarean section than white U.S. women. Use of a calculator that lowers the estimate of VBAC success for people of color could exacerbate these disparities. This dynamic is particularly

Table 1. Examples of Race Correction in Clinical Medicine.[‡]

Tool and Clinical Utility	Input Variables	Use of Race	Equity Concern
Cardiology The American Heart Association's Get with the Guidelines—Heart Failure ⁹ (https://www.mdcalc.com/gwtg-heart-failure-risk-score) <i>Predicts in-hospital mortality in patients with acute heart failure. Clinicians are advised to use this risk stratification to guide decisions regarding initiating medical therapy.</i>	Systolic blood pressure Blood urea nitrogen Sodium Age Heart rate History of COPD Race: black or nonblack	Adds 3 points to the risk score if the patient is identified as nonblack. This addition increases the estimated probability of death (higher scores predict higher mortality).	The original study envisioned using this score to "increase the use of recommended medical therapy in high-risk patients and reduce resource utilization in those at low risk." ⁹ The race correction regards black patients as lower risk and may raise the threshold for using clinical resources for black patients.
Cardiac surgery The Society of Thoracic Surgeons Short Term Risk Calculator ¹⁰ (http://riskcalc.sts.org/siteswebriskcalc/calculate) <i>Calculates a patient's risks of complications and death with the most common cardiac surgeries. Considers >60 variables, some of which are listed here.</i>	Operation type Age and sex Race: black/African American, Asian, American Indian/Alaskan Native, Native Hawaiian/Pacific Islander, or "Hispanic, Latino or Spanish ethnicity"; white race is the default setting. BMI	The risk score for operative mortality and major complications increases (in some cases, by 20%) if a patient is identified as black. Identification as another nonwhite race or ethnicity does not increase the risk score for death, but it does change the risk score for major complications such as renal failure, stroke, and prolonged ventilation.	When used preoperatively to assess a patient's risk, these calculations could steer minority patients, deemed higher risk, away from these procedures.
Nephrology Estimated glomerular filtration rate (eGFR) MDRD and CKD-EPI equations ¹¹ (https://ukidney.com/nephrology-resources/egfr-calculator) <i>Estimates glomerular filtration rate on the basis of a measurement of serum creatinine.</i>	Serum creatinine Age and sex Race: black vs. white or other	The MDRD equation reports a higher eGFR (by a factor of 1.210) if the patient is identified as black. This adjustment is similar in magnitude to the correction for sex (0.742 if female). The CKD-EPI equation (which included a larger number of black patients in the study population), proposes a more modest race correction (by a factor of 1.159) if the patient is identified as black. This correction is larger than the correction for sex (1.018 if female).	Both equations report higher eGFR values (given the same creatinine measurement) for patients identified as black, suggesting better kidney function. These higher eGFR values may delay referral to specialist care or listing for kidney transplantation.
Organ Procurement and Transplantation Network: Kidney Donor Risk Index (KDR) ¹² (https://optn.transplant.hrsa.gov/resources/allocation-calculators/kdri-calculator/) <i>Estimates predicted risk of donor kidney graft failure, which is used to predict viability of potential kidney donor.[†]</i>	Age Hypertension, diabetes Serum creatinine level Cause of death (e.g., cerebrovascular accident) Donation after cardiac death Hepatitis C Height and weight HLA matching Cold ischemia En bloc transplantation Double kidney transplantation Race: African American	Increases the predicted risk of kidney graft failure if the potential donor is identified as African American (coefficient, 0.179), a risk adjustment intermediate between those for hypertension (0.126) and diabetes (0.130) and that for elevated creatinine (0.209–0.220).	Use of this tool may reduce the pool of African-American kidney donors in the United States. Since African-American patients are more likely to receive kidneys from African-American donors, by reducing the pool of available kidneys, the KDR could exacerbate this racial inequity in access to kidneys for transplantation.

Obstetrics	Vaginal Birth after Cesarean (VBAC) Risk Calculator ^{13,14} (https://mfminetwork.bsc.gwu.edu/PublicBSC/MEMU/VGBirthCalc/.html) <i>Estimates the probability of successful vaginal birth after prior cesarean section. Clinicians can use this estimate to counsel people who have to decide whether to attempt a trial of labor rather than undergo a repeat cesarean section.</i>	Age BMI Prior vaginal delivery Prior VBAC Recurring indication for cesarean section African-American race Hispanic ethnicity	The African-American and Hispanic correction factors subtract from the estimated success rate for any person identified as black or Hispanic. The decrement for black (0.671) or Hispanic (0.680) is almost as large as the benefit from prior vaginal delivery (0.888) or prior VBAC (1.003).	The VBAC score predicts a lower chance of success if the person is identified as black or Hispanic. These lower estimates may dissuade clinicians from offering trials of labor to people of color.
Urology	STONE Score ^{15,16} <i>Predicts the risk of a ureteral stone in patients who present with flank pain</i>	Sex Acute onset of pain Race: black or nonblack Nausea or vomiting Hematuria	Produces a score on a 13-point scale, with a higher score indicating a higher risk of a ureteral stone; 3 points are added for nonblack race. This adjustment is the same magnitude as for hematuria.	By systematically reporting lower risk for black patients than for all nonblack patients, this calculator may steer clinicians away from aggressive evaluations of black patients.
	Urinary tract infection (UTI) calculator ¹⁷ (https://uticalc.pitt.edu/) <i>Estimates the risk of UTI in children 2–23 mo of age to guide decisions about when to pursue urine testing for definitive diagnosis</i>	Age <12 months Maximum temperature >39°C Race: Describes self as black (fully or partially) Female or uncircumcised male Other fever source	Assigns a lower likelihood of UTI if the child is black (i.e., reports a roughly 2.5-times increased risk in patients who do not describe themselves as black).	By systematically reporting lower risk for black children than for all nonblack children, this calculator may deter clinicians from pursuing definitive diagnostic testing for black children presenting with symptoms of UTI.
Oncology	Rectal Cancer Survival Calculator ¹⁸ (http://www3.mdanderson.org/app/medcalc/index.cfm?pname=rectumcancer) <i>Estimates conditional survival 1–5 yr after diagnosis with rectal cancer</i>	Age and sex Race: white, black, other Grade Stage Surgical history	White patients are assigned a regression coefficient of 1, with higher coefficients (depending on stage) assigned to black patients (1.18–1.72).	The calculator predicts that black patients will have shorter cancer-specific survival from rectal cancer than white patients. Clinicians might be more or less likely to offer interventions to patients with lower predicted survival rates.

Table 1. (Continued.)

Tool and Clinical Utility	Input Variables	Use of Race	Equity Concern
Breast Cancer Surveillance Consortium Risk Calculator ¹⁹ (https://tools.besc-scc.org/BC5yearRisk/calculator.htm) <i>Estimates 5- and 10-yr risk of developing breast cancer in women with no previous diagnosis of breast cancer, DCIS, prior breast augmentation, or prior mastectomy</i>	Age Race/ethnicity: white, black, Asian, Native American, other/multiple races, unknown BIRADS breast density score First-degree relative with breast cancer Pathology results from prior biopsies	The coefficients rank the race/ethnicity categories in the following descending order of risk: white, American Indian, black, Hispanic, Asian.	Returns lower risk estimates for all nonwhite race/ethnicity categories, potentially reducing the likelihood of close surveillance in these patients.
Osteoporosis Risk SCORE (Simple Calculated Osteoporosis Risk Estimation) ²⁰ (https://www.mndapp.co/osteoporosis-risk-score-calculator-316/) <i>Determines whether a woman is at low, moderate, or high risk for low bone density in order to guide decisions about screening with DXA scan</i>	Rheumatoid arthritis History of fracture Age Estrogen use Weight Race: black or not black	Assigns 5 additional points (maximum score of 50, indicating highest risk) if the patient is identified as nonblack	By systematically lowering the estimated risk of osteoporosis in black patients, SCORE may discourage clinicians from pursuing further evaluation (e.g., DXA scan) in black patients, potentially delaying diagnosis and intervention.
Fracture Risk Assessment Tool (FRAX) ²¹ (https://www.sheffield.ac.uk/FRAX/tool.aspx) <i>Estimates 10-yr risk of a hip fracture or other major osteoporotic fracture on the basis of patient demographics and risk-factor profile. Calculators are country-specific.[†]</i>	Age and sex Weight and height Previous fracture Parent who had a hip fracture Current smoking Glucocorticoid use Rheumatoid arthritis Secondary osteoporosis Alcohol use, ≥3 drinks per day Femoral neck bone mineral density	The U.S. calculator returns a lower fracture risk if a female patient is identified as black (by a factor of 0.43), Asian (0.50), or Hispanic (0.53). Estimates are not provided for Native American patients or for multiracial patients.	The calculator reports 10-yr risk of major osteoporotic fracture for black women as less than half that for white women with identical risk factors. For Asian and Hispanic women, risk is estimated at about half that for white women. This lower risk reported for nonwhite women may delay intervention with osteoporosis therapy.
Pulmonology Pulmonary-function tests ²² <i>Uses spirometry to measure lung volume and the rate of flow through airways in order to diagnose and monitor pulmonary disease</i>	Age and sex Height Race/ethnicity	In the U.S., spiroometers use correction factors for persons labeled as black (10–15%) or Asian (4–6%).	Inaccurate estimates of lung function may result in the misclassification of disease severity and impairment for racial/ethnic minorities (e.g., in asthma and COPD). ²³

* BIRADS denotes Breast Imaging Reporting and Data System, BMI body-mass index (the weight in kilograms divided by the square of the height in meters), CKD-EPI Chronic Kidney Disease Epidemiology Collaboration, COPD chronic obstructive pulmonary disease, DCIS ductal carcinoma in situ, DXA dual-energy x-ray absorptiometry, LCIS lobular carcinoma in situ, and MDRD Modification of Diet in Renal Disease study.

† The current calculator uses Ethnicity/Race, with the following options: American Indian or Alaska Native, Asian, Black or African American, Hispanic/Latino, Native Hawaiian or Other Pacific Islander, White, and Multiracial.

‡ Three countries' calculators are further subcategorized by race, ethnicity, or location: China (Mainland China, Hong Kong), Singapore (Chinese, Malay, Indian), and the United States (Caucasian, black, Hispanic, Asian).

troubling because black people already have higher rates of maternal mortality.³⁰

UROLOGY

The STONE score predicts the likelihood of kidney stones in patients who present to the emergency department with flank pain. The “origin/race” factor adds 3 points (of a possible 13) for a patient identified as “nonblack.”¹⁵ By assigning a lower score to black patients, the STONE algorithm may steer clinicians away from thorough evaluation for kidney stones in black patients. The developers of the algorithm did not suggest why black patients would be less likely to have a kidney stone. An effort to externally validate the STONE score determined that the origin/race variable was not actually predictive of the risk of kidney stones.¹⁶ In a parallel development, a new model for predicting urinary tract infection (UTI) in children similarly assigns lower risk to children identified as “fully or partially black.”¹⁷ This tool echoes UTI testing guidelines released by the American Academy of Pediatrics in 2011 that were recently criticized for categorizing black children as low risk.³¹

ASSESSMENT

Similar examples can be found throughout medicine. Some algorithm developers offer no explanation of why racial or ethnic differences might exist. Others offer rationales, but when these are traced to their origins, they lead to outdated, suspect racial science or to biased data.^{22,30,31} In the cases discussed here, researchers followed a defensible empirical logic. They examined data sets of clinical outcomes and patient characteristics and then performed regression analyses to identify which patient factors correlated significantly with the relevant outcomes. Since minority patients routinely have different health outcomes from white patients, race and ethnicity often correlated with the outcome of interest. Researchers then decided that it was appropriate — even essential — to adjust for race in their model.

These decisions are the crux of the problem. When compiling descriptive statistics, it may be appropriate to record data by race and ethnicity and to study their associations. But if race does appear to correlate with clinical outcomes, does

that justify its inclusion in diagnostic or predictive tools? The answer should depend on how race is understood to affect the outcome.³⁰ Arriving at such an understanding is not a simple matter: relationships between race and health reflect enmeshed social and biologic pathways.³² Epidemiologists continue to debate how to responsibly make causal inferences based on race.³³ Given this complexity, it is insufficient to translate a data signal into a race adjustment without determining what race might represent in the particular context. Most race corrections implicitly, if not explicitly, operate on the assumption that genetic difference tracks reliably with race. If the empirical differences seen between racial groups were actually due to genetic differences, then race adjustment might be justified: different coefficients for different bodies.

Such situations, however, are exceedingly unlikely. Studies of the genetic structure of human populations continue to find more variation within racial groups than between them.^{34,35} Moreover, the racial differences found in large data sets most likely often reflect effects of racism — that is, the experience of being black in America rather than being black itself — such as toxic stress and its physiological consequences.³² In such cases, race adjustment would do nothing to address the cause of the disparity. Instead, if adjustments deter clinicians from offering clinical services to certain patients, they risk baking inequity into the system.

This risk was demonstrated in 2019 when researchers revealed algorithmic bias in medical artificial intelligence.³⁶ A widely used clinical tool took past health care costs into consideration in predicting clinical risk. Since the health care system has spent more money, on average, on white patients than on black patients, the tool returned higher risk scores for white patients than for black patients. These scores may well have led to more referrals for white patients to specialty services, perpetuating both spending discrepancies and race bias in health care.

A second problem arises from the ways in which racial and ethnic categories are operationalized. Clinicians and medical researchers typically use the categories recommended by the Office of Management and Budget: five races and two ethnicities. But these categories are unreliable proxies for genetic differences and fail to capture the complexity of patients’ racial and

ethnic backgrounds.^{34,35} Race correction therefore forces clinicians into absurdly reductionistic exercises. For example, should a physician use a double correction in the VBAC calculator for a pregnant person from the Dominican Republic who identifies as black and Hispanic? Should eGFR be race-adjusted for a patient with a white mother and a black father? Guidelines are silent on such issues — an indication of their inadequacy.

Researchers are aware of this dangerous terrain. The Society of Thoracic Surgeons acknowledged concerns raised by clinicians and policy-makers “that inclusion of SES factors in risk models may ‘adjust away’ disparities in quality of care.” Nonetheless, it proceeded to consider “all preoperative factors that are independently and significantly associated with outcomes”: “Race has an empiric association with outcomes and has the potential to confound the interpretation of a hospital’s outcomes, although we do not know the underlying mechanism (e.g., genetic factors, differential effectiveness of certain medications, rates of certain associated diseases such as diabetes and hypertension, and potentially [socioeconomic status] for some outcomes such as readmission).”¹⁰ This decision reflects a default assumption in medicine: it is acceptable to use race adjustment even without understanding what race represents in a given context.

To be clear, we do not believe that physicians should ignore race. Doing so would blind us to the ways in which race and racism structure our society.³⁷⁻³⁹ However, when clinicians insert race into their tools, they risk interpreting racial disparities as immutable facts rather than as injustices that require intervention. Researchers and clinicians must distinguish between the use of race in descriptive statistics, where it plays a vital role in epidemiologic analyses, and in prescriptive clinical guidelines, where it can exacerbate inequities.

This problem is not unique to medicine. The criminal justice system, for instance, uses recidivism-prediction tools to guide decisions about bond amounts and prison sentences. One tool, COMPAS (Correctional Offender Management Profiling for Alternative Sanctions), while not using race per se, uses many factors that correlate with race and returns higher risk scores for black defendants.⁴⁰ The tool’s creators explained that their design simply reflected empirical data.⁴¹

But if the underlying data reflect racist social structures, then their use in predictive tools cements racism into practice and policy. When these tools influence high-stakes decisions, whether in the clinic or the courtroom, they propagate inequity into our future.

In 2003, Kaplan and Bennet asked researchers to exercise caution when they invoked race in medical research: whenever researchers publish a finding based on race or ethnicity, they should follow seven guidelines, including justifying their use of race and ethnicity, describing how subjects were assigned to each category, and carefully considering other factors — especially socioeconomic status — that might affect the results.⁴² We propose an adaptation of these guidelines to evaluate race correction in clinical settings. When developing or applying clinical algorithms, physicians should ask three questions: Is the need for race correction based on robust evidence and statistical analyses (e.g., with consideration of internal and external validity, potential confounders, and bias)? Is there a plausible causal mechanism for the racial difference that justifies the race correction? And would implementing this race correction relieve or exacerbate health inequities?

If doctors and clinical educators rigorously analyze algorithms that include race correction, they can judge, with fresh eyes, whether the use of race or ethnicity is appropriate. In many cases, this appraisal will require further research into the complex interactions among ancestry, race, racism, socioeconomic status, and environment. Much of the burden of this work falls on the researchers who propose race adjustment and on the institutions (e.g., professional societies, clinical laboratories) that endorse and implement clinical algorithms. But clinicians can be thoughtful and deliberate users. They can discern whether the correction is likely to relieve or exacerbate inequities. If the latter, then clinicians should examine whether the correction is warranted. Some tools, including eGFR and the VBAC calculator, have already been challenged; clinicians have advocated successfully for their institutions to remove the adjustment for race.^{43,44} Other algorithms may succumb to similar scrutiny.⁴⁵ A full reckoning will require medical specialties to critically appraise their tools and revise them when indicated.

Our understanding of race has advanced considerably in the past two decades. The clinical

tools we use daily should reflect these new insights to remain scientifically rigorous. Equally important is the project of making medicine a more antiracist field.⁴⁶ This involves revisiting how clinicians conceptualize race to begin with. One step in this process is reconsidering race correction in order to ensure that our clinical practices do not perpetuate the very inequities we aim to repair.

Disclosure forms provided by the authors are available at NEJM.org.

From the Department of Medicine, Massachusetts General Hospital (D.A.V.), and the Department of Global Health and Social Medicine, Harvard Medical School (D.S.J.) — both in Boston, the Department of the History of Science, Harvard University, Cambridge, MA (D.S.J.), and the Department of Medicine, NYU Langone Medical Center, New York (L.G.E.).

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